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

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended April 30, 2020

or

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

Commission File Number 333-68008

PHARMACYTE BIOTECH, INC.

(Exact name of registrant as specified in its charter)

Nevada	**62-1772151**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
23046 Avenida de la Carlota, Suite 600 **Laguna Hills, CA 92653**	**(917) 595-2850**
(Address of principal executive offices)	(Registrant's telephone number, including area code)

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

Title of each class	**Trading symbol(s)**	**Name of each exchange on which registered**
N/A	N/A	N/A

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

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405) during the precedent 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes☐ No ☒

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of October 31, 2019: $44,427,991.

As of August 11, 2020, the registrant had 2,333,810,405 outstanding shares of common stock.

DOCUMENTS INCORPORATED BY REFERENCE

None.

Cautionary Note Regarding Forward-Looking Statements

This Report on Form 10-K ("Report") includes "forward-looking statements" within the meaning of the federal securities laws. All statements other than statements of historical fact are "forward-looking statements" for purposes of this Report, including any projections of earnings, revenue or other financial items, any statements regarding the plans and objectives of management for future operations, any statements concerning proposed new products or services, any statements regarding future economic conditions or performance, any statements regarding expected benefits from any transactions and any statements of assumptions underlying any of the foregoing. In some cases, forward-looking statements can be identified by use of terminology such as "may," "will," "should," "believes," "intends," "expects," "plans," "anticipates," "estimates," "goal," "aim," "potential" or "continue," or the negative thereof or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements contained in this Report are reasonable, there can be no assurance that such expectations or any of the forward-looking statements will prove to be correct, and actual results could differ materially from those projected or assumed in the forward-looking statements. Thus, investors should refer to and carefully review information in future documents we file with the United States Securities and Exchange Commission ("Commission"). Our future financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risk and uncertainties, including, but not limited to, the risk factors set forth in "Part I, Item 1A – Risk Factors" set forth in this Report and for the reasons described elsewhere in this Report. Among others, these include our estimates regarding expenses, future revenues, capital requirements and needs for additional financing; whether the United States Food and Drug Administration ("FDA") approves our Investigational New Drug Application ("IND") after it has been submitted to, and reviewed by the FDA so that we can commence our planned clinical trial involving locally advanced, inoperable, non-metastatic pancreatic cancer ("LAPC"); the success and timing of our preclinical studies and clinical trials; the potential that results of preclinical studies and clinical trials may indicate that any of our technologies and product candidates are unsafe or ineffective; our dependence on third parties in the conduct of our preclinical studies and clinical trials; the difficulties and expenses associated with obtaining and maintaining regulatory approval of our product candidates; the material adverse impact that the coronavirus pandemic may have on our business, including our planned clinical trial involving LAPC, which could materially affect our operations as well as the business or operations of third parties with whom we conduct business; and whether the FDA will approve our product candidates after our clinical trials are completed, assuming the FDA allows our clinical trials to proceed after review of our proposed IND submission for LAPC. All forward- looking statements and reasons why results may differ included in this Report are made as of the date hereof, and we do not intend to update any forward-looking statements except as required by law or applicable regulations. Except where the context otherwise requires, in this Report, the "Company," "we," "us" and "our" refer to PharmaCyte Biotech, Inc., a Nevada corporation, and, where appropriate, its subsidiaries.

PART I

ITEM 1. BUSINESS.

Overview

We are a biotechnology company focused on developing cellular therapies for cancer and diabetes based upon a proprietary cellulose-based live cell encapsulation technology known as "Cell-in-a-Box®." The Cell-in-a-Box® technology is intended to be used as a platform upon which therapies for several types of cancer, including locally advanced, inoperable, non-metastatic pancreatic cancer ("LAPC"), and Type 1 and insulin dependent Type 2 diabetes will be developed.

We are developing therapies for pancreatic and other solid cancerous tumors by using genetically engineered live human cells that we believe are capable of converting a cancer prodrug into its cancer-killing form, encapsulating those cells using the Cell-in-a-Box® technology and placing those capsules in the body as close as possible to the tumor. In this way, we believe that when the cancer prodrug is administered to a patient with a particular type of cancer that may be affected by the prodrug, the killing of the patient's tumor may be optimized. We anticipate that shortly after the filing of this Report we will file an Investigational New Drug Application ("IND") with the United States Food and Drug Administration ("FDA") to allow us to commence a human clinical trial involving LAPC although no assurance as to the timing can be given.

We are also examining ways to exploit the benefits of the Cell-in-a-Box® technology to develop therapies for cancer that involve prodrugs based upon certain constituents of the *Cannabis* plant; these constituents are of the class of compounds known as "cannabinoids". Until the FDA allows us to commence the clinical trial involving LAPC described in our IND to be filed with the FDA, we are not spending any further resources developing this program.

In addition, we are developing a therapy to delay the production and accumulation of malignant ascites fluid that results from many types of abdominal cancerous tumors. Malignant ascites fluid is secreted by abdominal cancerous tumors into the abdomen after the tumors have reached a certain stage of growth. This fluid contains cancer cells that can seed and form new tumors throughout the abdomen. This fluid accumulates in the abdominal cavity, causing swelling of the abdomen, severe breathing difficulties and extreme pain. We are using our therapy for pancreatic cancer to determine if it can prevent or delay the production and accumulation of malignant ascites fluid. As with our *Cannabis* program, until the FDA allows us to commence the clinical trial involving LAPC described in our IND to be filed with the FDA, we are not spending any further resources developing this program.

We are also developing a therapy for Type 1 diabetes and insulin-dependent Type 2 diabetes. Our diabetes therapy consists of encapsulated genetically modified human liver cells and insulin-producing stem cells. The encapsulation for each type of cell will be done using the Cell-in-a-Box® technology. Implanting these cells in the body is designed to function as a bio-artificial pancreas for the purpose of insulin production. As with the two previous programs, we are not spending any further resources developing this program until the FDA allows us to commence the clinical trial involving LAPC described in our IND to be filed with the FDA. However, work at the University of Technology, Sydney ("UTS") on the Melligen cells continues. Melligen cells are human liver cells that have been genetically engineered to produce, store and release insulin in response to the levels of blood sugar in the body. The work is being funded by the Company and UTS. Our portion of the funding was previously paid by us to UTS. In prior animal pre-clinical studies, the Company has successfully encapsulated Melligen cells using Cell-in-a-Box® technology.

The Cell-in-a-Box® encapsulation technology potentially enables genetically engineered live human cells to be used as miniature factories for the production of various biologically active molecules. The technology results in the formation of pin-head sized cellulose-based porous capsules in which genetically modified live human cells can be encapsulated and maintained. In a laboratory setting, this proprietary live cell encapsulation technology has been shown to create a micro-environment in which encapsulated cells survive and flourish. They are protected from environmental challenges, such as the sheer forces associated with bioreactors, passage through catheters and needles, etc., which we believe enables greater growth and production. The capsules are largely composed of cellulose (cotton) and are bio inert.

Finally, we have licensed from Hai Kang Life Corporation Limited ("Hai Kang") the right to sell and distribute COVID-19 (defined below) diagnostic kits. Pursuant to a License Agreement with Hai Kang ("Hai Kang License Agreement"), the Company may directly (or through a third party) conduct research, use, develop, market, sell, distribute, import and export the kits for human and veterinary uses in North America, the United Kingdom and certain other European sites.

Cancer Therapy

Targeted Chemotherapy

Our live-cell encapsulation technology-based therapies consist of encapsulated genetically modified living cells, with the type of encapsulated cell dependent on the disease being treated. For our lead product candidate, a therapy for pancreatic cancer, we propose that approximately 20,000 genetically modified live cells that produce an enzyme (an isoform of cytochrome P450), which we believe will convert the chemotherapy prodrug ifosfamide into its cancer-killing form, will be encapsulated using Cell-in-a-Box® technology. In the clinical trial, if the FDA allows us to proceed, approximately 300 of these capsules will be placed in the patients' blood supply and guided into place using interventional radiography so that they finally reside as close to the tumor in the pancreas as possible. Low doses (one gram per square meter of body surface area of the patient) of the chemotherapy prodrug ifosfamide will then be given to the patient intravenously.

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

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

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

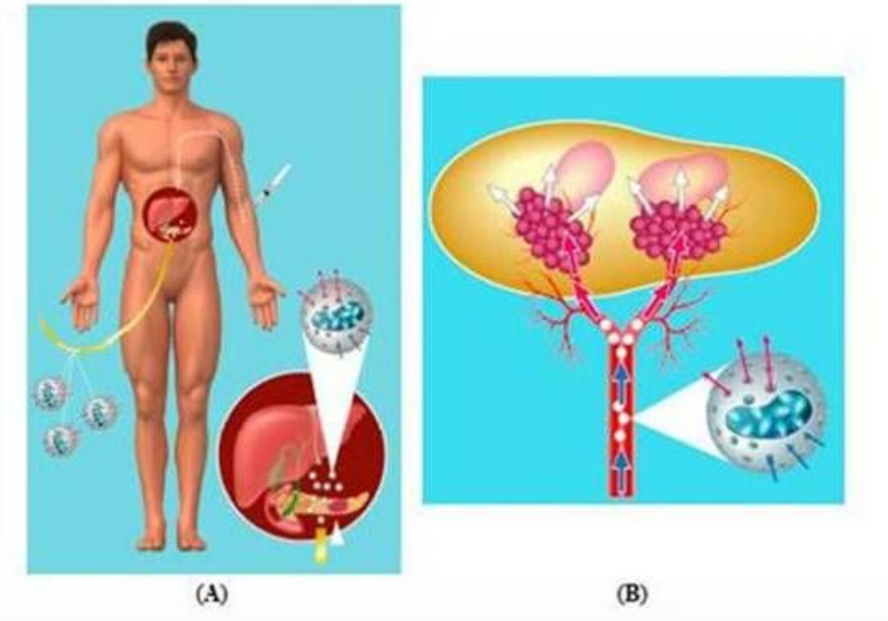
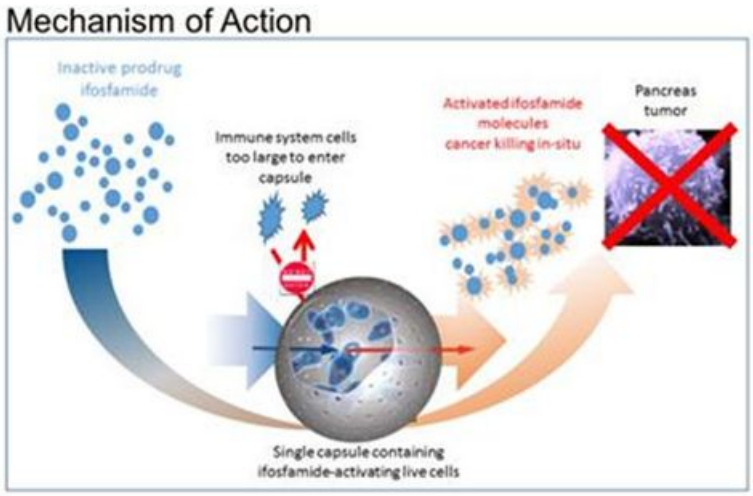


Chart (A)	Chart (B)
Cell-in-a-Box® capsules containing live ifosfamide-activating cells (shown in white) will be implanted in the blood vessels leading to the tumor in the pancreas. Then low dose ifosfamide will be given intravenously.	Chart B shows the human pancreas and generalized depictions of two pancreatic cancer tumors (shown in pink) as examples. In this chart, ifosfamide is converted to its cancer-killing form by the encapsulated live cells implanted near the tumors (shown in maroon). Legend *Blue Arrows*: Ifosfamide enters capsules *Red Arrows*: Conversion to active form *White Arrows*: Activated ifosfamide targets tumors

Figure 2: Mechanism of action of treatment for pancreatic cancer by targeted deployment of the encapsulated live cells and activation of the chemotherapy prodrug drug ifosfamide. The immune system cells are too large to enter the capsule.



Pancreatic Cancer Therapy

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

Other treatments are being tried at various cancer centers in the U.S. in an attempt to address this lack of an effective treatment for many LAPC patients, but their success is far from certain. We are developing a therapy comprised of Cell-in-a-Box® encapsulated live cells implanted near the pancreas tumor followed by the infusion of low doses of the cancer prodrug ifosfamide. We believe that our therapy can serve as a "consolidation therapy" that can be used with the current standards of care for LAPC and thus address this critical unmet medical need.

Subject to our filing an IND and the FDA allowing us to move forward with our clinical trial, we plan to commence a clinical trial involving patients with LAPC whose tumors have ceased to respond to either Abraxane® plus gemcitabine or FOLFIRINOX after 4-6 months of either therapy. We had a Pre-Investigational New Drug Application meeting ("Pre-IND meeting") with the Center for Biologics Evaluation and Research of the FDA ("CBER") in January 2017. At that Pre-IND meeting, the FDA communicated its agreement with certain aspects of our clinical development plan, charged us with completing numerous tasks and provided us with the guidance on the tasks we believe we need to complete for a successful IND submission for LAPC, although no assurance can be given whether the FDA will allow us to commence a Phase 2b clinical trial. We believe that we will be permitted to conduct a Phase 2b clinical trial because of the data developed from the two earlier trials conduct by Bavarian Nordic, a fully integrated biotechnology company in Denmark, using the same technology and same cell line. The results of those trials are discussed below. The trial would initially take place in the U.S. with possible study sites in Europe at a later date.

Our Investigational New Drug Application

Our proposed IND submission to the FDA with respect to LAPC will consist of all available preclinical information (e.g. animal toxicity studies), Chemistry, Manufacturing and Controls information and other pre-clinical information about our product candidate to treat LAPC, as well as information regarding our proposed clinical trial program and other information and documentation required by FDA regulations. Our FDA regulatory affairs consultant is leading the preparation of the IND.

Summary of the Company's Activities During the Period of this Report

During fiscal year 2020, we have focused our research and development ("R&D") efforts at completing Cell-in-a-Box® encapsulation engineering runs and production runs using cells from our Master Cell Bank ("MCB") that contain the genetically engineered human cells that can activate the prodrug ifosfamide into its cancer killing form. The MCB encapsulated cells from the final manufacturing run will be used for our planned clinical trial in LAPC. Several tests and experiments were completed to optimize the growth properties of the cells pre-and post-encapsulation – we believe resolving prior issues with growth properties in both phases of the encapsulation process.

These activities during fiscal year 2020 include:

1. Completion of two back to back manufacturing runs of our product candidate for use in the LAPC clinical trial.
2. Completion of all release testing on our product candidate for use in the LAPC clinical trial.
3. Completion of the final cGMP audit of the manufacturing facility for our product candidate for use in the LAPC clinical trial.
4. Commencement of the FDA required 24-Month stability study of our product candidate for use in the LAPC clinical trial.
5. Successful development of the FDA required "Change History" for our LAPC product candidate.
6. Successful completion of the pyrogenicity testing of our encapsulation material.
7. Preparation of our "Drug Master File" ("DMF") for submission to the FDA.
8. Completion of our Angiography Procedure Manual.
9. A new research agreement with UTS to create an advanced version of the Melligen cells to treat diabetes.
10. Appointment of cellular expert David A. Judd to our Medical and Scientific Advisory Board.
11. Confirmation that Dr. Manuel Hidalgo will be the Principal Investigator for the clinical trial of our LAPC product candidate.

Successfully Completed the First Two Manufacturing Runs of our Product Candidate for the treatment of LAPC

Austrianova Singapore Pte. Ltd. ("Austrianova"), our contract manufacturer, successfully completed two staggered and back to back manufacturing runs for the production of the Company's product candidate for the treatment of LAPC. After months of extensive R&D by a team of experts from Austrianova and the Company, a total of eight different changes were made to the manufacturing process. It was not until the eighth and final change was made that the encapsulated cells grew as well in Austrianova's GMP manufacturing facility in Thailand as they grew at Austrianova's R&D facility in Singapore.

Once the manufacturing runs were completed successfully, a representative sample of frozen syringes filled with the encapsulated genetically modified live cells inside were shipped to external testing laboratories for the release testing of the clinical trial product that is required by the FDA related to safety. Austrianova conducted "release testing" in-house related to the "functionality" of the encapsulated cells.

Completed All Release Testing on our Product Candidate for Use in the LAPC Clinical Trial

Both batches of our manufactured product candidate underwent and passed all 10 of the necessary "release tests" required by the FDA. Once completed, Austrianova prepared the paperwork to issue us a "Certificate of Analysis" for each batch of our product candidate. Austrianova also completed the FDA required batch records from each manufacturing run. The batch records underwent an extensive review by us to ensure that the product candidate is cGMP compliant. These tests and the batch records provided essential data for us to complete our IND to be submitted to the FDA to allow us to commence a clinical trial to treat LAPC.

Completed the Final cGMP Audit of the Manufacturing Facility for our Product Candidate for Use in the LAPC Clinical Trial

cGMP Validation, the company's cGMP consultant, completed its post manufacturing audit of the manufacturing facility in Thailand. The facility successfully passed the audit. This facility is where our product candidate was manufactured.

Began the FDA Required 24-Month Stability Study of our Product Candidate for Use in the LAPC Clinical Trial

We commenced a rolling two-year study stability study ("Stability Study") to demonstrate how the frozen CypCaps™ manufactured by Austrianova for patients with LAPC perform over time after being frozen for certain periods of time and then thawed and tested for safety and functionality. While the Stability Study will continue for 24 months, the FDA requires 3 months of stability data to be included in our IND to be submitted to the FDA.

The tests for the Stability Study started approximately 3 months (the first time point in the 2-year study) from the issuance of the Certificate of Analysis for the second successful manufacturing run and will continue for 24 months. Data from the balance of the Stability Study will be provided to the FDA as the data becomes available.

Successfully Developed the FDA Required "Change History" for our Product Candidate

We successfully completed development of the "change history" information and data for CypCaps™ (2nd generation product candidate) compared to CapCells™ (1st generation product candidate). The history of the changes to the manufacturing of the two generations of product is a critical component of our IND to be submitted to the FDA and is specifically required by the FDA.

Austrianova developed the needed information and data to be in a position to satisfy our cGMP consultant and our regulatory consultant. We believe that the information and supporting data should be sufficient to meet the FDA comparability requirements of the two generations of encapsulated live human cells.

The first generation of product candidate was referred to as "CapCells™", and the current generation of product candidate is referred to as "CypCaps™." Although the cellulose material is basically the same, a material of improved quality is used in the 2nd generation product candidate. The differences relate to control of impurities with heavy metal content and microbial and endotoxin levels being below the limits in the relevant literature for powdered cellulose. In addition, the production process for the cellulose is more closely controlled in the 2nd generation product candidate. The original cell line used is also now better characterized at the genetic level. Lastly, the encapsulated cells undergo a maturation process in the 2nd generation product candidate and are stored frozen for a longer shelf life.

In short, while both generations of product use the identical cell line, the CypCaps™ have improved quality and control of the cells, improved encapsulation material reproducibility, better controlled cell filling and a much-improved shelf life, resulting in a more robust product overall.

The FDA requires that all relevant information and data from different generations of the same manufactured medicinal product be compared to one another to ensure that the original manufactured product is essentially the same as the current one. There can be improvements to the product, but to use the data from the two clinical trials in the 1990s to support the Company's proposed Phase 2b clinical trial, it was imperative to develop information and data to support that the two generations of the products are essentially the same – the only difference being improvement to the overall product using the same manufacturing process.

Successfully Completed the Pyrogenicity Testing of our Encapsulation Material

We successfully completed the pyrogenicity testing that is required by the FDA of the encapsulation material used to manufacture our CypCaps™. The capsules, which house live human cells, passed the test and are deemed non-pyrogenic.

All medical products that are delivered to the body have to be pyrogen free. Pyrogens are fever inducing substances that can cause side effects and influenza-like symptoms. Substances produced by bacteria (endotoxins) can be pyrogens, but other nonbacterial substances can also be pyrogenic.

Preparation of our "Drug Master File" for submission to the FDA

Austrianova prepared the "Drug Master File" for submission of our LAPC product candidate to the FDA to provide detailed information about facilities, processes and materials used in the manufacturing, processing and packaging of our LAPC product candidate. It is a prerequisite to securing approval and commercialization of a product candidate and the information contained the "Drug Master File" is used to support, among other applications, an IND.

Completed our Angiography Procedure Manual

We completed a medical manual that is necessary for the completion of our IND. The manual, "Angiography Manual – Transarterial Chemoinfusion of the Pancreas" ("Angiography Procedure Manual"), will be used to guide Interventional Radiologists on the placement of a catheter that begins at the femoral artery in the leg and ends as close to the pancreatic tumor as possible in patients participating in our planned clinical trial. By following the directions in this manual, Interventional Radiologists will be able to precisely place the CypCaps™ inside patients.

Entered into a New Research Agreement to Create an Advanced Version of the Melligen Cells to Treat Diabetes

We entered into a new research agreement with UTS in Australia to create a new version of Melligen cells for the treatment of diabetes with the potential to express higher levels of insulin in a more stable cell line.

Melligen cells are human liver cells that have been genetically engineered to produce, store and release insulin in response to the levels of blood sugar in the body. We obtained the exclusive worldwide license rights from UTS to use these cells to develop a therapy for Type 1 and insulin-dependent Type 2 diabetes. We plan to encapsulate Melligen cells using the Cell-in-a-Box® technology to protect the Melligen cells from immune system attack in the body and thus function as a "bioartificial pancreas" for purposes of insulin production.

The work undertaken by us, UTS and our International Diabetes Consortium over the last few years resulted in an opportunity to re-engineer the Melligen cells with the aim of increasing their insulin production as well as the bioactivity of the produced insulin. With this new agreement in place, the related research will be done in Australia under the leadership of Prof. Ann Simpson, the developer of the original Melligen cell line.

Appointed Cellular Expert David A. Judd to our Medical and Scientific Advisory Board

We appointed David A. Judd to our Medical and Scientific Advisory Board. Mr. Judd has had over 30 years of experience in the research and development of cell culture materials and methods for the culturing various types of human cells. Most importantly, Mr. Judd has worked for many years with the cells that we propose to use in our treatment of cancer and has a wealth of knowledge regarding their growth properties.

Mr. Judd made significant contributions to our efforts in working with Austrianova to ensure that the cells from our MCB grow as they should, both pre-and post-encapsulation. During a critical time in realigning certain aspects of the manufacturing process, Mr. Judd accompanied us as an advisor to Austrianova's cGMP manufacturing facility in Bangkok, Thailand, where the encapsulation of our cells took place.

Mr. Judd is a graduate of the Biotechnology program at Rochester Institute of Technology, the first Biotechnology program in the U.S. He has over 30-years of experience in cell culture and biochemistry in research and in a cGMP environment. Also, he has extensive experience in research and development of cell culture medium, both in the upstream and downstream processes.

Mr. Judd is currently employed by the Grand Island Biotechnology Company (Gibco) and is involved in research, process development and cGMP production of biotechnology and cell therapy processes. Mr. Judd has been employed by Gibco (now owned by ThermoFischer Scientific) for 29 years and is a co-inventor on 5 patents involving cell culture materials.

We Confirmed that Dr. Manuel Hidalgo Will Be the Principal Investigator for the Clinical Trial of our LAPC Product Candidate

Dr. Manuel Hidalgo confirmed that he will be the Principal Investigator for our planned clinical trial for LAPC. Dr. Hidalgo is a leading physician-scientist who specializes in pancreatic cancer and drug development. He currently serves as Chief of the Division of Hematology and Medical Oncology at Weill Cornell Medicine and New York-Presbyterian/Weill Cornell Medical Center. Previously, Dr. Hidalgo was a Professor of Medicine at the Harvard Medical School and the Chief of the Division of Hematology Oncology and Director of the Rosenberg Clinical Cancer Center at the Beth Israel Deaconess Medical Center.

Other Activities of the Company During the Period of this Report

Entered into a License Agreement for COVID-19 Diagnostic Kits

Effective as of April 2, 2020, we entered into the Hai Kang License Agreement with Hai Kang ("Licensor"), pursuant to which the Licensor granted to us a license to certain technology owned or controlled by the Licensor related to COVID-19 diagnostic kits ("Kits"). Pursuant to the Hai Kang License Agreement, we may directly (or through a third party) conduct research, use, develop, market, sell, distribute, import and export Products for human and veterinary uses in North America, the United Kingdom and certain other European cities.

Received Medical Devices Registration and Submitted a Pre-EUA Application to the FDA for our COVID-19 Diagnostic Kit

We registered as a Medical Devices Establishment, specifically as an Initial Importer FDA's Center for Devices and Radiological Health ("CDRH") Device Registration and Listing Database. CDRH requires this registration for companies that plan to import medical devices from overseas suppliers. We also established ourselves as the sole U.S. agent for Hai Kang for the importation of SARS-CoV-2 in vitro diagnostic test kits. We plan to market the diagnostic tests kits only to certain Clinical Laboratory Improvement Amendments ("CLIA") certified labs throughout the U. S., but as of the date of this Report, have not yet commenced marketing.

We also submitted a Pre-Emergency Use Authorization ("EUA") application to the FDA. An EUA is a means for the FDA to expeditiously authorize new drugs and new medical devices during a declared national emergency. For COVID-19 diagnostic test kits, the FDA recommends that manufacturers and suppliers file a Pre-EUA with the FDA in order to interactively work towards an eventual EUA submission and authorization by the FDA. We are in the process of exchanging information with the FDA about our diagnostic test kits.

Cannabinoids to Treat Cancer

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

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

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

In May 2014, we entered into a research agreement with the University of Northern Colorado ("UNC"). The goal of the original research was to develop methods for the identification, separation and quantification of constituents of *Cannabis*, some of which are prodrugs, which may be used in combination with the Cell-in-a-Box® technology to treat cancer.

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

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

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

Until the IND involving LAPC has been submitted to the FDA and the FDA allows us to commence our clinical trial, we are not spending any further resources developing this program.

Malignant Ascites Fluid Therapy

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

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

Until the IND involving LAPC has been submitted to the FDA and the FDA allows us to commence our clinical trial, we are not spending any further resources developing this program.

Diabetes Therapy

A Bio-Artificial Pancreas for Diabetes

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

The cell line we select will be encapsulated using the Cell-in-a-Box® encapsulation technology. If appropriate animal testing is completed successfully, we intend to submit an IND to seek the FDA's approval to transplant encapsulated insulin-producing cells into diabetic patients. The goal for these approaches is to develop a bio-artificial pancreas for purposes of insulin production for diabetics who are insulin-dependent.

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

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

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

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

Prof. Ann Simpson, who created the Melligen cells, and her team of research scientists at UTS will be conducting this new research project. The work is being funded by the Company and UTS. Our portion of the funding was previously paid to UTS. Until we have submitted our IND to the FDA for the treatment of LAPC and the FDA allows us to commence our clinical trial, we will not be spending any further resources developing our Diabetes Program.

Impact of the COVID-19 Pandemic on Our Operations

The coronavirus SARS-Cov2 ("COVID-19") pandemic is causing significant, industry-wide delays in clinical trials. Subject to the FDA allowing us to proceed with clinical trials following review of our IND, once submitted, it is possible that we will be able to commence human testing in the 4^{th} quarter of 2020 or the 1st quarter of 2021. Currently, many clinical trials are being delayed due to COVID-19. There are numerous reasons for these delays. For example, patients have shown reluctance to enroll or continue in a clinical trial due to fear of exposure to COVID-19 when they are in a hospital or doctor's office. There are local, regional and state-wide shelter-in-place orders and regulations. These discourage patient visits to a doctor's office if the visit is not COVID-19 related. Healthcare providers and health systems are shifting their resources away from clinical trials toward the care of COVID-19 patients. The FDA and other healthcare providers are making product candidates for the treatment of COVID-19 a priority over product candidates unrelated to COVID-19. As of the date of this Report, the COVID-19 pandemic has had an impact upon our operations with respect to the delivery of materials and pre-IND testing, although we believe that impact is not material. They primarily relate to delays in tasks associated with the preparation of our IND.

As a result of the COVID-19 pandemic, submission and FDA review of our IND with respect to LAPC may be delayed which will, in turn, delay commencement of our planned clinical trial to treat LAPC. Moreover, enrollment may be difficult for the reasons discussed above. In addition, after enrollment in the trial, if enrolled patients contract COVID-19 during their participation in our trial or are subject to isolation or shelter in place restrictions, this may cause them to drop out of our trial, miss scheduled therapy appointments or follow-up visits or otherwise fail to follow our trial protocol. If patients are unable to follow the trial protocol or if our trial results are otherwise affected by the consequences of the COVID-19 pandemic on patient participation or actions taken to mitigate COVID-19 spread, the integrity of data from our trial may be compromised or not accepted by the FDA. This could adversely impact or delay our clinical development program.

Given that we are uncertain when we will be able to commence our clinical trial to treat LAPC, it is highly speculative to project the effects of COVID-19 on our proposed clinical development program and the Company generally. The effects of COVID-19 are difficult to predict, and no one is able to say with certainty when the pandemic will subside and life as we knew it before the pandemic will return to normal.

Relationship between PharmaCyte, S.G. Austria and Austrianova

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

Key Consultants

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

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

In September 2014, Prof. Günzburg was appointed as our Chief Scientific Officer. He served in that capacity through 2019. Prof. Günzburg was compensated for being our Chief Scientific Officer by our issuing Vin-de-Bona 500,000 restricted shares of our common stock each year in which he served as our Chief Scientific Officer.

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

History of the Business

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

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

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

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

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

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

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

In June 2013, we acquired from Austrianova an exclusive, worldwide license to use the Cell-in-a-Box® technology and trademark for the development of a therapy for Type 1 and insulin-dependent Type 2 diabetes ("Diabetes Licensing Agreement"). This allows us to develop a therapy to treat diabetes through encapsulation of a human cell line that has been genetically modified to produce, store and release insulin in response to the levels of blood sugar in the human body.

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

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

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

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

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

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

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

One of the Binding Term Sheet Amendments requires that we pay $900,000 to Austrianova ratably over a nine-month period in the amount of two $50,000 payments each month during the nine-month period on the days of the month to be agreed upon between the parties, with a cure period of 20 calendar days after receipt by us of written notice from Austrianova that we have failed to pay timely a monthly payment. As of April 30, 2020, the $900,000 amount has been paid in full. The Binding Term Sheet Amendments also provide that Austrianova receives 50% of any other financial and non-financial consideration received from our sublicensees of the Cell-in-a-Box® technology.

Goal and Strategies to Implement

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

Our strategies to implement our goal consist of the following:

- Submission of our LAPC related IND to the FDA and for the FDA to allow us to commence a clinical trial to treat LAPC;
- Completion of preclinical studies and clinical trials that demonstrate the effectiveness of our cancer therapy in reducing the production and accumulation of malignant ascites fluid in the abdomen that is characteristic of pancreatic and other abdominal cancers;
- Completion of preclinical studies and clinical trials that involve the encapsulation of the Melligen cells and genetically modified stem cells using the Cell-in-a-Box® technology to develop a therapy for Type 1 and insulin-dependent Type 2 diabetes;
- Enhancement of our ability to expand into the biotechnology arena through further research and partnering agreements with one or more third parties involved in the development of cancer and diabetes therapies and COVID-19 project;
- Acquisition of contracts that generate revenue or provide research and development capital utilizing our sublicensing rights;
- Further development of uses of the Cell-in-a-Box® technology platform through contracts, licensing agreements and joint ventures with other companies; and
- Completion of testing, expansion and marketing of existing and newly derived product candidates.

Market Opportunity and the Competitive Landscape

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

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

The cells encapsulated using the Cell-in-a-Box® technology can be frozen for extended periods of time. When thawed, the cells are recovered with approximately 85% to 90% viability. We are unaware of any other cell encapsulation material that is capable of protecting their encapsulated cells to this degree. The implications of this property of the Cell-in-a-Box® technology are obvious - long-term storage of encapsulated cells and shipment of encapsulated cells over long distances.

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

- Cancerous diseases may be treated by placing encapsulated drug-converting cells that convert a chemotherapy prodrug near the cancerous tumor;
- Confinement and maintenance of therapeutic cells that activate a chemotherapy prodrug may be placed at the site of implantation in a blood vessel near the cancerous tumor results in "targeted chemotherapy;"
- Increased efficacy of a chemotherapy prodrug may allow for lower doses of the drug to be given to a patient, significantly reducing or even eliminating side effects from the chemotherapy;
- Encapsulating genetically modified live cells has the potential for the treatment of systemic diseases of various types, including diabetes;
- Multi-layered patent and trade secret protection and marketing exclusivity for our technology exists and is being expanded;
- Cell-in-a-Box® capsules can prevent immune system attack of functional cells inside them without the need for immunosuppressive drug therapy; and
- Safety and effectiveness of the Cell-in-a-Box® technology and the cells used with our technology have already been shown in both human clinical trials and animal studies.

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

Pancreatic cancer is increasing in most industrialized countries. The American Cancer Society estimates that in 2020 there will be 57,600 people in the U.S. diagnosed with pancreatic cancer. It also estimates 47,050 patients with pancreatic cancer will die in 2020.

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

We face intense competition in the field of treating pancreatic cancer. In addition to commercial entities such as Halozyme, Inc., OncoMed Pharmaceuticals, Inc. and Boston Biomedical, Inc., to name a few of the smaller companies, several academic institutions and cancer centers are trying to improve the outcome for pancreatic cancer patients. There are several drugs already available and in the pipelines of pharmaceutical companies worldwide, not the least of which is the combination of the drugs of Abraxane® and gemcitabine. This is the primary FDA-approved combination of drugs for treating advanced pancreatic cancer. In Europe, and more recently in the U.S., the 4-drug combination known as FOLFIRINOX has also found use as a first-line treatment for advanced pancreatic cancer. Some of our competitive strengths include the Orphan Drug Designation we have been granted by the FDA and the European Medicines Agency ("EMA") for our pancreatic cancer therapy, our trade secrets, the patents we are seeking and the licensing agreements we have that are described in this Report. Yet many of our competitors have substantially greater financial and marketing resources than we do. They also have stronger name recognition, better brand loyalty and long-standing relationships with customers and suppliers. Our future success will be dependent upon our ability to compete.

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

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

Previous Clinical Trials Using Our Encapsulation Technology

Two previous clinical trials using what is now our encapsulation technology were carried out in Europe by Bavarian Nordic in 1998-1999 and 2000, respectively. Both employed the combination of the cellulose-based live cell encapsulation technology with low doses of the anticancer drug ifosfamide. However, the FDA may not accept the results of these trials for various reasons, none of which are in our control. In such event, we may have to conduct a Phase 1 trial, not a Phase 2b trial, or even further pre-clinical animal trials.

The results of the two clinical trials have been published in the peer-reviewed scientific literature and are summarized as follows:

Phase 1/2 Clinical Trial

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Within the 20-week study period, three patients died from disease progression (on days 9, 85 and 132). Upon postmortem examination, the patient who died on day 9 from recurrent pulmonary embolism was found to have extensive tumor necrosis.
The chemotherapy regimen was well tolerated. No toxicity beyond Grade 2 (moderate adverse effect) was detected in any of the 14 patients.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In the Phase 1/2 clinical trial only a small number of patients were evaluated. Statistical parameters were not used in the published reports of the Phase 1/2 trial to validate the anticancer efficacy of the Cell-in-a-Box® plus low-dose ifosfamide combination in patients with advanced, inoperable pancreatic cancer. In the opinion of the investigators, the results indicate a trend towards efficacy; accordingly, the results should not be viewed as absolute numbers. It should be noted, however, that because the results were not statistically significant, any observations of efficacy must be weighed against the possibility that the results were due to chance alone. The purpose of the clinical trial was not to obtain data so that marketing approval could be obtained from regulatory authorities. Rather, the clinical trial allowed the investigators to determine whether the Cell-in-a- Box® capsules plus low-dose ifosfamide combination holds promise as a therapy for advanced pancreatic cancer. In the cancer arena, Phase 1/2 clinical trials are used to: (i) establish the safety of the drug or treatment being investigated; and (ii) determine if a trend towards efficacy exists. In accordance with FDA guidance, as well as similar guidance from other regulatory authorities in countries other than the U.S., we realize that a large, multicenter, randomized, comparative study needs to be conducted and the results from such a trial would have to confirm the results from this previous Phase 1/2 trial before an application for marketing approval could be filed with the FDA or EMA. We expect that shortly after the filing of this Report we will file an IND with the FDA to allow us to commence a human clinical trial involving LAPC although no assurance as to timing can be given.

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

Phase 2 Clinical Trial

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

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

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

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

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

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

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

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

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

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

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

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

Manufacturing

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

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

Government Regulation and Product Approval

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

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

U.S. Government Regulation

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

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

- completion of preclinical studies and formulation studies in compliance with the FDA's Good Laboratory Practices ("GLP"), protocols and regulations;
- satisfactory completion of an FDA inspection of the manufacturing facilities at which the investigational product candidate is produced to assess compliance with cGMP and proof that the facilities, methods and controls are adequate;
- submission to the FDA of an IND to support human clinical testing in the U.S.;
- approval by an IRB at each clinical site before a trial may be initiated at that site;
- performance of adequate and well-controlled clinical trials in accordance with federal regulations and with Good Clinical Practices ("GCPs") to establish the safety and efficacy of the investigational product candidate for each target indication;
- Submission to the FDA of a New Drug Application ("NDA") or a drug or Biologics License Application ("BLA") for a biologic such as the therapies we are developing;
- satisfactory completion of an FDA Advisory Committee review, if applicable; and
- FDA review and approval of the NDA or BLA.

Clinical Development

Before a drug or biologic product may be given to humans, it must undergo preclinical testing. Preclinical tests include laboratory evaluation of a product candidate's chemical and biological activities and animal studies to assess potential safety and efficacy in humans. The results of these studies must be submitted to the FDA as part of an IND which must be reviewed by the FDA for safety and other considerations before testing can begin in humans.

An IND is a request for authorization from the FDA to administer an investigational product candidate to humans. This authorization is required before interstate shipping and administration can commence of any new drug or biologic product destined for use in humans in the U.S. A 30-day waiting period after the submission of each IND is required before commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period after submission of the IND, the clinical trial proposed in the IND may begin. A clinical trial involves the administration of the investigational product candidate to patients under the supervision of qualified investigators following GCP standards. These international standards are meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors. A clinical trial is conducted under protocols that detail the parameters to be used in monitoring safety, and the efficacy criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

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

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

Phase 2 Clinical Trial: A Phase 2 clinical trial is conducted on a limited number of patients; these patients can have a specific targeted disease. An initial evaluation of the product candidate's effectiveness on patients is performed. Additional information on the product candidate's safety and dosage range is obtained. For many diseases, a Phase 2 clinical trial can include up to several hundred patients.

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

The decision to terminate development of an investigational product candidate may be made by either a health authority body, such as the FDA, by IRB/ethics committees, or by the sponsor for various reasons. The FDA may order the temporary or permanent discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the patients enrolled in the trial. In some cases, a clinical trial is overseen by an independent group of qualified experts organized by the trial sponsor, or the clinical monitoring board. This group provides authorization for whether a trial may move forward at designated checkpoints. These decisions are based on the limited access to data from the ongoing trial. The suspension or termination of development can occur during any phase of a clinical trial if it is determined that the patients are being exposed to an unacceptable health risk. There are also requirements for the registration of an ongoing clinical trial of a product candidate on public registries and the disclosure of certain information pertaining to the trial, as well as clinical trial results after completion.

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

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, detailed investigational product candidate information is submitted to the FDA in the form of an NDA or BLA to request regulatory approval for the product in the specified indication.

New Drug Applications and Biologic Licensing Applications

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

In most cases, the NDA, in the case of a drug, or BLA, in the case of a biologic, must be accompanied by a substantial user fee. There may be some instances in which the user fee is waived. The FDA will initially review the NDA or BLA for completeness before it accepts the application for filing. The FDA has 60 days from its receipt of an NDA or BLA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. After the NDA or BLA submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of NDAs and BLAs. During a normal review cycle, a product is given an FDA action or Prescription Drug User Fee Act ("PDUFA") date within 12 months of the submission, if the submission is accepted. The FDA can extend this review by three months to consider certain late-submitted information or information intended to clarify information already provided in the submission. The FDA reviews the NDA or BLA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP standards. The FDA may refer applications for novel product candidates which present difficult questions of safety or efficacy to an advisory committee. This is typically a panel that includes clinicians and other experts for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA or a BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product candidate unless it determines that the manufacturing processes and facilities follow cGMP requirements and are adequate to assure consistent production of the product within required specifications. Manufacturers of human cellular or tissue-based biologics also must comply with the FDA's Good Tissue Practices ("GTPs"), as applicable, and with the general biological product standards. After the FDA evaluates the NDA or BLA and the sponsor company's manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA or BLA, the FDA will issue an approval letter. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The time to final marketing approval can vary from months to years, depending on several variables. These variables can include such things as the disease type, the strength and complexity of the data presented, the novelty of the target or compound, risk-management approval and whether multiple rounds of review are required for the agency to evaluate the submission. After evaluating the NDA or BLA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical or preclinical testing in order for FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information, which may include contraindications, warnings or precautions, for certain indications. After approval, some types of changes to the approved product, such as adding new indications and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Post Approval Regulations

After regulatory approval of a drug or biologic is obtained, a company is required to comply with certain post-approval requirements. For example, as a condition of approval of an NDA or BLA, the FDA may require post-marketing testing, including a Phase 4 clinical trial and surveillance to further assess and monitor the product's safety and effectiveness after commercialization has begun. Also, as a holder of an approved NDA or BLA, a company is required to: (i) report adverse reactions and production problems to the FDA; (ii) provide updated safety and efficacy information; and (iii) comply with requirements concerning advertising and promotional labeling for any of its products. Also, quality control and manufacturing procedures must continue to conform to cGMP standards after approval to assure and preserve the long-term stability of the drug or biological product. The FDA periodically inspects manufacturing facilities to assess compliance with cGMP standards, which imposes extensive procedural and substantive record keeping requirements. Also, changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. In addition, FDA regulations require investigation and correction of any deviations from cGMP standards and impose reporting and documentation requirements upon a company and any third-party manufacturers that a company may decide to use. Manufacturers must continue to expend time, money and effort in production and quality control to maintain compliance with cGMP standards and other aspects of regulatory compliance.

Disclosure of Clinical Trial Information

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

Advertising and Promotion

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

U.S. Patent Extension and Marketing Exclusivity

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

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

Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act ("FCPA") prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for influencing any act or decision of the foreign entity to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the U.S. to comply with accounting provisions requiring such companies to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. In Europe, and throughout the world, other countries have enacted anti-bribery laws and/or regulations similar to the FCPA.

European and Other International Government Regulation

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

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

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

Orphan Drug Status

In accordance with laws and regulations pertaining to regulatory agencies, a sponsor may request that the regulatory agencies designate a drug or biologic intended to treat a "Rare Disease or Condition" as an "Orphan Drug." For example, in the U.S., a "Rare Disease or Condition" is defined as one which affects less than 200,000 people in the U.S., or which affects more than 200,000 people but for which the cost of developing and making available the product is not expected to be recovered from sales of the product in the U.S. Upon the approval of the first NDA or BLA for a drug or biologic designated as an Orphan Drug for a specified indication, the sponsor of that NDA or BLA is entitled to 7 years of exclusive marketing rights in the U.S. for the drug or biologic for the particular indication unless the sponsor cannot assure the availability of sufficient quantities to meet the needs of persons with the disease. In Europe, this exclusivity is 10 years. However, Orphan Drug status for an approved indication does not prevent another company from seeking approval of a drug that has other labeled indications that are not under orphan or other exclusivities. An Orphan Drug may also be eligible for federal income tax credits for costs associated with the disease state, the strength and complexity of the data presented, the novelty of the target or compound, the risk-management approval and whether multiple rounds of review are required for the agency to evaluate the submission. There is no guarantee that a potential treatment will receive marketing approval or that decisions on marketing approvals or treatment indications will be consistent across geographic areas. Our therapy for pancreatic cancer and received Orphan Drug status in the U.S. and European Union.

Special FDA Expedited Review and Approval Programs

The FDA has various programs, including fast track designation, accelerated approval, priority review, and breakthrough therapy designation, which are intended to expedite or simplify the process for the development and FDA review of drugs or biologics that are intended for the treatment of serious or life-threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures.

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

The FDA may give a priority review designation to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under current PDUFA guidelines. Under the new PDUFA agreement, these six and ten month review periods are measured from the "filing" date rather than the receipt date for NDAs for new molecular entities, which typically adds approximately two months to the timeline for review and decision from the date of submission. Most products that are eligible for fast track designation are also likely to be considered appropriate to receive a priority review.

In addition, products tested for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may be eligible for accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, or IMM, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require a sponsor of a drug receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on IMM or other clinical endpoint, and the drug may be subject to accelerated withdrawal procedures.

Moreover, under the provisions of the Food and Drug Administration Safety and Innovation Act, or FDASIA, passed in July 2012, a sponsor can request designation of a product candidate as a "breakthrough therapy." 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. Drugs designated as breakthrough therapies are also eligible for accelerated approval. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. We may explore some of these opportunities for our product candidates as appropriate.

Accelerated Approval Pathway

The FDA may grant accelerated approval to a drug for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on IMM, and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. Drugs granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

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

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

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. As a result, a drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

Under a centralized procedure in the European Union, the maximum timeframe for the evaluation of a MAA is 210 days (excluding "clock stops," when additional written or oral information is to be provided by the applicant in response to questions asked by the Committee for Medicinal Products for Human Use ("CHMP")). Accelerated evaluation might be granted by the CHMP in exceptional cases, for example, when a medicinal product is expected to be of a major public health interest, which takes into consideration: (i) the seriousness of the disease (e.g., heavy disabling or life-threatening diseases) to be treated; (ii) the absence or insufficiency of an appropriate alternative therapeutic approach; and (iii) anticipation of high therapeutic benefit. In this circumstance, the EMA ensures that the opinion of the CHMP is given within 150 days.

Healthcare Reform

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

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

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

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

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

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

Coverage and Reimbursement

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

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

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

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

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

Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Other U.S. Healthcare Laws and Compliance Requirements

In the U.S., our activities are potentially subject to additional regulation by various federal, state and local authorities in addition to the FDA, including the CMS, other divisions of the HHS and its Office of Inspector General, the Office for Civil Rights that has jurisdiction over matters relating to individuals' privacy and protected health information, the DOJ, individual U.S. Attorney offices within the DOJ and state and local governments.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare program. The Anti-Kickback Statute has been interpreted broadly to proscribe arrangements and conduct where only one purpose of the remuneration between the parties was to induce or reward referrals. The term remuneration has been interpreted broadly to include anything of value. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers, on one hand, and prescribers, purchasers and formulary managers on the other. Although there are several statutory exemptions and regulatory safe harbors protecting some business arrangements from prosecution, the exemptions and safe harbors are drawn narrowly and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all the criteria for safe harbor protection from federal Anti-Kickback Statute liability. Failure to meet all the requirements of an applicable safe harbor or statutory exemption, however, does not make the arrangement or conduct *per se* unlawful under the Anti-Kickback Statute; instead, in such cases, the legality of the arrangement would be evaluated on a case-by-case basis based on a consideration of all the facts and circumstances to ascertain the parties' intent.

Moreover, the intent standard under the Anti-Kickback Statute was amended by the Affordable Care Act to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it to have committed a violation. In addition, the Affordable Care Act codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act, as discussed below.

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

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

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH") and its implementing regulations, imposes requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates," such as independent contractors or agents of covered entities that receive or obtain protected health information with providing a service on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons. It also gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing these actions. In addition, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect - thus complicating compliance efforts.

We may be subject to other state and federal privacy laws, including laws that prohibit unfair privacy and security practices and deceptive statements about privacy and security, laws that place specific requirements on certain types of activities, such as data security and texting, and laws requiring holders of personal information to maintain safeguards and to take certain actions in response to a data breach. EU member states, the United Kingdom, Switzerland and other jurisdictions have also adopted data protection laws and regulations, which impose significant compliance obligations. In the EEA and the United Kingdom, the collection and use of personal data, including clinical trial data, is governed by the provisions of the General Data Protection Regulation, or GDPR. The GDPR became effective on May 25, 2018, repealing its predecessor directive and increasing responsibility and liability of pharmaceutical and medical device companies in relation to the processing of personal data of EU data subjects. The GDPR, together with national legislation, regulations and guidelines of the EU member states and the United Kingdom governing the processing of personal data, impose strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. In particular, these obligations and restrictions concern the consent of the individuals to whom the personal data relates, the information provided to the individuals, the transfer of personal data out of the EEA or the United Kingdom, security breach notifications, security and confidentiality of the personal data and imposition of substantial potential fines for breaches of the data protection obligations. European data protection authorities may interpret the GDPR and national laws differently and impose additional requirements, which add to the complexity of processing personal data in or from the EEA or United Kingdom. Guidance on implementation and compliance practices are often updated or otherwise revised.

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

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

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

Controlled Substances Regulation

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

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

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

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

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

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

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

Patents, Intellectual Property and Trade Secrets

Intellectual property and patent protection are of paramount importance to our business, as are the trade secrets and other strategies we have employed with Austrianova to protect the proprietary Cell-in-a-Box® technology. Although we believe we take reasonable measures to protect our intellectual property and trade secrets and those of Austrianova, we cannot guarantee we will be able to protect and enforce our IP or obtain patent protection for our product candidates as needed. We license technology and trademarks relating to three areas: (i) live cell encapsulation with cells that express cytochrome P450 where the capsule is permeable to prodrug molecules and the cells are retained within the capsules; (ii) treatment of solid cancerous tumors and (ii) encapsulation of cells for producing retroviral particles for gene therapy. We also have exclusive worldwide licensing rights to patents, trademarks and know-how using Cell-in-a-Box® technology in the diabetes field and in the treatment of diseases and related conditions using cannabinoids.

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

Intellectual Property Agreements and Patent Applications

The following agreements are a material component of our intellectual property:

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

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

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

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

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

The Melligen Cell License Agreement provides us with an exclusive worldwide license, with a right to sublicense, to use genetically modified human cells that have been modified to comprise pancreas islet cell glucokinase for use in developing a therapy for diabetes. The Melligen cells are patent protected in the U.S. and Europe, which expire in August 2028, subject to any applicable patent term adjustment or extension that may be available.

The following patent applications are pending:

We own pending patent applications in the U.S., Australia, Canada and Europe directed at methods of treating cancerous tumors, such as those of the pancreas, liver, breast and colon, using the live-cell encapsulation of genetically modified human cells that overexpress a form of the cytochrome P450 enzyme system normally found in the liver. The methods involve administering encapsulated cells expressing the cytochrome P450 enzyme system along with a prodrug, such as an oxazaphosphorine or ifosfamide, which gets converted to an active form by the cytochrome P450 enzyme system. These applications, if approved, will expire on March 21, 2038, subject to any applicable patent term adjustment or extension that may be available. We are in the process of prosecuting these patent applications.

Details of Our Material Agreements

Third Addendum to the SG Austria APA

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

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

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

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

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

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

Diabetes Licensing Agreement

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

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

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

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

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

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

In May 2018, we entered into amendments to the Diabetes Licensing Agreement. For a full description of these amendments, see Item 1. "History of the Business."

Cannabis Licensing Agreement

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

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

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

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

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

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

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

In May 2018, we entered into amendments to the Cannabis Licensing Agreement. For a full description of these amendments, see Item 1. “History of the Business.”

Melligen Cell License Agreement

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

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

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

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

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

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

Sources and Availability of Raw Materials

The entire encapsulation process relating to the encapsulation of the cells for the oncology and diabetes-based therapies we are developing is to be carried out by Austrianova. Austrianova is the sole source of our product candidates. Austrianova is responsible for acquiring all of the necessary raw materials used in this process, including the cellulose sulfate necessary for encapsulating the live cells. Those cells have been grown by Eurofins to populate a MCB for our future clinical trials. See also “—Manufacturing” in this Item 1. “Business.”

Employees

As of April 30, 2020, we had four full-time employees and eleven consultants who devote substantial time to us. The consultants are physicians, scientists, regulatory experts, clinical operation experts and cGMP experts. All of our R&D efforts are handled by our consultants.

Medical and Scientific Advisory Board

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

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

Financial Information Concerning Geographic Areas

We had no revenues in the fiscal years ended April 30, 2020 and 2019, including no revenues from foreign countries. We have long-lived assets, other than financial instruments, located in the following geographical areas:

	FY 2020	FY 2019
United States:	$ 5,128,992	$ 5,128,992
All foreign countries, in total:	$ 0	$ 0

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

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

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

ITEM 1A. RISK FACTORS

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

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

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

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

We are a clinical stage biotechnology company focused on developing cellular therapies for cancer and diabetes based upon a proprietary cellulose-based live cell encapsulation technology known as “Cell-in-a-Box®.” In recent years, we have devoted substantially all our resources to the development of our product candidates. We have limited resources, a limited operating history, no products approved for clinical trials or commercial sale and therefore have not produced any revenues. We have generated significant operating losses since our inception. Our net losses for the years ended April 30, 2020 and 2019 were approximately $3.8 million and $4.1 million, respectively. As of April 30, 2020, we had an accumulated deficit of approximately $104 million. Substantially all our losses have resulted from expenses incurred relating to our research and development programs and from general and administrative expenses and operating losses associated with our business.

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

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

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

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

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

Our business and its operations, including, but not limited to, our clinical development program, supply chain operations, research and development activities and fundraising activities, could be adversely affected by the COVID-19 pandemic in areas where we have business operations. Also, this pandemic could cause significant disruption in the operations of third parties upon whom we rely to conduct the Company's business. COVID-19 was reported to have started in Wuhan, China in late 2019. Since then, COVID-19 has spread to other countries and throughout the U.S. In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic. Shortly thereafter, the U.S. government-imposed restrictions on travel between the U.S., Europe, and certain other countries. The President of the U.S. declared the COVID-19 pandemic a national emergency. Since March 2020, numerous state, regional and local jurisdictions, including the jurisdictions where our headquarters are located, have imposed, and others in the future may impose, quarantines, shelter-in-place orders, executive, and similar government orders for their residents to control the spread of COVID-19. As of the date of this Report, the COVID-19 pandemic has had an impact upon our operations, although we believe that impact is not material.

The effects of the executive orders, the shelter-in-place orders and our work-from-home policies may negatively impact productivity, disrupt our business, and delay our clinical development program and timeline, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition.

Quarantines, shelter-in-place, executive, and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to COVID-19, could impact personnel at our third-party manufacturing facilities in Thailand, or the availability or cost of materials we use or require to conduct our business, including product development, which would disrupt our supply chain. Some of our suppliers and vendors of certain materials used in our operations and research and development activities are located in areas that are subject to executive orders and shelter-in-place orders. While many of these materials may be obtained from more than one supplier, port closures and other restrictions resulting from the COVID-19 pandemic may disrupt our supply chain or limit our ability to obtain sufficient materials to operate our business. To date, we are aware of certain suppliers for our research and development activities that have experienced operational delays directly related to the COVID-19 pandemic.

Depending upon the length of the COVID-19 pandemic and whether the FDA allows us to commence our clinical trial once we submit our proposed IND, we anticipate our planned clinical trial in LAPC may be affected by the COVID-19 pandemic. If COVID-19 continues to spread in the U.S. and elsewhere, we may experience additional disruptions that could adversely impact our business and clinical trial, including: (i) delays or difficulties in enrolling patients in our clinical trial if the FDA allows us to go forward; (ii) delays or difficulties in clinical site activation, including difficulties in recruiting clinical site investigators and clinical site personnel; (iii) delays in clinical sites receiving the supplies and materials needed to conduct our clinical trial, including interruption in global shipping that may affect the transport of our clinical trial product; (iv) changes in local regulations as part of a response to the COVID-19 pandemic which may require us to change the ways in which our clinical trial is to be conducted, which may result in unexpected costs, or to discontinue the clinical trial altogether; (v) diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trial; (vi) interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data; (vii) risk that participants enrolled in our clinical trials will acquire COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events; (viii) delays in necessary interactions with local regulators, ethics committees, and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; (ix) limitations in employee resources that would otherwise be focused on the conduct of our clinical trial because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; (x) refusal of the FDA to accept data from clinical trials in affected geographies; and (xi) interruption or delays to our clinical trial activities.

The spread of COVID-19, which has caused a widespread impact throughout the world, may materially affect us economically. The potential economic impact brought about by the COVID-19 pandemic, and the duration of such impact, is difficult to assess or predict. The pandemic has resulted in significant disruption of global financial markets, which could reduce our ability to access capital and negatively affect our future liquidity. Also, a recession or market correction resulting from the spread of COVID-19 and related government orders and restrictions could materially affect our business and the value of our common stock. The COVID-19 pandemic continues to evolve. The ultimate impact of the COVID-19 pandemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trial, healthcare systems or the global economy.

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

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

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

- Our present and future capital requirements will be significant and will depend on many factors, including:
- the progress and results of our development efforts for our product candidates;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the effect of competing technological and market developments;
- market acceptance of our product candidates;
- the rate of progress in establishing coverage and reimbursement arrangements with domestic and international commercial third-party payors and government payors;
- the extent to which we acquire or in-license other products and technologies; and
- legal, accounting, insurance and other professional and business-related costs.
- We may not be able to acquire additional funds on acceptable terms, or at all. If we are unable to raise adequate funds, we may have to liquidate some or all of our assets or delay, reduce the scope of or eliminate some or all of our development programs.
- If we do not have, or are not able to obtain, sufficient funds, we may be required to delay development or commercialization of our product candidates. We also may have to reduce the resources devoted to our product candidates or cease operations. Any of these factors could harm our operating results.

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

We seek to maintain a process of prioritization and resource allocation to maintain an optimal balance between aggressively advancing lead programs and ensuring replenishment of our portfolio.

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

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

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

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

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

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

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

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

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

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

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

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

Specifically, there are numerous companies developing or marketing therapies for cancer and diabetes, including many major pharmaceutical and biotechnology companies. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we can enter the market.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology sectors may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

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

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

Subject to our submission of our IND and FDA approval, we plan to commence a Phase 2b clinical trial in LAPC. A Pre-IND meeting with the FDA was held on January 17, 2017, at which the FDA provided us with guidance to complete the IND process and communicated its agreement with certain aspects of our clinical development plan. We were delayed in submitting our IND to the FDA, due to guidance provided by the FDA and due to delays in preparing the materials necessary to submit our IND. No assurance can be given whether the FDA will approve our IND which we expect will be filed shortly after the filing of this Report although no assurance as to timing of our submission can be given. The FDA may put us on a clinical hold until we satisfy its requirements to commence our clinical trial involving LAPC, which may never occur. We cannot provide assurance as to the FDA's reaction to it. In the event the FDA does not allow us to commence our planned clinical trial in LAPC which would likely have a material adverse effect on us. The FDA may require us to conduct a Phase 1 clinical trial rather than beginning with a Phase 2b clinical trial or conduct preclinical studies before starting any clinical trials. Such actions would have a material adverse effect on our business plans and operations.

Our plan to first pursue a Phase 2b clinical trial before a pivotal Phase 3 trial will likely result in additional costs to us and resultant delays in the FDA review process and any future commercialization and marketing, if regulatory approval is obtained.

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

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

Our ability to submit an IND to the FDA depends on a variety of factors. We must submit the results of various preclinical tests, together with manufacturing information, analytical data, any available past clinical data or literature and a proposed clinical protocol to the FDA as part of the IND. Preclinical tests include laboratory evaluations of product chemistry and formulation, as well as other studies to assess the potential safety and activity of the pharmaceutical product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements. The FDA may require that we conduct additional preclinical testing or for any product candidate before it allows us to initiate the clinical testing under any IND, which may lead to additional delays and increase the costs of our preclinical and clinical development. An IND also involves considerable work from our employees and advisors.

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

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

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

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

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

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

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

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

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

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

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

Risks related to Hai Kang licensed COVID-19 diagnostic kits

With respect to our license for Hai Kang developed COVID-19 diagnostic kits, we may not be able to (i) develop a related product candidate with our current resources, on a timely basis, or at all; (ii) obtain the necessary regulatory approvals for such a product candidate; (iii) commercialize any such product candidate; or (iv) obtain reimbursement for such a product candidate in the U.S. and elsewhere. It is uncertain that any such product candidates will comply with U.S. regulatory requirements or that any health care facility or provider will be willing or able to use such product candidates.

We intend to conduct clinical trials for certain of our product candidates at sites outside of the U.S., and the U.S. regulatory agencies may not accept data from trials conducted in such locations.

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

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

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

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

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

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

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

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

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

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

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

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

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

- Clinical trials of our product candidates may produce unfavorable or inconclusive results;
- We may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs or candidates;

- The number of patients required for clinical trials of our product candidates may be larger than we anticipate, patient enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials at a higher rate than we anticipate;

- Our third-party contractors, including those manufacturing our product candidates or components or ingredients thereof or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner or at all;

- Regulators or IRBs may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;

- We may experience delays in reaching or may fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;

- Patients who enroll in a clinical trial may misrepresent their eligibility to do so or may otherwise not comply with the clinical trial protocol, resulting in the need to drop the patients from the clinical trial, increase the needed enrollment size for the clinical trial or extend the clinical trial's duration;

- We may have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks, undesirable side effects or other unexpected characteristics of a product candidate;

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

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

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

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

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

Product development costs for us will increase if we experience delays in testing or pursuing marketing approvals. We may also be required to obtain additional funds to complete clinical trials and prepare for possible commercialization of our product candidates. We do not know whether any preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule or at all. Significant preclinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations. In addition, many of the factors that cause, or lead to, clinical trial delays may ultimately lead to the denial of marketing approval of any of our product candidates.

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

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll enough eligible patients to participate in our clinical trials. Patient enrollment is a significant factor in the overall duration of a clinical trial and is affected by many factors, including:

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

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

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

We may be eligible for priority review designation for our product candidates if the regulatory agencies determine such product candidates offer major advances in treatment or provide a treatment where no adequate therapy exists. A priority review designation means that the time required for the regulatory agencies to review an application is less than the standard review period. The regulatory agencies have broad discretion with respect to whether to grant priority review status to a product candidate, so even if we believe a product candidate is eligible for such designation or status, the regulatory agencies may decide not to grant it. Thus, while the regulatory agencies have granted priority review to other oncology and diabetes products, our product candidates, should we determine to seek priority review of them, may not receive similar designation. Moreover, even if one of our product candidates is designated for priority review, such a designation does not necessarily mean a faster overall regulatory review process or necessarily confer any advantage with respect to approval compared to conventional procedures of the regulatory agencies.

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

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

We anticipate that we may seek an accelerated approval pathway for certain of our product candidates. Under the accelerated approval provisions or their implementing regulations of the regulatory agencies, they may grant accelerated approval to a product designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product influences a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. Regulatory agencies consider a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. If such post-approval studies fail to confirm the drug's clinical benefit, regulatory agencies may withdraw their approval of the drug.

Prior to seeking such accelerated approval, we will seek feedback from the regulatory agencies and will otherwise evaluate our ability to seek and receive such accelerated approval. There can also be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit an NDA, a BLA or an MAA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent feedback from regulatory agencies that we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to apply for accelerated approval or under another expedited regulatory designation (such as the Breakthrough Therapy designation or Fast Track designation), there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis or at all. Regulatory agencies could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for any of our product candidates that we determine to seek accelerated approval for would result in a longer time to commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

We may seek Orphan Drug designation for some of our product candidates, and we may be unsuccessful.

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

We have been granted Orphan Drug designation for our pancreatic cancer therapy, including LAPC, in the U.S. and European Union. Orphan Drug exclusivity may be lost if a regulatory agency determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Marketing exclusivity for a product designated as an Orphan Drug may not effectively protect the product candidate from competition because different drugs can be approved for the same condition. Even after an Orphan Drug is approved, the regulatory agency can subsequently approve a different drug for the same condition if they conclude that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

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

We do not currently have Fast Track designation by the FDA or similar designation by another regulatory agency for any of our product candidates but intend to seek such designation based upon the data generated from our clinical trials, if successful. If a drug or biologic is intended for the treatment of a serious or life-threatening condition and the product candidate demonstrates the potential to address unmet medical needs for this condition, the sponsor may apply for Fast Track designation by the FDA or similar designation by another regulatory agency. Regulatory agencies have broad discretion whether to grant this designation by the FDA or similar designation by another regulatory agency. Even if we believe a product candidate is eligible for this designation, we cannot assure you that a regulatory agency would decide to grant it. Even if we do receive Fast Track or similar designation, we may not experience a faster development process, review or approval compared to conventional procedures adopted by a regulatory agency. In addition, a regulatory agency may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Many product candidates that have received Fast Track designation have failed to obtain marketing approval.

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

We do not currently have Breakthrough Therapy designation by the FDA or similar designation by another regulatory agency for any of our product candidates but intend seek such designation based upon the data we generate during our clinical trials, if successful.

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

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

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

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

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

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

Also, later discovery of previously unknown adverse events or other problems with our product candidates, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- Restrictions on such products, manufacturers or manufacturing processes;
- Restrictions on the labeling or marketing of a product;
- Restrictions on product distribution or use;
- Requirements to conduct post-marketing studies or clinical trials;
- Warning or untitled letters;
- Withdrawal of the products from the market;
- Refusal to approve pending applications or supplements to approved applications that we submit;
- Recall of products;
- Fines, restitution or disgorgement of profits or revenues;
- Suspension or withdrawal of marketing approvals;
- Refusal to permit the import or export of our product candidates;
- Product seizure; or
- Injunctions or the imposition of civil or criminal penalties

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

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, substantial civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable federal and state fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval. Restrictions under applicable healthcare laws and regulations include the following:

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

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

HIPAA imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. HIPAA, as amended by HITECH and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. Federal law requires applicable manufacturers of covered drugs to report payments and other transfers of value to physicians and teaching hospitals, which includes data collection and reporting obligations. The information is to be made publicly available on a searchable website. Analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

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

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of our product candidates from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

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

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

In March 2010, former President Obama signed into law the Affordable Care Act, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The Affordable Care Act, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates.

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

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

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

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

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

Risks Related to the Commercialization of Our Product Candidates

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

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

Even if one of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third party payors and others in the medical community necessary for commercial success and the market opportunity for the product candidate may be smaller than we anticipated.

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

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

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

- The efficacy and safety of the product;
- The potential advantages of the product compared to alternative treatments;
- The prevalence and severity of any side effects;
- The clinical indications for which the product is approved;
- Whether the product is designated under physician treatment guidelines as a first-line therapy or as a second- or third-line therapy;
- Limitations or warnings, including distribution or use restrictions, contained in the product's approved labeling;
- Our ability to offer the product for sale at competitive prices;
- Our ability to establish and maintain pricing sufficient to realize a meaningful return on our investment;
- The product's convenience and ease of administration compared to alternative treatments;
- The willingness of the target patient population to try, and of physicians to prescribe, the product;

- The strength of sales, marketing and distribution support;
- The approval of other new products for the same indications;
- Changes in the standard of care for the targeted indications for the product;
- The timing of market introduction of our approved products as well as competitive products and other therapies;
- Availability and amount of reimbursement from government payors, managed care plans and other third-party payors;
- Adverse publicity about the product or favorable publicity about competitive products; and
- Potential product liability claims.

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Dependence on Third Parties

We rely and expect to continue to rely heavily on third parties to conduct our preclinical studies and clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such studies and trials.

We currently rely on third parties to plan for and conduct our clinical trials. We expect to continue to rely heavily on third parties, such as a CRO, a clinical data management organization, a medical institution, a clinical investigator and others to plan for and conduct our clinical trials. Our agreements with these third parties generally allow the third party to terminate our agreement with them at any time. If we are required to enter alternative arrangements because of any such termination, the introduction of our product candidates to market could be delayed.

Our reliance on these third parties for R&D activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we design our clinical trials and will remain responsible for ensuring that each is conducted in accordance with the general investigational plan and protocol for the trial. Moreover, regulatory agencies require us to comply with cGMP standards for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database of regulatory agencies within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

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

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

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

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

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

For some of our product candidates, we may in the future determine to collaborate with pharmaceutical and biotechnology companies for development of our product candidates. We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for any collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of several factors. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay our potential development schedule or increase our expenditures and undertake preclinical and clinical development activities at our own expense. If we fail to enter collaborations and do not have sufficient funds or expertise to undertake the necessary development activities, we may not be able to further develop our product candidates or continue to develop our product candidates and our business may be materially and adversely affected.

Future collaborations we may enter may involve the following risks:

- Collaborators may have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- Collaborators may not perform their obligations as expected;
- Changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, may divert resources or create competing priorities;
- Collaborators may delay discovery and preclinical development, provide insufficient funding for product development of targets selected by us, stop or abandon preclinical or clinical development of a product candidate or must repeat or conduct new preclinical and clinical development of a product candidate;

- Collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed than ours;
- Product candidates may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the development of our product candidates;
- Disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development might cause delays or termination of the preclinical or clinical development or commercialization of product candidates. This might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- Collaborators may not properly maintain or defend our intellectual property rights or intellectual property rights licensed to us or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- Collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- Collaborations may be terminated at the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of our product candidates.

In addition, subject to its contractual obligations to us, if a collaborator of ours is involved in a business combination, the collaborator might deemphasize or terminate the development of any of our product candidates. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the business and financial communities could be adversely affected. If we are unable to maintain our collaborations, development of our product candidates could be delayed, and we may need additional resources to develop them.

We rely on Prof. Günzburg, 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.

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

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

We do not currently own or operate manufacturing facilities to produce clinical quantities of our encapsulated live cell and ifosfamide product for pancreatic cancer and other encapsulated product candidates and have limited personnel with manufacturing experience. We currently rely on and expect to continue to rely on third party contract manufacturers to manufacture supplies of our product candidates for preclinical studies and clinical trials, as well as for commercial manufacture of our product candidates, and these must be maintained for us to receive marketing approval for our product candidates.

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

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

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

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

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

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

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

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

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

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

The processes involved in manufacturing our product candidates are complex, expensive, highly regulated and subject to multiple risks. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. Further, as product candidates are developed through preclinical studies to potential future clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials. We expect to rely on third-party manufacturers for the manufacturing of our products.

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

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

Risks Related to Our Intellectual Property

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

Our success depends in large part on our ability to obtain and maintain patent protection in the U.S. and other countries with respect to our proprietary technology and products. We seek to protect our proprietary position by filing patents in the U.S. and abroad related to our product candidates. Our patent portfolio relating to the Cell-in-the-Box® technology was formerly licensed from Bavarian Nordic/GSF. The Bavarian Nordic/GSF patents covered capsules encapsulating cells expressing cytochrome P450 and treatment methods using the same. These patents expired on March 27, 2017. We exclusively license from UTS patented Melligen cells, which cover our product candidate for the treatment of diabetes. The patents are issued in the U.S. and Europe and expire in August 2028. Currently, we do not have any issued patents in any countries covering our product candidate for the treatment of cancer; we have pending applications in the U.S., Australia, Canada and Europe relating to our product candidate for the treatment of pancreatic cancer. If issued, such patents would expire in March 2038.

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

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

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

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

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

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

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

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the U.S. and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Thus, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

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

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

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

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

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

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of some countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or misappropriation of our intellectual property rights generally. Proceedings to enforce our patent and other intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents or intellectual property rights at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful.

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

Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

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

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

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

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

We have licensed rights to intellectual property from third parties to commercialize our product candidates, including our Cell-in-a-Box® Technology for LAPC and diabetes and our COVID-19 diagnostic kits. If we materially breach or fail to perform any provision under these license and collaboration agreements, including failure to make payments to a licensor or collaborator when due for royalties and failure to use commercially reasonable efforts to develop and commercialize our product candidates, such licensors and collaborators have the right to terminate our agreements, and upon the effective date of such termination, our right to practice the licensed intellectual property would end. Any uncured, material breach under the agreements could result in our loss of rights to practice the patent rights and other intellectual property licensed to us under the agreements and could result in the loss of our ability to develop or commercialize our product candidates.

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

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

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

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

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

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

Because our programs may involve additional product candidates that may require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights. We may be unable to acquire or in-license any compositions, methods of use or other third-party intellectual property rights from third parties that we identify. The licensing and acquisition of third-party intellectual property rights is a competitive area, and numerous established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

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

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

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

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

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

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

We employ individuals and use consultants and independent contractors who were previously employed at other biotechnology or pharmaceutical companies. Although we seek to ensure that our employees and our consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed trade secrets, or other confidential information of our employees', consultants' or independent contractors' former employers, clients or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Even if we are successful, litigation could result in substantial cost and be a distraction to our management and others working for us.

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

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

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

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

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

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

Additional Risks Related to Our Business Model and Operations

Development of brand awareness is critical to our success.

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

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

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

Our success depends on additional states legalizing medical Cannabis.

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

Medicinal Cannabis faces strong opposition.

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

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

Our product candidates involving *Cannabis* contain controlled substances as defined in the CSA. Controlled substances that are pharmaceutical products are subject to a high degree of regulation under the CSA, which establishes, among other things, certain registration, manufacturing quotas, security, recordkeeping, reporting, import, export and other requirements administered by the DEA. The DEA classifies controlled substances into five schedules: Schedule I, II, III, IV or V substances. Schedule I substances by definition have a high potential for abuse, have not currently "accepted medical use" in the U.S., lack accepted safety for use under medical supervision, and may not be prescribed, marketed or sold in the U.S. Pharmaceutical products approved for use in the U.S. may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest potential for abuse or dependence and Schedule V substances the lowest relative risk of abuse among such substances. Schedule I and II drugs are subject to the strictest controls under the CSA, including manufacturing and procurement quotas, security requirements and criteria for importation. In addition, dispensing of Schedule II drugs is further restricted. For example, they may not be refilled without a new prescription.

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

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

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

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

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

The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford expensive treatments. Sales of our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

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

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

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

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

In the U.S., there have been numerous legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities or affect our ability to profitably sell any product candidates for which we obtain marketing approval. The Affordable Care Act, among other things, imposes a significant annual fee on companies that manufacture or import branded prescription drug products. It also contains substantial provisions intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers, and impose additional health policy reforms, any of which could negatively impact our business. The Affordable Care Act and other legislative changes are likely to continue the downward pressure on pharmaceutical and medical device pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risk Factors Related to Our Stock and Financial Condition

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

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

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

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

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

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

To be eligible to use Form S-3 for a registered offering of our securities to investors, either: (i) the aggregate market value of our common stock held by non-affiliates must exceed $75 million; or (ii) our common stock must be listed and registered on a national securities exchange. We do not currently meet either of these eligibility requirements and are therefore precluded from conducting a registered offering of our securities to investors by means of filing a Form S-3 or effecting a "shelf" offering after the date of the filing of this Report. In addition, we failed to timely file a Form 8-K that also caused us to be ineligible to file a new Form S-3 until November 1, 2020.

Penny stock rules may have an adverse effect on us.

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

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

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

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

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

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

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

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

Because of the price volatility in our shares we have observed since its inception, investors in our common stock may not be able to sell their shares when they desire to do so at a price the investors desire to attain. The inability to sell securities in a rapidly declining market may substantially increase the risk of loss because the price of our common stock may suffer greater declines due to the historical price volatility of our shares. Certain factors, some of which are beyond our control, that may cause our share price to fluctuate significantly include, but are not limited to, the following:

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

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

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

We have not paid dividends on our shares of common stock and do not anticipate paying such dividends in the foreseeable future.

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

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

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

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

We are an early-stage biotechnology company with a limited operating history. As of April 30, 2020, we had four full-time employees and eleven key consultants. We are highly dependent on the R&D, clinical and business development expertise of the principal members of our management, scientific and clinical teams, specifically, on our Chief Executive Officer, Chief Operating Officer and Chief Financial Officer. Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. The loss of the services of our Chief Executive Officer, Chief Operating Officer and Chief Financial Officer or other key employees or consultants could severely impede the achievement of our R&D and commercialization of our product candidates and seriously harm our ability to successfully implement our business strategy.

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

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

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

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 R&D tax credits) to offset its post-change income and taxes may be limited. In general, an "ownership change" occurs if there is a cumulative change in our ownership by "5% shareholders" that exceeds 50 percentage points over a rolling three-year period. Similar rules may apply under state tax laws.

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

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

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

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

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The recent global financial crisis related to COVID-19 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. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could adversely impact our business.

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

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

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

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

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

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

On December 22, 2017, President Trump signed into law the final version of the Tax Act. The Tax Act significantly reforms the Internal Revenue Code of 1986, as amended, with many of its provisions effective for tax years beginning on or after January 1, 2018. The Tax Act, among other things, contains significant changes to corporate taxation, including a permanent reduction of the corporate income tax rate, a partial limitation on the deductibility of business interest expense, a limitation of the deduction for net operating loss carryforwards to 80% of current year taxable income, an indefinite net operating loss carryforward and the elimination of the two-year net operating loss carryback, temporary, immediate expensing for certain new investments and the modification or repeal of many business deductions and credits.

In addition, on March 27, 2020, the U.S. government enacted the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"). The CARES Act makes the following changes to the U.S. tax code that will affect our 2019 and 2020 taxes, including, but not limited to, (1) temporary modification of the adjusted taxable income limitation under Section 163(j) from 30% to 50% for tax years 2019 and 2020 only; (2) modification to the net operating loss rules surrounding the ability to now carryback five years net operating losses generated in 2018, 2019, and 2020; (3) temporary repeal of the net operating loss taxable income limitation of 80%; and (4) temporary enhancement of corporate charitable contribution limitation to 25% of taxable income for tax year 2020 only.

We continue to examine the impact this tax reform legislation may have on our business. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Act is uncertain and our business and financial condition could be adversely affected. The impact of these reforms on our stockholders is uncertain. Stockholders should consult with their tax advisors regarding the effect of the Tax Act and the CARES Act and other potential changes to the U.S. Federal tax laws on them.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our principal office is located at 23046 Avenida de la Carlota, Suite 600, Laguna Hills, California 92653. The office we lease (“Leased Premises”) consist of approximately 400 square feet plus the use of certain shared facilities, such as a lobby, conference rooms, a kitchen and open workspaces. The term of our current lease agreement expires on August 31, 2020. On May 28, 2020, 2020, we entered into a new lease agreement at our current location for an additional twelve-month term, expiring on February 28, 2021. The Leased Premises will consist of approximately 200 square feet plus the use of the same shared facilities and areas.

ITEM 3. LEGAL PROCEEDINGS

There is no material litigation currently pending against us or any of our subsidiaries or to which any of our or our subsidiaries’ property is subject. To our knowledge, there is no material litigation against any of our officers or directors in their capacity as such, and no such litigation is contemplated by any governmental authorities.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

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

The following table sets forth the high and low bid quotations reported on the OTCQB for our shares for each quarter during the two fiscal years ("FYs") ended April 30, 2020 and 2019. The prices reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

Date	Bid Price	
FY 2020	HIGH	LOW
First Quarter	$ 0.04	0.04
Second Quarter	$ 0.04	0.03
Third Quarter	$ 0.07	0.03
Fourth Quarter	$ 0.06	0.02
FY 2019		
First Quarter	$ 0.11	0.05
Second Quarter	$ 0.07	0.05
Third Quarter	$ 0.06	0.04
Fourth Quarter	$ 0.07	0.04

As of April 30, 2020, there were 1,638,637,839 issued and outstanding shares of common stock. We are informed these shares are held by approximately 1,300 shareholders of record.

Dividend Policy

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

Securities Authorized for Issuance under Equity Compensation Plans

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

Recent Issuance of Unregistered Securities

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

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

Sale Date	Warrants Issued	Exercise Price
May 30, 2018	1,388,889	$0.018
June 28, 2018	1,923,077	$0.026
November 1, 2018	2,272,727	$0.011
March 26, 2019	1,250,000	$0.010
March 26, 2019	1,250,000	$0.010
June 13, 2019	1,388,889	$0.009
July 15, 2019	1,944,444	$0.009
August 7, 2019	3,500,000	$0.005
February 24, 2020	2,000,000	$0.005
March 24, 2020	3,500,000	$0.005
March 31, 2020	1,000,000	$0.005
April 7, 2020	2,500,000	$0.010
April 21, 2020	833,333	$0.015

In addition to issuances of unregistered securities by us to our officers and directors previously disclosed in our Quarterly Reports on Form 10-Q, our Form 8-Ks and this Report, on March 9, 2020, we issued 500,000 shares of restricted common stock to a consultant for services provided to us. The non-cash expense for these share issuances total $27,500.

All such shares were issued without registration under the Securities Act in reliance upon the exemption afforded by Section 4(a)(2) of the Securities Act based on the limited number of investors, the sophistication of the individuals involved and the use of restrictive legends on the share certificates issued to prevent a public distribution of the relevant securities.

ITEM 6. SELECTED FINANCIAL DATA

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

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

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

Overview

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

We are actively engaged with Austrianova and other entities in preparation for a Phase 2b clinical trial in LAPC using encapsulated live cells like those used in the previous Phase 1/2 and Phase 2 clinical trials discussed above. A Pre-IND meeting with the FDA was held on January 17, 2017, at which the FDA communicated its agreement with certain aspects of our clinical development plan, charged us with completing numerous tasks and provided us with the guidance we need to complete what we expect will be a successful IND process. We anticipate that shortly after the filing of this Report we will file an IND with the FDA to allow us to commence a human clinical trial involving LAPC although no assurance as to time can be given.

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

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

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

However, with respect to our programs involving cannabinoids, malignant ascites fluid and diabetes, until the FDA allow us to commence the clinical trial involving LAPC described in our IND to filed with the FDA, we are not spending any further resources developing this program.

Finally, we are working with Hai Kang to obtain an EUA from the FDA to develop and sell COVID-19 molecular diagnostic kits in the U.S., Canada and certain European countries.

COVID-19 Potential Impact on the Financial Condition and Results of Operations

The development of our product candidates could be disrupted and materially adversely affected in the future by a pandemic like the recent outbreak of COVID-19. For example, as a result of measures imposed by the governments in states affected by COVID-19, businesses and schools have been suspended due to quarantines or stay at home orders intended to contain the pandemic. COVID-19 continues to spread globally and, as of April 30, 2020, has spread to over 150 countries, including the U.S. While the COVID-19 pandemic is thought to be in its early stages, international stock markets continue to reflect the uncertainty associated with the slow-down in the world economies and the reduced levels of international travel experienced since the beginning of January 2020. As of the date of this Report, the COVID-19 pandemic has had an impact upon our operations, although we believe that impact is not material.

We are still assessing our business plans and the impact COVID-19 may have on our ability to advance the development of our product candidates or to raise financing to support the development of our product candidates, but no assurances can be given that this analysis will enable us to avoid part or all of any impact from the spread of COVID-019 or its consequences, including downturns in the business sector generally or in our sector in particular. The spread of COVID-19 may also result in the inability of our suppliers to deliver components or raw materials on a timely basis or materially and adversely affect our collaborators' and potential strategic partners' ability to conduct our planned clinical trial in LAPC and our other operations. See "Risk Factors — The recent and ongoing COVID-19 pandemic could materially affect our operations, as well as the business or operations of third parties with whom we conduct business. Our business could be adversely affected by the effects of other future health pandemics in regions where we or third parties on which we rely have significant business operations. See Page 39 for a more detailed presentation of our risks associated with the COVID-19 pandemic.

Performance Indicators

Non-financial performance indicators used by management to manage and assess how the business is progressing will include, but are not limited to, the ability to: (i) acquire appropriate funding for all aspects of our operations; (ii) acquire and complete necessary contracts; (iii) complete activities for producing genetically modified human cells and having them encapsulated for our preclinical studies and the planned Phase 2b clinical trial in LAPC; (iv) have regulatory work completed to enable studies and trials to be submitted to regulatory agencies; (v) complete all required tests and studies on the cells and capsules we plan to use in our clinical trial in patients with LAPC; and (vi) ensure completion of the production of encapsulated cells according to cGMP regulations to use in our planned clinical trial.

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

Liquidity and Capital Resources

Our Consolidated Financial statements and related Notes have been prepared on a going-concern basis, however, the following conditions raise substantial doubt about the Company's ability to do so. Therefore, the Consolidated Financial Statements do not include any adjustments that might be necessary should we be unable to continue in existence. We have not generated any revenues and have not yet achieved profitable operations. There is no assurance that profitable operations, if ever achieved, could be sustained on a continuing basis. Also, development activities, preclinical studies, clinical trials and commercialization of our product candidates will require significant additional capital resources. Our deficit accumulated through April 30, 2020 was $103,858,258. We expect to incur substantial and increasing losses in future periods. Our total cash in the bank was $894,861 and $515,253 as of April 30, 2020 and 2019, respectively. Our net loss was $3,826,888 and $4,067,228 for the years ended April 30, 2020 and 2019, respectively. Cash flows from investing activities were $0 for the years ended April 30, 2020 and 2019. Net cash provided by financing activities was $2,725,848 and $2,342,500 for the years ended April 30, 2020 and 2019, respectively. For more information, see the discussion under the caption "—Discussion of Operating, Investing and Financing Activities" in this Item 7.

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

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

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

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

On February 22, 2018, we entered into a financial advisory offering and an “at the market offering” engagement agreement (“Aeon Agreement”) with Aeon Capital, Inc. (“Aeon”) pursuant to which Aeon agreed to use its reasonable best efforts to act as our agent for the sale of up to $25,000,000 of our common stock in “at-the-market,” or privately negotiated transactions, or transactions structured as a public offering of a distinct block or blocks of the shares of our common stock (“Block Trades”). In connection with a transaction deemed to be an “at the market offering”, we agreed to pay Aeon a cash fee of 3% of the aggregate sales price from the sale of shares of our common stock. In connection with a transaction structured as a Block Trade, we agreed to pay Aeon a cash fee of 7% of the aggregate sales price of any Block Trade sold under the Aeon Agreement unless the Company introduced the investor to Aeon, in which event the fee is 4%, plus five-year warrants representing 5% of the number of shares of common stock sold at an exercise price equal to the price per share at which the shares were sold in the Block Trade. We also agreed to reimburse certain expenses of Aeon in an amount not to exceed $10,000. In addition, we agreed to provide Aeon with customary indemnification rights. The offering of the shares of our common stock will terminate upon the earliest to occur of: (i) the sale of all of the shares to be sold; or (ii) the termination of the Aeon Agreement by us or Aeon upon thirty days written notice prior to the effective date of the termination. Upon the filing of this Report, we will no longer be eligible to use the Form S-3 in at-the-market or Block Trade transactions until November 1, 2020.

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

From May 1, 2018 to April 30, 2020, the Company sold 495,027,195 shares of our common stock structured as a Block Trade. The issuance of these shares resulted in gross proceeds of approximately $4.9 million. Pursuant to the Aeon Agreement, we incurred fees to Aeon of $337,000 and provided warrant coverage of 5% of the number of shares sold with a five-year term of approximately 24.8 million warrant shares.

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

As of April 30, 2020, we had approximately $895,000 in cash in our bank account at that time the cash expenditures were approximately $200,000 per month. Subsequent to the fiscal year end, the Company raised additional capital in the amount of approximately $4.7 million from Block Trades and "at-the-market" trades. As of the date of this Report, the Company had approximately $4.9 in the bank account.

We believe our cash on hand, potential sales of unregistered shares of our common stock and any public offerings of common stock in which we may engage in will provide sufficient capital to meet our capital requirements and to fund our operations through August 31, 2021.

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

Year ended April 30, 2020 compared to year ended April 30, 2019

Revenue

We had no revenues in the fiscal years ended April 30, 2020 and 2019.

Operating Expenses

The total operating expenses during the year ended April 30, 2020 decreased by $274,234 to $3,826,395 from $4,100,629 in the year ended April 30, 2019. The decrease is mainly attributable to a decrease in R&D costs, compensation expense and in consulting expense as we awarded less stock-based consulting fees and compensation in 2020 than in 2019.

Operating expenses:	Year ended April 30, 2020	Change - Increase (Decrease) and Percent	Year ended April 30, 2019
R&D	$ 301,221	$ (158,831) (35%)	$ 460,052
Compensation expense	$ 1,586,583	$ 31,325 2%	$ 1,555,258
Director fees	$ 316,892	$ (89,920) (22%)	$ 406,812
General and administrative, legal and professional	$ 1,621,699	$ (56,808) (3%)	$ 1,678,507

Loss from Operations

Loss from operations during the year ended April 30, 2020 decreased by $274,234 to $3,826,395 from $4,100,629 in the year ended April 30, 2019. The decrease is mainly attributable to decreases in R&D costs, director fees and in consulting expense net of an increase in compensation expense.

Other Income (Expenses), Net

Other income for the year ended April 30, 2019 was $33,401 as compared to other expense, net of $493 in the year ended April 30, 2020. Other income for the year ended April 30, 2019, is attributable to the Australian research and development credit and the Goods and Services Tax ("GST") refund. The Australian research and development credits relate to qualified research and development expenditures incurred in Australia. An annual tax incentive schedule is filed with the Australian Taxation Office to apply for the credit. A GST refund request form is submitted to the Australian Taxation Office for the return of qualifying GST amounts paid in Australia.

Discussion of Operating, Investing and Financing Activities

The following table presents a summary of our sources and uses of cash for the years ended April 30, 2020 and 2019.

	Year Ended April 30, 2020	Year Ended April 30, 2019
Net cash used in operating activities:	$ (2,338,373)	$ (2,877,912)
Net cash used in investing activities:	$ –	$ –
Net cash provided by financing activities:	$ 2,725,848	$ 2,342,500
Effect of currency rate exchange	$ (7,867)	$ (9,133)
Increase (decrease) in cash	$ 379,608	$ (544,545)

Operating Activities:

The cash used in operating activities for the years ended April 30, 2020 and 2019 are a result of our net losses offset by securities issued for services and compensation, changes to prepaid expenses, accounts payable and accrued expenses.

Investing Activities: We had no investing activities for the years ended April 30, 2020 and 2019.

Financing Activities:

The cash provided from financing activities for the years ended April 30, 2020 and 2019 is mainly attributable to the proceeds from the sale of our common stock.

Off-Balance Sheet Arrangements

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

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

Critical Accounting Estimates and Policies

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

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

Research and Development Expenses

R&D expenses consist of costs incurred for direct and overhead-related research expenses and are expensed as incurred. Costs to acquire technologies, including licenses, that are utilized in R&D and that have no alternative future use are expensed when incurred. Technology developed for use in our product candidates is expensed as incurred until technological feasibility has been established.

Stock-Based Compensation

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

Net Income (Loss) Per Share

Basic net income (loss) per share of common stock is computed using the weighted-average number of common stock shares outstanding. Diluted net income (loss) per share of common stock is computed using the weighted-average number of shares of common stock and shares of common stock equivalents outstanding. Potentially dilutive stock options and warrants to purchase 115,090,155 and 149,527,797 shares of common stock at April 30, 2020 and 2019, respectively, were excluded from the computation of diluted net income (loss) per share because the effect would be anti-dilutive.

New Accounting Pronouncements

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

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our Consolidated Balance Sheets, as of April 30, 2020 and 2019, and our Consolidated Statements of Operations, Comprehensive Loss, Stockholders Equity and Cash Flows for each of the two years in the period ended April 30, 2020 and associated Notes and Schedules, together with the reports thereon of our independent registered public accounting firm, are set forth on pages F-1 to F-27 of this Report and are incorporated by reference herein.

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

Our principal independent public accountant is Armanino LLP ("Armanino"). During our fiscal year ended April 30, 2020 and 2019, there have been no disagreements with Armanino on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure which, if not resolved to Armanino's satisfaction, would have caused Armanino to refer to the subject matter in its report on our Consolidated Financial Statements for such periods.

During our fiscal year ended April 30, 2020 and 2019, there were no "reportable events" requiring disclosure pursuant to Item 304(a)(1)(v) of Regulation S-K. As used herein, the term "reportable event" means any of the items listed in paragraphs (a)(1)(v)(A) - (D) of Item 304 of Regulation S-K.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our Chief Executive Officer, President and General Counsel, as our principal executive officer ("Chief Executive Officer"), and our Chief Financial Officer, as our principal financial officer ("Chief Financial Officer"), evaluated the effectiveness of our "disclosure controls and procedures," as such term is defined in Rule 13a-15(e) promulgated under the Exchange Act. Disclosure controls and procedures are designed to ensure that the information required to be disclosed in the reports that we file or submit to the Commission pursuant to the Exchange Act are recorded, processed, summarized and reported within the period specified by the Commission's rules and forms and are accumulated and communicated to our management, including our Chief Executive Officer, as appropriate to allow timely decisions regarding required disclosures. Based upon this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, as of April 30, 2020, our disclosure controls and procedures were not effective due to the material weaknesses in internal control over financial reporting.

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

Management's Report on Internal Controls over Financial Reporting

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

Under the supervision and with the participation of our Chief Executive Officer and our Chief Financial Officer, management conducted an evaluation of the effectiveness of our internal controls over financial reporting as of April 30, 2020 based on the criteria outlined in Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") and identified the following material weaknesses in internal controls over financial reporting:

- Insufficient procedures and control documentation to implement control procedures including lack of timely contract preparation and review. We have developed procedures to provide ample review time of financial information, including contract preparation and review by qualified personnel as well as management. We have implemented these procedures, determined they are still insufficient and will continue to review these procedures to determine ways to further improve them.

- Insufficient segregation of duties of the Chief Financial Officer. We have delegated some of the duties of our Chief Financial Officer to other personnel within the Company and have added review and approval processes performed by the Chief Executive Officer. However, we have determined that we still have insufficient segregation of the duties of our Chief Financial Officer and will continue to review these procedures to determine ways to further improve them given our limited staff.

- Insufficient information technology controls and documentation. We currently use accounting software which we have determined is inadequate to provide the level of controls required by COSO. We are in the process of initiating a review process to fully evaluate the deficiencies in our technology controls and documentation. Based upon the results of this review process, we intend to implement the required remediation measures when it is reasonable to do so.

Because of these material weaknesses, our Chief Executive Officer and our Chief Financial Officer concluded that, as of April 30, 2020, our internal controls over financial reporting were not effective based on the COSO criteria.

We are in the process of investigating new procedures and controls for fiscal year 2021. We plan to make changes to our procedures and controls that we believe are reasonably likely to strengthen and materially affect our internal controls over financial reporting.

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

Changes in Internal Controls over Financial Reporting

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

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

ITEM 9B. OTHER INFORMATION

Effective as of April 2, 2020, entered into a License Agreement with Hai Kang pursuant to which Hai Kang granted to the us a license to certain technology owned or controlled by Hai Kang related to COVID-19 diagnostic kits. Pursuant to the License Agreement, the Company may directly (or through a third party) conduct research, use, develop, market, sell, distribute, import and export Products for human and veterinary uses in North America, the United Kingdom and certain other European cites (“Territory”). A “Product” is defined as any existing Kit of Hai Kang or any future Kit derived from Hai Kang’s Kits and includes an in vitro diagnostic test that is designed, manufactured and used within a single laboratory for which the FDA is not enforcing any premarket review or other regulatory approval requirements.

The Company is required to use its commercially reasonable efforts to develop and commercialize at least one Product in the Territory. This obligation to develop and commercialize a Product includes, among other things, the performance of non-clinical and clinical studies of any Product, the preparation, filing and prosecution of certain regulatory approvals for such Product (including to allow the Company to market and sell the Product and to get the Product approved for reimbursement). Hai Kang is responsible for all aspects of the manufacture and supply of the Products to be developed and sold under the Hai Kang License Agreement.

During the term of the Hai Kang License Agreement, the Company is required to pay a monthly fee to Hai Kang in the amount of $6,000, which monthly fee increases to $50,000 once the first Product receives regulatory approval from the FDA. In addition, upon the first commercial sale of a Product, the Company is required to make quarterly royalty payments equal to 10% of Net Sales (as defined in the Hai Kang License Agreement) of any Product sold pursuant to the License Agreement.

The Agreement has a perpetual term but may be terminated: (i) by the Company unilaterally with 120 days prior written notice; (ii) in the event one party believes the other party to be in breach of the Hai Kang License Agreement, by the non-breaching party if the breaching party does not cure the breach within 60 days after the date the breaching party was given notice of such breach; or (iii) by the Company with the prior written consent of Hai Kang (acting in its sole discretion), but such consent is not to be withheld or delayed if the Company wishes to terminate on account of demonstrable safety or efficacy concerns in respect of the Product. The Hai Kang License Agreement also provides for indemnification by Hai Kang and the Company under certain circumstances set forth in the Hai Kang License Agreement. The Company may not sell a competing COVID-19 diagnostic kit during the term of the Hai Kang License Agreement.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

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

	Age	Position
Kenneth L. Waggoner, JD	72	Chairman of the Board, Chief Executive Officer, President and General Counsel
Gerald W. Crabtree, PhD.	79	Director and Chief Operating Officer
Carlos A. Trujillo, CPA	62	Director and Chief Financial Officer
Thomas Liquard	47	Director
Thomas C. K. Yuen	68	Director
Michael M. Abecassis, MD	62	Director
Raymond C.F. Tong, MD.	61	Director

Kenneth L. Waggoner, JD

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

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

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

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

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

Gerald W. Crabtree, PhD

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

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

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

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

Carlos A. Trujillo, CPA

Carlos A. Trujillo began working for us as an independent contractor in September 2014. In January 2015, Mr. Trujillo became a full-time employee as the Vice President of Finance of both us and Viridis Biotech, and in March 2017, Mr. Trujillo was appointed as our Chief Financial Officer. Mr. Trujillo has been a member of the Board since March 2017. Mr. Trujillo has over three decades of experience in management, business, operations and financial accounting. It was his education, experience and leadership skills that led us to elect him to the Board.

Mr. Trujillo is a Certified Public Accountant with an active license from the State of California. He has more than three decades of experience in finance, accounting and management. Mr. Trujillo started his career in public accounting and was the manager of an audit department a large regional public accounting firm. Mr. Trujillo then established a consulting and accounting practice which he operated for ten years and provided services as the Chief Financial Accountant to numerous organizations in several different industries. His experience has extended to companies in the biotechnology, telecommunications, manufacturing, construction and real estate development sectors.

For the last thirteen years, Mr. Trujillo has been the Chief Financial Officer for both privately held and publicly traded and multinational companies. From June 2008 through September 2014, Mr. Trujillo was the Chief Financial Officer of VelaTel Global Communications, Inc. As a result, he brings extensive experience to us in preparing and filing periodic reports with the Commission, in mergers and acquisitions and in the filing of comprehensive financial statements.

Mr. Trujillo received his Bachelor of Accounting degree from California State University, Fullerton in 1982.

Thomas Liquard

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

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

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

Thomas C. K. Yuen

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

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

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

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

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

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

Michael M. Abecassis, MD

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

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

Dr. Abecassis received his Medical Degree from the University of Toronto in 1983 and was awarded a Master of Business Administration degree from the Kellogg School of Management at Northwestern University in 2000. After his postgraduate tenure in Toronto, Dr. Abecassis began his clinical career as Assistant Professor of Surgery and Director of Liver Transplantation and Hepatobiliary Surgery at the University of Iowa. In 1993, Dr. Abecassis became Northwestern University's Director of Liver Transplantation, where he initiated Northwestern's liver transplant program. In 2004, Dr. Abecassis was named Chief of the Division of Transplantation at the Feinberg School of Medicine. He became Founding Director of the Comprehensive Transplant Center at Northwestern in 2009 and was appointed Dean for Clinical Affairs at the Feinberg School of Medicine in 2008, serving until 2011.

Dr. Abecassis has received continuous funding from the National Institutes of Health ("NIH") for the past 17 years. He is the principal investigator in research that includes both laboratory and clinical studies. He is also the principal investigator of the clinical core of the NIH Genomics of Transplantation Cooperative Research Program. Dr. Abecassis has trained numerous clinical and research fellows.

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

Dr. Abecassis has been a course director for the American Society of Transplant Surgeons Leadership Development Program since 2010 and was course director for the Advanced Leader Development Program in 2013 at Northwestern's Kellogg School of Management. He was a voting member of the Medicare Coverage Advisory Committee and served on the United HealthCare Group Physician Advisory Board on Healthcare Performance and Quality. Dr. Abecassis has been a member of various local, regional and national regulatory committees and has published seminal papers on both the regulatory and financial aspects of transplantation, including the Healthcare Reform and the Affordable Care Act.

Raymond C.K Tong, MD

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

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

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

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

Family Relationships

There are no family relationships among our executive officers, directors and significant employees. As of April 30, 2020, our personnel do not have any involvement in legal proceedings requiring disclosure pursuant to the Rules and Regulations of the Commission.

Corporate Governance and Committees

Our Board has adopted a written Code of Business Conduct and Ethics, an Insider Trading Policy and Software Policies that apply to our directors, officers, employees and contractors. These documents can be viewed and downloaded from the "Governance" dropdown menu of our website under the "Company" tab. The content of these documents is not incorporated into this Form 10-K.

Board Leadership and Structure

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

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

Audit Committee

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

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

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

Compensation Committee

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

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

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

Nominating and Corporate Governance Committee

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

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

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

Board Practices

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

Policy Regarding Board Attendance

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

Shareholder Communications

We have a process for shareholders who wish to communicate with our Board. Shareholders who wish to communicate with our Board may write to the Board at our address set forth at the beginning of this Report. These communications will be reviewed by our Chief Executive Officer and Chief Financial Officer. They will determine whether the communications should be presented to our Board. The purpose of this screening is to allow the Board to avoid having to consider irrelevant or inappropriate communications.

ITEM 11. EXECUTIVE COMPENSATION

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

For our fiscal year ended April 30, 2020, our Named Executive Officers and their positions were as follows:

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

The following tables provide information about compensation earned during our fiscal years ended April 30, 2020 and 2019 by our Named Executive Officers.

Summary Compensation Table

Name	Principal Position	Fiscal Year	Salary ($)	Stock Awards ($)(1)	Option Awards ($)(1)	Total ($)
Kenneth L. Waggoner, JD(2)	Chief Executive Officer,	2020	$ 316,667	$ 201,600	$ 148,508	$ 666,775
	President and	2019	$ 375,000	$ 178,200	$ 121,698	$ 674,898
	General Counsel					
Gerald W. Crabtree, PhD(2)	Chief Operating Officer	2020	$ 109,667	$ 33,600	$ 49,503	$ 192,770
		2019	$ 138,000	$ 29,700	$ 40,566	$ 208,266
Carlos A. Trujillo, CPA (2)	Chief Financial Officer	2020	$ 250,000	$ 134,400	$ 99,006	$ 483,406
		2019	$ 275,000	$ 118,800	$ 81,132	$ 474,932

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

(2) We did not pay or accrue any other compensation, in the form of bonuses, incentive plan compensation or nonqualified deferred compensation earnings to any Named Executive officer for services as an executive officer during the fiscal years ended April 30, 2020 and 2019; neither were there any perquisites or other personal benefits payable to our Named Executive Officers. On October 15, 2018, we adopted a retirement plan for eligible employees named the PharmaCyte Biotech, Inc 401(k) Plan (“Plan”). The Plan allows eligible employees to contribute a portion of their salaries into the Plan. We are not required to and do not contribute to the highly compensated employees accounts and we do not match the contributions of the Named Executive Officers.

Outstanding Equity Awards at Fiscal Year End

	Option Awards				Stock Awards		
Name	Number of Securities Underlying Unexercised Options (#) Exercisable (1)	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)(1)	Market Value of Shares or Units of Stock That Have Not Vested ($)(2)
Kenneth L. Waggoner						
	6,000,000	–	$ 0.063	12/31/2020	–	$ –
	4,500,000	–	$ 0.104	03/09/2022	–	$ –
	4,500,000	–	$ 0.054	12/31/2023	–	$ –
	4,500,000	-	$ 0.0495	03/20/2024	–	$ –
	1,500,000	3,000,000	$ 0.0408	01/02/2025	–	$ –
	–	–	$ –	–	2,400,000	$ 58,800
Gerald W. Crabtree						
	4,800,000	–	$ 0.063	12/31/2020	–	$ –
	1,500,000	–	$ 0.104	03/09/2022	–	$ –
	1,500,000	–	$ 0.054	12/31/2023	–	$ –
	1,500,000	–	$ 0.0495	12/31/2024	–	$ –
	500,000	1,000,000	$ 0.0408	01/02/2025	–	$ –
	–	–	$ –	–	400,000	$ 9,800
Carlos A. Trujillo						
	4,800,000	–	$ 0.063	12/31/2020	–	$ –
	3,000,000	–	$ 0.104	03/09/2022	–	$ –
	3,000,000	–	$ 0.054	12/31/2023	–	$ –
	3,000,000	–	$ 0.0495	12/31/2024	–	$ –
	1,000,000	2,000,000	$ 0.0408	01/02/2025	–	$ –
	–	–	$ –	–	1,600,000	$ 39,200

(1) Subject to the Named Executive Officer's continued employment, 1/12th of each grant vests monthly after the grant date. The unexercisable/unvested awards shown in this table were each granted on January 1, 2020.

(2) The market value is based on the closing stock price of $0.0245 on April 30, 2020, the last day of trading in this fiscal year.

Employment Arrangements

Kenneth L. Waggoner, JD

We have entered into an Executive Compensation Agreement with Mr. Waggoner ("Waggoner Compensation Agreement"). The current term of the Waggoner Compensation Agreement extends until December 31, 2020 with annual extensions at the end of the term (or any extension of the term), unless we or Mr. Waggoner provide 90-days written notice of termination. The Waggoner Compensation Agreement provides that Mr. Waggoner will be employed as a member of our Board, as our Chief Executive Officer, President and General Counsel and as the Chief Executive Officer and General Counsel of our subsidiary Viridis Biotech. Under this agreement, Mr. Waggoner is paid a base salary of $375,000 subject to annual increases in the discretion of our Compensation Committee. The Waggoner Compensation Agreement also provides that, during his continued employment, Mr. Waggoner receives an annual stock grant of 3,600,000 shares of restricted common stock, vesting at the rate of 300,000 shares per month, and an annual stock option grant to purchase 4,500,000 shares of common stock exercisable over a five-year term at an exercise price per share equal to the closing price of the common stock on the date of grant, vesting at the rate of 375,000 option shares per month.

Effective January 1, 2020, Mr. Waggoner agreed to waive any cash compensation in excess of $200,000 annually until the IND for LAPC is submitted to the FDA.

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

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

If Mr. Waggoner's employment ceases due to his death, (i) any otherwise unvested equity awards held by him at the time of his death would become vested, (ii) his eligible dependents would be entitled to continued healthcare coverage at the Company's expense for up to 12 months, and (iii) his designated beneficiary or estate would receive the proceeds, if any, from any life insurance.

If Mr. Waggoner's employment is terminated due to "Disability" (as such term is defined in the Waggoner Compensation Agreement) he would receive continued health coverage and life insurance coverage, if any, for 12 months at our expense, as well as any disability benefits payable under any long term disability plan or policy we maintain. In addition, any otherwise unvested equity awards would then become vested.

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

Gerald W. Crabtree, PhD

We have entered into an Executive Compensation Agreement with Dr. Crabtree ("Crabtree Compensation Agreement"). The current term of the Crabtree Compensation Agreement extends until December 31, 2020 with annual extensions at the end of the term (or any extension of the term) unless we or Dr. Crabtree provide 90-days written notice of termination. The Crabtree Compensation Agreement provides that Dr. Crabtree will be employed as a member of our Board, as our Chief Operating Officer and as the Chief Operating Officer of our subsidiary Viridis Biotech. Dr. Crabtree is paid a base salary of $138,000 subject to annual increases in the discretion of our Compensation Committee. The Crabtree Compensation Agreement also provides that, during his continued employment, Dr. Crabtree will receive annual stock grants of 600,000 shares of restricted common stock, vesting at the rate of 50,000 shares per month, and an annual stock option grant to purchase 1,500,000 shares of common stock exercisable over a five-year term at an exercise price per share equal to the closing price of the common stock on the date of grant, vesting at the rate of 125,000 option shares per month.

Effective January 1, 2020, Dr. Crabtree agreed to waive any cash compensation in excess of $53,000 annually until the IND for LAPC is submitted to the FDA.

All other terms are substantially the same as disclosed above for the Waggoner Agreement

Carlos A. Trujillo, CPA

We have entered into an Executive Compensation Agreement with Mr. Trujillo ("Trujillo Compensation Agreement"). The current term of the Trujillo Compensation Agreement extends until December 31, 2020 with annual extensions at the end of the term (or any extension of the term) unless we or Mr. Trujillo provide 90-days written notice of termination.

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

Effective January 1, 2020, Mr. Trujillo agreed to waive any cash compensation in excess of $200,000 annually until the IND for LAPC is submitted to the FDA.

All other terms are substantially the same as disclosed above for the Waggoner Agreement.

Directors Compensation

The following table sets forth information concerning compensation paid or to our directors, other than our Named Executive Officers who also serve as directors, during the year ended April 30, 2020.

Director Compensation Table

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)(1)	Option Awards ($)(1)(2)	Total ($)
Thomas Liquard	$ 50,000	20,200	10,992	$ 81,192
Thomas C.K Yuen	$ 50,000	20,200	10,992	$ 81,192
Michael M. Abecassis, MD	$ 50,000	18,500	9,992	$ 78,492
Raymond C.K. Tong, MD	$ 50,000	17,000	9,057	$ 76,057

(1) The amounts in the columns titled “Stock Awards” and “Option Awards” reflect the grant date fair values of awards made during the fiscal year ended April 30, 2020, as computed in accordance with FASB ASC Topic 718 and the assumptions stated in Note 4 and Note 5 of the Consolidated Financial Statements to this Report.

(2) As of April 30, 2020, each of Mr. Liquard, Mr. Yuen, Dr. Abecassis and Dr. Tong held unexercised options to purchase 1,500,000 shares. These include options granted during the year ended April 30, 2020 (shown in this column) and options granted in prior years.

Each non-employee director is party to an agreement to serve as a director. The agreements provide that each non-employee director receives a cash retainer of $12,500 per quarter (pro-rated for periods of service less than a quarter). In addition, we annually grant to each non-employee director: (i) 500,000 shares of our common stock; and (ii) a stock option to purchase 500,000 shares of our common stock with a term of five years and an exercise price per share equal to the closing price of the common stock on the date of grant. Each of these equity awards is fully vested upon grant.

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

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

The following table sets forth as of July 16, 2020, certain information with respect to the beneficial ownership of our common stock by each person known by us to be the beneficial owner of more than five percent (5%) of our common stock, by each of our directors, by each of our Named Executive Officers and by all executive officers and directors as a group.

Name and Address	Amount and Nature of Beneficial Ownership (1)	Percentage of Common Stock (1)
Kenneth L. Waggoner, JD, Chairman of the Board, Chief Executive Officer, President and General Counsel	45,862,500	2.52%
Gerald W. Crabtree, PhD, Chief Operating Officer and Board Member	25,187,500	1.39%
Carlos A. Trujillo, CPA, Chief Financial Officer and Board Member	23,975,000	1.32%
Thomas Liquard, Board Member	4,000,000	*
Thomas C.K. Yuen, Board Member	4,000,000	*
Michael M. Abecassis, MD, Board Member	6,400,000	*
Raymond C.K. Tong, MD, Board Member	3,000,000	*
All directors and executive officers as a group (7 persons)	112,425,000	6.09%

* Indicates percentage is less than 1.0%.

(1) Percentages based on 1,727,977,071 shares of common stock issued and outstanding as of July 16, 2020. Percentages include the option to purchase shares that are unexercised, but which are exercisable within sixty days of July 16, 2020, presented as follows:

Kenneth L. Waggoner, JD	22,875,000
Gerald W. Crabtree, PhD	7,050,000
Carlos A. Trujillo, CPA	16,050,000
Thomas Liquard	2,000,000
Thomas C.K. Yuen	2,000,000
Michael M. Abecassis, MD	3,200,000
Raymond C.K. Tong, MD	1,500,000

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

Securities Authorized for Issuance under Equity Compensation Plans

The following table sets forth certain aggregated information with respect to compensation plans (including individual arrangements) under which our securities are authorized for issuance as of April 30, 2020:

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders	–	–	–
Equity compensation plans not approved by security holders	67,200,000	$0.06	–
Total	67,200,000	$0.06	–

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

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

We had the following related party transactions during the years ended April 30, 2020 and 2019, respectively.

We own 14.5% of the equity in SG Austria and is reported on the cost method of accounting. SG Austria has two subsidiaries: (i) Austrianova; and (ii) Austrianova Thailand. We purchased products and services from these subsidiaries in the approximate amounts of $153,000 and $168,000 in the years ended April 30, 2020 and 2019, respectively.

In April 2014, we entered a consulting agreement with Vin-de-Bona pursuant to which it agreed to provide professional consulting services to the Company. Vin-de-Bona is owned by Prof. Günzburg and Dr. Salmons, both of whom are involved in numerous aspects of our scientific endeavors relating to cancer and diabetes (Prof. Gunzburg is the Chairman of Austrianova, and Dr. Salmons is the Chief Executive Officer and President of Austrianova). The term of the agreement is for 12 months, automatically renewable for successive 12-month terms. After the initial term, either party can terminate the agreement by giving the other party 30 days' written notice before the effective date of termination. The amounts we paid Vin-de-Bona for the years ended April 30, 2020 and 2019 were approximately $24,000 and $18,000, respectively. In addition, during the year ended April 30, 2020 we issued 250,000 common shares to Dr. Salmons. We recorded a noncash consulting expense of approximately $10,000 relating to these share issuances.

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

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

A summary of the fees billed by our independent audit firm, Armanino for professional services rendered for the years ended April 30, 2020 and 2019 is set forth below.

Service	2020	2019
Audit Fees	$ 75,121	$ 94,799
Quarterly Review Fees	60,106	59,248
Tax Fees	–	–
All Other Fees	–	–
Total	$ 135,227	$ 154,047

During the years ended April 30, 2020 and 2019, we paid Armanino $75,121 and $94,799 in annual audit fees, respectively, and $60,106 and $59,248 in quarterly review fees, respectively.

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

ITEM 15. EXHIBITS

(a) Documents filed as part of this Report:

(1) Financial Statements.

Our Consolidated Financial Statements and associated Notes and Schedules, as of April 30, 2020 and 2019, and for each of the two years in the period ended April 30, 2020, together with the reports thereon of our independent registered public accounting firm, are set forth on pages F-1 to F-27 of this Report.

(2) Financial Statement Schedules.

Schedule II - Valuation and Qualifying Accounts for the Years Ended 2020 and 2019 are incorporated by reference to page F-27 of the financial statements included herewith. Exhibit 15(a)(2) is being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall such exhibit be deemed to be incorporated by reference in any registration statement or other document filed under the Securities Act or the Exchange Act, except as otherwise stated in such filing.

(3) Exhibits.

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

Exhibit No.	Description	Location
3.1	Articles of Incorporation of the Company, as amended, dated October 31, 2019	Incorporated by reference from the Company's Quarterly Report on Form 10-Q filed with the SEC on March 13, 2020.
3.2	Corporate Bylaws.	Incorporated by reference from the Company's Registration Statement on Form SB-2 (File No. 333-68008) filed with the SEC on August 20, 2001.
3.3	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.
3.4	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	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.
4.2	Warrant, dated January 7, 2016, issued to Berkshire Capital Management Co., Inc.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on January 12, 2016.
4.3	Warrant, dated January 7, 2016, issued to SPYR, Inc.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on January 12, 2016.
4.4	Subscription Agreement, dated October 30, 2019, between Kenneth L. Waggoner and the Company.	Incorporated by reference from the Company's Quarterly Report on Form 10-Q filed with the SEC on December 23, 2019.
4.5	Voting Rights Agreement, dated September 16, 2019, among Brown Stone Capital, LP, Silver Rock Associates, Inc., Homie Doroodian and the Company.	Incorporated by reference from the Company's Quarterly Report on Form 10-Q filed with the SEC on December 23, 2019.
4.6	Share Subscription Agreement, dated January 17, 2020, between Homie Doroodian and the Company.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on January 21, 2020.
10.1	Asset Purchase Agreement, dated May 26, 2011, between SG Austria Pte. Ltd. and the Company.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on June 28, 2012.
10.2	First Addendum, dated June 11, 2011, to Asset Purchase Agreement between SG Austria Pte. Ltd. and the Company.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on June 28, 2012.
10.3	Second Addendum, dated June 14, 2012, to Asset Purchase Agreement between SG Austria Pte. Ltd. and the Company.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on June 28, 2012.
10.4	Third Addendum, dated June 25, 2013, to Asset Purchase Agreement between SG Austria Private Limited and the Company.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on July 18, 2013.
10.5	Licensing Agreement, dated June 25, 2013, between Austrianova Singapore Pte. Ltd. and the Company.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on July 18, 2013.
10.6	Manufacturing Framework Agreement, dated March 20, 2014, between Austrianova Singapore Pte. Ltd. and the Company.	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the SEC on August 4, 2014.
10.7	Master Services Agreement, dated April 7, 2014, between ViruSure GmbH and the Company.	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the SEC on August 4, 2014.
10.8	Consulting Agreement, dated April 1, 2014, between Vin-de-Bona Trading Company Pte. Ltd. and the Company.	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the SEC on August 4, 2014.
10.9	License Agreement, dated October 13, 2014, between University of Technology, Sydney and PharmaCyte Biotech Australia Pty Ltd (formerly, Nuvilex Australia Pty Ltd).	Incorporated by reference from Amendment No. 1 to the Company's Annual Report on Form 10-K/A filed with the SEC on October 17, 2014.
10.10	Master Services Agreement, dated March 7, 2014, between ViruSure GmbH and the Company.	Incorporated by reference from Amendment No. 1 to the Company's Annual Report on Form 10-K/A filed with the SEC on October 17, 2014.
10.11	Licensing Agreement, dated December 1, 2014, between Austrianova Singapore Pte. Ltd. and the Company.	Incorporated by reference to the Company's Quarterly Report on Form 10-Q filed with the SEC on December 15, 2014.
10.12†	Executive Compensation Agreement, dated March 10, 2015, between Kenneth L. Waggoner and the Company.	Incorporated by reference from the Company's Quarterly Report on Form 10-Q filed with the SEC on March 13, 2015.
10.13†	First Stock Option Agreement, dated March 10, 2015, between Kenneth L. Waggoner and the Company.	Incorporated by reference from the Company's Quarterly Report on Form 10-Q filed with the SEC on March 13, 2015.

10.15†	Second Stock Option Agreement, dated March 10, 2015, between Kenneth L. Waggoner and the Company.	Incorporated by reference from the Company's Quarterly Report on Form 10-Q filed with the SEC on March 13, 2015.
10.16†	Executive Compensation Agreement, dated January 1, 2015, between Gerald W. Crabtree and the Company.	Incorporated by reference from the Company's Quarterly Report on Form 10-Q filed with the SEC on March 13, 2015.
10.17†	First Stock Option Agreement, dated March 10, 2015, between Gerald W. Crabtree and the Company.	Incorporated by reference from the Company's Quarterly Report on Form 10-Q filed with the SEC on March 13, 2015.
10.18†	Second Stock Option Agreement, dated March 10, 2015, between Gerald W. Crabtree and the Company.	Incorporated by reference from the Company's Quarterly Report on Form 10-Q filed with the SEC on March 13, 2015.
10.19†	Letter agreement, dated April 20, 2015, between Thomas Liquard and the Company.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on April 29, 2015.
10.20	Stock and Warrant Purchase Agreement, dated January 7, 2016, between Berkshire Capital Management Co., Inc. and the Company.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on January 12, 2016.
10.21	Stock and Warrant Purchase Agreement, dated January 7, 2016, between SPYR, Inc. and the Company.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on January 12, 2016.
10.22†	Amendment No. 1, dated December 30, 2015, to Executive Compensation Agreement between Gerald W. Crabtree and the Company.	Incorporated by reference from the Company's Quarterly Report on Form 10-Q filed with the SEC on March 8, 2016.
10.23†	Amendment No. 1, December 30, 2015, to Executive Compensation Agreement between Kenneth L. Waggoner and the Company.	Incorporated by reference from the Company's Quarterly Report on Form 10-Q filed with the SEC on March 8, 2016.
10.24†	Third Stock Option Agreement, dated December 30, 2015, between Gerald W. Crabtree and the Company.	Incorporated by reference from the Company's Quarterly Report on Form 10-Q filed with the SEC on March 8, 2016.
10.25†	Third Stock Option Agreement, dated December 30, 2015, between Kenneth L. Waggoner and the Company.	Incorporated by reference from the Company's Quarterly Report on Form 10-Q filed with the SEC on March 8, 2016.
10.26	First Amendment, dated June 30, 2015, to Licensing Agreement, dated December 1, 2014, between Austrianova Singapore Pte. Ltd. and the Company.	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the SEC on July 29, 2016.
10.27	Second Amendment, dated October 19, 2015, to Licensing Agreement, dated December 1, 2014, between Austrianova Singapore Pte. Ltd. and the Company.	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the SEC on July 29, 2016.
10.28	Variation, dated April 20, 2016, to License Agreement, October 13, 2014, between University of Technology, Sydney and PharmaCyte Biotech Australia Pty Ltd (formerly, Nuvilex Australia Pty Ltd).	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the SEC on July 29, 2016.
10.29	First Amendment, dated June 24, 2016, to Licensing Agreement, dated June 25, 2013, between Austrianova Singapore Pte. Ltd. and the Company.	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the SEC on July 29, 2016.
10.30	Binding Memorandum of Understanding, dated July 28, 2016, between Austrianova Singapore Pte Ltd. and the Company.	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the SEC on July 29, 2016.
10.31†	Amendment No. 2, dated March 10, 2017, to Executive Compensation Agreement between Kenneth L. Waggoner and the Company.	Incorporated by reference from the Company's Quarterly Report on Form 10-Q filed with the SEC on March 13, 2017.
10.32†	Amendment No. 2, dated March 10, 2017, to Executive Compensation Agreement between Carlos A. Trujillo and the Company.	Incorporated by reference from the Company's Quarterly Report on Form 10-Q filed with the SEC on March 13, 2017.
10.33†	Amendment No. 2, dated March 10, 2017, to Executive Compensation Agreement between Gerald W. Crabtree and the Company.	Incorporated by reference from the Company's Quarterly Report on Form 10-Q filed with the SEC on March 13, 2017.
10.34†	Fourth Stock Option Agreement, dated March 10, 2017, between Kenneth L. Waggoner and the Company.	Incorporated by reference from the Company's Quarterly Report on Form 10-Q filed with the SEC on March 13, 2017.
10.35†	Third Stock Option Agreement, dated March 10, 2017, between Carlos A. Trujillo and the Company.	Incorporated by reference from the Company's Quarterly Report on Form 10-Q filed with the SEC on March 13, 2017.

10.36†	Fourth Stock Option Agreement, dated March 10, 2017, between Gerald W. Crabtree and the Company.	Incorporated by reference from the Company's Quarterly Report on Form 10-Q filed with the SEC on March 13, 2017.
10.37†	Amendment No. 1, dated March 10, 2017, to Letter Agreement between Thomas Liquard and the Company.	Incorporated by reference from the Company's Quarterly Report on Form 10-Q filed with the SEC on March 13, 2017.
10.38†	Letter Agreement, dated May 1, 2017, between Thomas C. K. Yuen and the Company.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on May 2, 2017.
10.39†	Letter agreement, dated June 29, 2017, between Michael Abecassis, M.D. and the Company.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on July 10, 2017.
10.40	Binding Term Sheet, dated August 30, 2017, among Austrianova Singapore Pte. Ltd., SG Austria Pte. Ltd. and the Company.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on September 6, 2017.
10.41†	Letter agreement, dated October 9, 2017, between Raymond C. F. Tong and the Company.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on October 10, 2017.
10.42	Financial Advisory, Offering and At the Market Offering Letter Agreement, dated February 22, 2018, between Aeon Capital, Inc. and the Company.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on February 22, 2018.
10.43	Fourth Addendum, dated May 14, 2018, to Asset Purchase Agreement between SG Austria Pte. Ltd. and the Company.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on May 15, 2018.
10.44	Third Amendment, dated May 14, 2018, to Licensing Agreement, dated December 1, 2014, between Austrianova Singapore Pte. Ltd and the Company.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on May 15, 2018.
10.45	Second Amendment, dated May 14, 2018, to the Licensing Agreement, dated June 25, 2013, between Austrianova Singapore Pte. Ltd and the Company.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on May 15, 2018.
10.46	License Agreement, dated April 2, 2020, between Hai Kang Life Corporation Limited and the Company.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on April 8, 2020.
14.1	PharmaCyte Biotech, Inc. Code of Business Conduct and Ethics.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on September 25, 2014.
15(a)(2)	Schedule II - Valuation and Qualifying Accounts for the Years Ended April 30, 2019 and 2018.	Incorporated by reference to page F-27 of the financial statements included herewith.
21.1	List of Subsidiaries.	Filed herewith.
23.1	Consent of Armanino LLP.	Filed herewith.
31.1	Certification of Chief Executive Officer (Principal Executive Officer) pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under Sarbanes-Oxley Act of 1934, as amended.	Filed herewith.
31.2	Certification of Chief Financial Officer (Principal Financial and Principal Accounting Officer) pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under Sarbanes-Oxley Act of 1934, as amended.	Filed herewith.
32.1	Certification of Chief Executive Officer (Principal Executive Officer) pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Furnished herewith.
32.2	Certification of Chief Financial Officer (Principal Financial and Principal Accounting Officer) pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Furnished herewith.
101	Interactive Data Files for PharmaCyte Biotech, Inc. Form 10-K for the period ended April 30, 2019.	Submitted herewith.

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

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

Financial Statements Schedule:

The following financial statement schedule is set forth on page F-27 of this Report:

Schedule II — Valuation and Qualifying Accounts for the years ended April 30, 2020 and 2019.

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

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

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

PharmaCyte Biotech, Inc.

August 13, 2020 By: /s/ Kenneth L. Waggoner
Kenneth L. Waggoner
Chief Executive Officer
(Duly Authorized Officer and Principal Executive Officer)

August 13, 2020 By: /s/ Carlos A Trujillo
Carlos A. Trujillo
Chief Financial Officer (Duly Authorized Officer and Principal Financial and Accounting Officer)

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

August 13, 2020 By: /s/ Kenneth L. Waggoner
Kenneth L. Waggoner
Chief Executive Officer, Chairman of the Board and Director
(Principal Executive Officer)

August 13, 2020 By: /s/ Carlos A. Trujillo
Chief Financial Officer and Director
(Principal Financial and Accounting Officer)

August 13, 2020 By: /s/ Gerald W. Crabtree
Gerald W. Crabtree, Director

August 13, 2020 By: /s/ Thomas Liquard
Thomas Liquard, Director

August 13, 2020 By: /s/ Thomas C.K. Yuen
Thomas C.K. Yuen, Director

August 13, 2020 By: /s/ Raymond C.F. Tong
Raymond C.F. Tong, Director

August 13, 2020 By: /s/ Michael M. Abecassis
Michael M. Abecassis, Director

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

The registrant has not sent to its security holders any annual report covering the registrant's fiscal year ended April 30, 2020.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

PHARMACYTE BIOTECH, INC.
CONTENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of PharmaCyte Biotech, Inc. and Subsidiaries (collectively the "Company") as of April 30, 2020 and 2019, and the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the two years in the period ended April 30, 2020, and the related notes (collectively referred to as the consolidated financial statements).

In our opinion, the consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Company as of April 30, 2020 and 2019, and the related consolidated results of its operations and cash flows for each of the two years in the period ended April 30, 2020, in conformity with U.S. generally accepted accounting principles. In addition, in our opinion, the consolidated financial statement schedules listed in the accompanying index presents fairly, in all material respects, the information set form therein when read in conjunction with the related consolidated financial statements.

Basis for Opinion

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

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

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

Emphasis of Matter – COVID-19

As described in Note 1 to the consolidated financial statements, the World Health Organization has declared COVID-19 a global pandemic leading to broader global economic uncertainties. The measures taken by government agencies to slow the progression of the disease are uncertain and may adversely affect the Company's result of operations, cash flows and financial position. Our opinion is not modified with respect to this matter.

/s/ Armanino LLP
San Jose, California

August 13, 2020

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

PHARMACYTE BIOTECH, INC.
CONSOLIDATED BALANCE SHEETS

	April 30, 2020	April 30, 2019
ASSETS		
Current assets:		
Cash	$ 894,861	$ 515,253
Prepaid expenses and other current assets	142,785	138,151
Total current assets	1,037,646	653,404
Other assets:		
Intangibles	3,549,427	3,549,427
Investment in SG Austria	1,572,193	1,572,193
Other assets	7,372	7,372
Total other assets	5,128,992	5,128,992
Total Assets	$ 6,166,638	$ 5,782,396
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 185,842	$ 121,885
Accrued expenses	816,638	620,966
Current portion of Small Business Administration – Paycheck Protection Program loan	28,918	–
Total current liabilities	1,031,398	742,851
Long-term liabilities, less current portion:		
Small Business Administration – Paycheck Protection Program loan	46,282	–
Total Liabilities	1,077,680	742,851
Commitments and Contingencies (Notes 7 and 9)		
Stockholders' equity:		
Common stock, authorized: 2,490,000,000 shares, $0.0001 par value; 1,638,637,839 and 1,186,004,505 shares issued and outstanding as of April 30, 2020 and 2019, respectively	163,864	118,600
Additional paid-in capital	108,805,062	104,966,158
Accumulated deficit	(103,858,259)	(100,031,371)
Accumulated other comprehensive loss	(21,709)	(13,842)
Total stockholders' equity	5,088,958	5,039,545
Total Liabilities and Stockholders' Equity	$ 6,166,638	$ 5,782,396

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

PHARMACYTE BIOTECH, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended April 30,	
	2020	**2019**
Revenue	$ –	$ –
Operating Expenses:		
Research and development costs	301,221	460,052
Compensation expense	1,586,583	1,555,258
Director fees	316,892	406,812
Legal and professional	459,146	299,963
General and administrative	1,162,553	1,378,544
Total operating expenses	3,826,395	4,100,629
Loss from operations	(3,826,395)	(4,100,629)
Other income (expense):		
Interest expense	(453)	–
Other income (expense)	(40)	33,401
Total other income (expense), net	(493)	33,401
Net loss	$ (3,826,888)	$ (4,067,228)
Basic and diluted loss per share	$ (0.00)	$ (0.00)
Weighted average shares outstanding basic and diluted	1,355,717,271	1,100,104,338

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

PHARMACYTE BIOTECH, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Years Ended April 30,	
	2020	**2019**
Net loss	$ (3,826,888)	$ (4,067,228)
Other comprehensive loss:		
Foreign currency translation adjustments	(7,867)	(9,133)
Other comprehensive loss	(7,867)	(9,133)
Comprehensive loss	$ (3,834,755)	$ (4,076,361)

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

PHARMACYTE BIOTECH, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
YEARS ENDED APRIL 30, 2020 AND 2019

	Common stock		Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Capital	Deficit	Loss	Equity
Balance, April 30, 2018	**1,013,260,644**	**$ 101,326**	**$ 101,636,215**	**$ (95,964,143)**	$ (4,709)	**$ 5,768,689**
Shares issued for compensation	6,600,000	660	292,669	–	–	293,329
Shares issued for services	4,450,000	445	316,094	–	–	316,539
Shares issued for cash, net of issuance costs of $175,000	161,693,861	16,169	2,308,831	–	–	2,325,000
Stock options granted	–	–	412,349	–	–	412,349
Foreign currency translation adjustment	–	–	–	–	(9,133)	(9,133)
Net loss	–	–	–	(4,067,228)	–	(4,067,228)
Balance, April 30, 2019	**1,186,004,505**	**118,600**	**104,966,158**	**(100,031,371)**	**(13,842)**	**5,039,545**
Shares issued for compensation	6,600,000	660	367,990	–	–	368,650
Shares issued for services	9,700,000	970	472,171	–	–	473,141
Shares issued for cash, net of issuance costs of $202,000	436,333,334	43,634	2,619,366	–	–	2,663,000
Stock options granted	–	–	379,377	–	–	379,377
Foreign currency translation adjustments	–	–	–	–	(7,867)	(7,867)
Net loss	–	–	–	(3,826,888)	–	(3,826,888)
Balance, April 30, 2020	**1,638,637,839**	**$ 163,864**	**$ 108,805,062**	**$ (103,858,259)**	**$ (21,709)**	**$ 5,088,958**

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

PHARMACYTE BIOTECH, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended April 30,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (3,826,888)	$ (4,067,228)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock issued for services	473,141	316,539
Stock issued for compensation	368,650	293,329
Stock-based compensation - options	379,375	412,349
Change in operating assets and liabilities:		
(Increase) / decrease in prepaid expenses and other current assets	(4,634)	85,916
Increase (decrease) in accounts payable	63,958	(230,736)
Increase in accrued expenses	208,025	311,919
Net cash used in operating activities	(2,338,373)	(2,877,912)
Cash flows from investing activities:		
Net cash used in investing activities	–	–
Cash flows from financing activities:		
Proceeds from sale of Series A Preferred stock	1	–
Repurchase of Series A Preferred stock	(1)	–
Use of funds for payment of insurance financing loan	(12,352)	–
Proceeds from Small Business Administration – Paycheck Protection Program	75,200	–
Proceeds from sale of common stock, net of issuance costs	2,663,000	2,342,500
Net cash provided by financing activities	2,725,848	2,342,500
Effect of currency rate exchange on cash	(7,867)	(9,133)
Net increase (decrease) in cash	379,608	(544,545)
Cash at beginning of the year	515,253	1,059,798
Cash at end of the year	$ 894,861	$ 515,253
Supplemental disclosure of cash flows information:		
Cash paid during the years for taxes	$ 800	$ 800
Cash paid during the years for interest expense	$ 453	–
Supplemental schedule of noncash investing and financing activity:		
Issuance costs for shares issued	$ –	$ 17,500

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

NOTE 1 – NATURE OF BUSINESS

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

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

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

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

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

Finally, the Company licensed from Hai Kang the right to sell and distribute COVID-19 diagnostic kits. Pursuant to the Hai Kang License Agreement, the Company may directly (or through a third party) conduct research, use, develop, market, sell, distribute, import and export these kits for human and veterinary uses in North America, the United Kingdom and certain European cites.

Impact of the COVID-19 Pandemic on the Company's Operations

The COVID-19 pandemic is causing significant, industry-wide delays in clinical trials. Although the Company is not yet in a clinical trial, one is being planned. Currently, clinical trials are being delayed due to COVID-19. There are numerous reasons for these delays. For example, patients have shown a reluctance to enroll or continue in a clinical trial due to fear of exposure to COVID-19 when they are in a hospital or doctor's office. There are local, regional and state-wide shelter-in-place orders and regulations. These discourage and interfere with patient visits to a doctor's office if the visit is not COVID-19 related. Healthcare providers and health systems are shifting their resources away from clinical trials toward the care of COVID-19 patients. The FDA and other healthcare providers are making product candidates for the treatment of COVID-19 a priority over product candidates unrelated to COVID-19. As of the date of this Report, the COVID-19 pandemic has had an impact upon the Company's operations, although the Company believes that impact is not material. They primarily relate to delays in tasks associated with the preparation of the Company's IND.

As a result of the COVID-19 pandemic, commencement the Company's planned clinical trial to treat LAPC may be delayed. Also, enrollment may be difficult for the reasons discussed above. In addition, after enrollment in the trial, if patients contract COVID-19 during their participation in the trial or are subject to isolation or shelter in place restrictions, this may cause them to drop out of our trial, miss scheduled therapy appointments or follow-up visits or otherwise fail to follow the trial protocol. If patients are unable to follow the trial protocol or if the trial results are otherwise affected by the consequences of the COVID-19 pandemic on patient participation or actions taken to mitigate COVID-19 spread, the integrity of data from the trial may be compromised or not be accepted by the FDA. This could impact or delay on the Company's clinical development program.

Given when the Company's clinical trial to treat LAPC is planned to commence, it is highly speculative in projecting the effects of COVID-19 on the Company's clinical development program and the Company generally. COVID-19 quickly and dramatically changes over time. Its evolution is difficult to predict, and no one is able to say with certainty when the pandemic will subside and life as we knew it before the pandemic will return to normal.

Cancer Therapy

Targeted Chemotherapy

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

Pancreatic Cancer Therapy

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

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

Cannabinoid Therapy to Treat Cancer

The Company plans to use cannabinoids, constituents of the *Cannabis* plant, to develop therapies for cancer, with the initial target of brain cancer. The Company is focusing on developing specific therapies based on carefully chosen molecules rather than using complex *Cannabis* extracts.

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

Malignant Ascites Fluid Therapy

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

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

Diabetes Therapy

Bio-Artificial Pancreas for Diabetes

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

COVID-19 Diagnostic Kits

The Company entered into the Hai Kang License Agreement pursuant to which Hai Kang granted to the Company a license to conduct research, use, develop, market, sell, distribute, import and export the COVID-19 diagnostic kits for human and veterinary uses in North America, the United Kingdom and certain other European cities.

Company Background and Material Agreements

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

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

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

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

Effective as of the same date of the Third Addendum, the parties entered the Clarification Agreement to clarify and include certain language that was inadvertently left out of the Third Addendum. Among other things, the Clarification Agreement confirmed that the Third Addendum granted the Company an exclusive, worldwide license to use, with a right to sublicense, the Cell-in-a-Box® encapsulation technology for the development of treatments for cancer and use of Austrianova's Cell-in-a-Box® trademark and its associated technology.

With respect to Bio Blue Bird, Bavarian Nordic/GSF and Bio Blue Bird entered into the Bavarian Nordic/GSF License Agreement in July 2005 whereby Bio Blue Bird was granted a non-exclusive license to further develop, make, have made (including services under contract for Bio Blue Bird or a sub-licensee), by Contract Manufacturing Organizations, Contract Research Organizations, Consultants, Logistics Companies or others), obtain marketing approval, sell and offer for sale the clinical data generated from the second pancreatic cancer clinical trial which contained proprietary information from the 1st Interim Analysis of the trial that used the cells and capsules developed by Bavarian Nordic/GSF or otherwise use the licensed patent rights related thereto in the countries in which patents had been granted.

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

In June 2013, the Company entered into the Diabetes Licensing Agreement pursuant to which the Company is provided an exclusive, worldwide license to use the Cell-in-a-Box® encapsulation technology and trademark for the development of a therapy for Type 1 and insulin-dependent Type 2 diabetes.

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

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

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

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

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

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

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

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

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

In April 2020, the Company entered into the Hai Kang License Agreement pursuant to which Hai Kang granted to the Company a license to certain technology owned or controlled by Hai Kang related to COVID-19 diagnostic kits. Pursuant to the Hai Kang License Agreement, the Company may directly (or through a third party) conduct research, use, develop, market, sell, distribute, import and export Products for human and veterinary uses in North America, the United Kingdom and certain other European cites. A "Product" is defined as any existing Kit of Hai Kang or any future Kit derived from Hai Kang's Kits and includes an in vitro diagnostic test that is designed, manufactured and used within a single laboratory for which the FDA is not enforcing any premarket review or other regulatory approval requirements.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation and Basis of Presentation

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

Use of Estimates

The preparation of financial statements in accordance with U.S. GAAP requires the use of estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities known to exist as of the date the financial statements are published and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, the Company evaluates these estimates including those related to fair values of financial instruments, intangible assets, fair value of stock-based awards, income taxes and contingent liabilities, among others. Uncertainties with respect to such estimates and assumptions are inherent in the preparation of the Company's consolidated financial statements; accordingly, it is possible that the actual results could differ from these estimates and assumptions, which could have a material effect on the reported amounts of the Company's consolidated financial position and results of operations.

Intangible Assets

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

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

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

The Company concluded that there was no impairment of the carrying value of the intangibles for the years ended April 30, 2020 and 2019.

Impairment of Long-Lived Assets

The Company evaluates long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be fully recoverable. If the estimated future cash flows (undiscounted and without interest charges) from the use of an asset are less than carrying value, a write-down would be recorded to reduce the related asset to its estimated fair value. No impairment was identified or recorded during the years ended April 30, 2020 and 2019.

Fair Value of Financial Instruments

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

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

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

Income Taxes

Deferred taxes are calculated using the liability method whereby deferred tax assets are recognized for deductible temporary differences and operating loss and tax credit carry forwards, and deferred tax liabilities are recognized for taxable temporary differences. Temporary differences are the differences between the reported amounts of assets and liabilities and their tax bases. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all the deferred tax assets will not be realized. Deferred tax assets and liabilities are adjusted for the effects of changes in tax laws and rates on the date of enactment.

A valuation allowance is provided for deferred income tax assets when, in management's judgment, based upon currently available information and other factors, it is more likely than not that all or a portion of such deferred income tax assets will not be realized. The determination of the need for a valuation allowance is based on an on-going evaluation of current information including, among other things, historical operating results, estimates of future earnings in different taxing jurisdictions and the expected timing of the reversals of temporary differences. The Company believes the determination to record a valuation allowance to reduce a deferred income tax asset is a significant accounting estimate because it is based on, among other things, an estimate of future taxable income in the U.S. and certain other jurisdictions, which is susceptible to change and may or may not occur, and because the impact of adjusting a valuation allowance may be material. In determining when to release the valuation allowance established against the Company's net deferred income tax assets, the Company considers all available evidence, both positive and negative. Consistent with the Company's policy, and because of the Company's history of operating losses, the Company does not currently recognize the benefit of all its deferred tax assets, including tax loss carry forwards, which may be used to offset future taxable income. The Company continually assesses its ability to generate sufficient taxable income during future periods in which deferred tax assets may be realized. When the Company believes it is more likely than not that it will recover its deferred tax assets, the Company will reverse the valuation allowance as an income tax benefit in the statements of operations.

The U.S. GAAP method of accounting for uncertain tax positions utilizes a two-step approach to evaluate tax positions. Step one, recognition, requires evaluation of the tax position to determine if based solely on technical merits it is more likely than not to be sustained upon examination. Step two, measurement, is addressed only if a position is more likely than not to be sustained. In step two, the tax benefit is measured as the largest amount of benefit, determined on a cumulative probability basis, which is more likely than not to be realized upon ultimate settlement with tax authorities. If a position does not meet the more likely than not threshold for recognition in step one, no benefit is recorded until the first subsequent period in which the more likely than not standard is met, the issue is resolved with the taxing authority or the statute of limitations expires. Positions previously recognized are derecognized when the Company subsequently determines the position no longer is more likely than not to be sustained. Evaluation of tax positions, their technical merits and measurements using cumulative probability are highly subjective management estimates. Actual results could differ materially from these estimates.

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

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

On March 27, 2020, Congress enacted the Coronavirus Aid, Relief and Economic Security ("CARES") Act to provide certain relief as a result of the Coronavirus Disease 2019 outbreak. The Company maintains a full valuation allowance on its U.S. net deferred tax assets. Deferred tax asset remeasurement (tax expense) was offset by a net decrease in valuation allowance, that resulted in no impact on the Company's income tax expense. Therefore, the Company does not expect the provisions in the CARES Act will impact the Company’s consolidated financial statements.

Research and Development

R&D expenses consist of costs incurred for direct and overhead-related research expenses and are expensed as incurred. Costs to acquire technologies, including licenses, that are utilized in research and development and that have no alternative future use are expensed when incurred. Technology developed for use in the Company’s product candidates is expensed as incurred until technological feasibility has been established.

R&D costs for the years ended April 30, 2020 and 2019 were $301,221 and $460,052, respectively.

Stock-Based Compensation

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

Concentration of Credit Risk

The Company has no significant off-balance-sheet concentrations of credit risk such as foreign exchange contracts, options contracts or other foreign hedging arrangements. The Company maintains most of its cash balance at a financial institution located in California. Accounts at this institution are insured by the Federal Deposit Insurance Corporation up to $250,000. Uninsured balances aggregated approximately $618,000 and $127,000 at April 30, 2020 and 2019, respectively. The Company has not experienced any losses in such accounts. Management believes it is not exposed to any significant credit risk on cash.

Foreign Currency Translation

The Company translates the financial statements of its foreign subsidiary from the local (functional) currencies to U.S. dollars in accordance with FASB ASC 830*Foreign Currency Matters*. All assets and liabilities of the Company’s foreign subsidiaries are translated at year-end exchange rates, while revenue and expenses are translated at average exchange rates prevailing during the year. Adjustments for foreign currency translation fluctuations are excluded from net loss and are included in other comprehensive income. Gains and losses on short-term intercompany foreign currency transactions are recognized as incurred.

Going Concern

The accompanying Consolidated Financial Statements have been prepared assuming that the Company will continue as a going concern; however, the following conditions raise substantial doubt about the Company's ability to do so. As of April 30, 2020, the Company has an accumulated deficit of $103,858,259 and incurred a net loss for year ended April 30, 2020 of $3,826,888. The Company requires substantial additional capital to finance its planned business operations and expects to incur operating losses in future periods due to the expenses related to the Company's core businesses. The Company has not realized any revenue since it commenced doing business in the biotechnology sector, and there can be no assurance that it will be successful in generating revenues in the future in this sector. The Consolidated Financial Statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result should the Company be unable to continue as a going concern.

Over the past year, funding was provided by investors to maintain and expand the Company. Sales of the Company's common stock were made under the Second S-3 allowing for offerings of up to $50 million dollars in transactions that are deemed to be "at the market offerings" as defined in Rule 415 under the Securities Act or transactions structured as a public offering of a distinct block or blocks of the shares of the Company's common stock. Over the past year, the Company continued to acquire funds through the Company's Second S-3 pursuant to which the placement agent sells shares of common stock "at-the-market" in a program which is structured to provide up to $25 million to the Company less certain commissions pursuant to the Second S-3. From May 1, 2019 through April 30, 2020 the Company raised capital of approximately $2.15 million in Block Trade transactions. Additionally, the Company raised approximately $500,000 through the sale of unregistered shares of its Common Stock in private placement transactions. Subsequent to fiscal year end, the Company raised additional capital in the amount of approximately $4.7 million from Block Trades and "at-the-market" trades. As of the date of this Report, the Company has approximately $4.9 million in its bank account.

With the filing of this Report, the S-3 will no longer be available to the Company to use to raise capital. The Company plans to continue to sell unregistered shares to raise capital to fund operations and R&D expenses.

Management determined that these plans alleviate substantial doubt about the Company's ability to continue as a going concern. The Company believes the cash on hand at April 30, 2020, the potential sales of unregistered shares of its common stock and any public offerings of common stock in which the Company may engage in will provide sufficient capital to meet the Company's capital requirements and to fund the Company's operations through August 31, 2021.

Recent Accounting Pronouncements

On May 1, 2019, the Company adopted Accounting Standards Update ("ASU") No. 2016-02, "Leases (Topic 842)," which requires the recognition of right-of-use ("ROU") assets and lease liabilities on the consolidated balance sheet. This ASU retains a distinction between finance leases and operating leases, and the classification criteria for distinguishing between finance leases and operating leases are substantially similar to the classification criteria for distinguishing between capital leases and operating leases in the current accounting literature. Under the standard, disclosures are required to meet the objective of enabling users of financial statements to assess the amount, timing, and uncertainty of cash flows arising from leases. The Company elected the available practical expedients on adoption. Adoption of the new standard resulted in an immaterial amount of total lease liabilities and ROU assets of as of May 1, 2019.

There were no material impacts on the Company's consolidated financial statements resulting from the adoption during the year ended April 30, 2020 of: (i) ASU No. 2018-07, *Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting;* (ii) ASU 2018-19, *ASC Topic 326: Codification Improvements to Financial Instruments*; (iii) ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement;* and (iv) ASU No. 2019-07, *Codification Updates to SEC Sections: Amendments to SEC Paragraphs Pursuant to SEC Final Rule Releases No. 33-10532, Disclosure Update and Simplification, and Nos. 33-10231 and 33-10442, Investment Company Reporting Modernization, and Miscellaneous Updates.*

ASU No. 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"), was issued in June 2016. Under ASU 2016-13, existing guidance on reporting credit losses for trade and other receivables and available for sale debt securities will be replaced with a new forward-looking "expected loss" model that generally will result in the earlier recognition of allowances for losses. The Company will adopt ASU 2016-13 in 2021 using the modified retrospective transition approach and does not expect to have a material impact on the Company's consolidated financial statements.

ASU No. 2019-12, *Simplifying the Accounting for Income Taxes* ("ASU 2019-12"), was issued in December 2019. Under ASU 2019-12, the accounting for income taxes is simplified by eliminating certain exceptions and implementing additional requirements which result in a more consistent application of ASC 740. The Company is currently in the process of evaluating the impact of adopting ASU 2019-12 in 2021, but it does not expect it to have a material impact on the Company's consolidated financial statements.

NOTE 3 – ACCRUED EXPENSES

Accrued expenses at April 30, 2020 and 2019 are summarized below:

	2020	2019
Payroll related costs	$ 435,577	$ 358,616
Share issuance compensation	–	240,015
Director and Officer insurance financing	113,245	–
Other	267,816	22,335
Total	$ 816,638	$ 620,966

The Company financed the Director and Officer insurance policy. The term of the policy is from March 8, 2020 through March 8, 2021. The financing agreement has an interest rate of 4.25% per annum and requires eight monthly payments of $12,806. The unpaid balances as of April 30, 2020 of $113,245 is included in accrued expenses.

NOTE 4 – SMALL BUSINESS ADMINISTRATION – PAYCHECK PROTECTION PROGRAM

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") was enacted to provide financial aid to family and businesses impacted by the COVID-19 pandemic. The Company participated in the CARES Act, and on April 15, 2020, the Company entered into a note payable with a bank under the Small Business Administration ("SBA"), Paycheck Protection Program ("PPP") in the amount of $75,200. This note payable matures on April 15, 2022 with a fixed interest rate of 1% per annum with interest deferred for six months. The PPP loan has an initial term of two years, is unsecured and guaranteed by the SBA. Under the terms of the PPP note, the Company may apply for forgiveness of the amount due on the PPP loan. The Company used the proceeds from the PPP loan for qualifying expenses as defined in the PPP. The Company intends to apply for forgiveness of the PPP loan in accordance with the terms of the Cares Act. However, the Company cannot assure at this time that the PPP loan will be forgiven partially or in full. If the loan is not forgiven based on the PPP guidelines to be issued by the SBA, as defined, then, the monthly payment amount will be $4,229 beginning on October 15, 2020 through April 15, 2022. The current portion of the PPP loan is $28,918 and the long-term portion is $46,282.

NOTE 5 – COMMON STOCK TRANSACTIONS

A summary of the Company's compensatory stock activity and related weighted average grant date fair value information for the years ended April 30, 2020 and 2019 are as follows:

During the year ended April 30, 2018, the Company issued 1,750,000 shares of common stock to four non-employee members of the Company's Board of Directors (the "Board") pursuant to Director Letter Agreements with the Company ("DLAs"). The shares vested upon issuance and the Company recorded a non-cash expense of $0 and $24,165 for the years ended April 30, 2020 and 2019, respectively.

During the year ended April 30, 2018, the Company issued 4,200,000 shares of common stock to three consultants. The terms of two of the agreements are for twelve months and one agreement is for eighteen months. The shares vest monthly over a twelve-month to eighteen-month period and are subject to the consultants providing services under the agreements. The Company recorded a non-cash consulting expense in the amount of $0 and $73,800 for the years ended April 30, 2020 and 2019, respectively. There were zero unvested shares as of April 30, 2020 and 2019, respectively.

The Company awarded 6,600,000 shares of common stock to officers as part of their compensation agreements for 2018. These shares vest monthly over a twelve-month period and are subject to them continuing service under the agreements. During the years ended April 30, 2020 and 2019, the Company recorded a non-cash compensation expense in the amount of $0 and $245,520. There were zero unvested shares as of April 30, 2020 and 2019, respectively.

During the year ended April 30, 2019, the Company issued 4,450,000 shares of common stock to four consultants. The terms of the agreements are for twelve months. The shares vest monthly over a twelve-month period and are subject to the consultants providing services under the agreements. The Company recorded a non-cash consulting expense in the amount of $24,726 and $230,829 for the year ended April 30, 2020 and 2019, respectively. There were zero and 408,333 unvested shares as of April 30, 2020 and 2019, respectively.

The Company awarded 6,600,000 shares of common stock to officers as part of their compensation agreements for 2019. These shares vest monthly over a twelve-month period and are subject to them continuing service under the agreements. During the years ended April 30, 2020 and 2019, the Company recorded a non-cash compensation expense in the amount of $278,891 and $47,809, respectively. There were zero and 4,400,000 unvested shares as of April 30, 2020 and 2019, respectively.

During the year ended April 30, 2020, the four non-employee members of the Board were issued 2,000,000 shares of common stock pursuant to their DLAs and relating to their services for the prior year. The shares were fully vested upon issuance. The Company recorded a non-cash expense of $19,212 and $101,288 for the years ended April 30, 2020 and 2019, respectively. There were zero unvested shares of Common Stock remaining related to these DLAs as of April 30, 2020.

During the year ended April 30, 2020, a consultant was issued 2,500,000 shares of common stock in respect of his services as the Chairman of the Company's Medical and Scientific Advisory Board over a five-year period vested upon issuance are subject to the consultant providing services to the Company. The Company recorded a non-cash consulting expense in the amount of $22,584 and $107,749 for the years ended April 30, 2020 and 2019, respectively. There were zero unvested shares remaining related to his compensation agreements as of April 30, 2020.

During the year ended April 30, 2020, the four non-employee members of the Board were issued 2,000,000 shares of Common Stock pursuant to their DLAs in respect of their service during that year. The shares were fully vested upon issuance. The Company recorded a non-cash expense of $65,339 for the year ended April 30, 2020, respectively. There were zero unvested shares remaining related to a DLA as of April 30, 2020.

During the year ended April 30, 2020, five consultants were issued 3,200,000 shares of restricted Common Stock pursuant to their respective consulting agreement with the Company. The terms of the agreements are for twelve months. The share issuances covered current and prior years. The shares vest monthly over a twelve-month period and are subject to the consultants providing services under the consultant's respective consulting agreement. The Company recorded a non-cash consulting expense in the amount of $108,575 and $17,350 for the years ended April 30, 2020 and 2019, respectively. There were 200,000 unvested shares remaining related to these consulting agreements as of April 30, 2020.

The Company awarded 6,600,000 shares of common stock to officers as part of their compensation agreements for 2020. These shares vest monthly over a twelve-month period and are subject to them continuing service under the agreements. During the year ended April 30, 2020, the Company recorded a non-cash compensation expense in the amount of $89,759. There were 4,400,000 unvested shares as of April 30, 2020.

During the year ended April 30, 2020, the Company entered into four stock subscription agreements resulting in the sale and issuance of one-hundred-three million (103 million) shares of restricted Common Stock. The Company received $515,000 from the sale of these shares.

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

On September 28, 2017, the Second S-3 was declared effective by the Commission for a public offering of up to $50 million on a "shelf offering" basis. During the years ended April 30, 2020 and 2019, the Company sold and issued approximately 333.3 and 161.7 million shares of common stock, respectively, at prices ranging from $0.01 to $0.03 per share. Net of underwriting discounts, legal, accounting and other offering expenses, the Company received proceeds of approximately $2.1 and $2.3 million from the sale of these shares for the years ended April 30, 2020 and 2019, respectively. The Company has filed a prospectus supplement for an "at-the-market" offering with an investment bank as sales agent. The Company will not be eligible to use the S-3 once the 10-K is filed.

A summary of the Company's non-vested restricted stock activity and related weighted average grant date fair value information for the last three years ended April 30, 2020 are as follows:

	Shares	Weighted Average Grant Date Fair Value
Unvested, at April 30, 2018	5,600,000	$ 0.06
Granted	11,050,000	0.05
Vested	(12,050,000)	0.06
Forfeited	–	–
Unvested, at April 30, 2019	4,600,000	0.05
Granted	16,300,000	0.05
Vested	(16,300,000)	0.05
Forfeited	–	–
Unvested, at April 30, 2020	4,600,000	$ 0.06

NOTE 6 – STOCK OPTIONS AND WARRANTS

Stock Options

As of April 30, 2020, the Company had 67,200,000 outstanding stock options to its directors and officers (collectively, "Employee Options") and consultants ("Non-Employee Options").

During the years ended April 30, 2020 and 2019, the Company granted 11,000,000 and 11,000,000 Employee Options, respectively.

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

	Years Ended April 30,	
	2020	**2019**
Risk-free interest rate	1.8%	2.0%
Expected volatility	91%	97%
Expected lives (years)	2.7	2.7
Expected dividend yield	0.00%	0.00%

The Company's computation of expected volatility is based on the historical daily volatility of its publicly traded stock. For stock option grants issued during years ended April 30, 2020 and 2019, the Company used a calculated volatility for each grant. The Company lacks adequate information about the exercise behavior now and has determined the expected term assumption under the simplified method provided for under ASC 718, which averages the contractual term of the Company's stock options of five years with the average vesting term of two and one-half years for an average of three years. The dividend yield assumption of zero is based upon the fact the Company has never paid cash dividends and presently has no intention of paying cash dividends. The risk-free interest rate used for each grant is equal to the U.S. Treasury rates in effect at the time of the grant for instruments with a similar expected life.

During the years ended April 30, 2020 and 2019, the Company granted Non-Employee Options of 1,200,000 and 1,200,000, respectively.

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

	Years Ended April 30,	
	2020	**2019**
Risk-free interest rate	1.6%	2.5%
Expected volatility	90%	98%
Expected lives (years)	5.0	5.0
Expected dividend yield	0.00%	0.00%

Non-Employee Option grants that do not vest immediately upon grant are recorded as an expense over the vesting period. Effective August 1, 2018 the Company adopted ASU 2018-07 early using the modified retrospective transition approach. The Company determined there was no transition adjustment upon adoption of ASU 2018-07.

A summary of the Company's stock option activity and related information for the two years ended April 30, 2020 are shown below:

	Options	**Weighted Average Exercise Price**	**Weighted Average Grant Date Fair Value per Share**
Outstanding, April 30, 2018	95,250,000	$ 0.11	$ 0.11
Issued	12,200,000	0.05	0.05
Forfeited	–	–	–
Exercised	–	–	–
Outstanding, April 30, 2019	107,450,000	0.11	0.11
Issued	12,200,000	0.04	0.04
Forfeited	(52,450,000)	0.15	0.14
Exercised	–	–	–
Outstanding, April 30, 2020	67,200,000	$ 0.06	$ 0.06
Exercisable, April 30, 2020	61,000,000	$ 0.07	$ –
Vested and expected to vest	67,200,000	$ 0.06	$ –

A summary of the activity for unvested stock options during the years ended April 30, 2020 and 2019 is as follows:

	Options	Weighted Average Grant Date Fair Value per Share
Unvested, April 30, 2018	7,200,000	$ –
Granted	12,200,000	0.05
Vested	(13,200,000)	–
Forfeited	–	–
Unvested, April 30, 2019	6,200,000	–
Granted	12,200,000	0.04
Vested	(12,200,000)	–
Forfeited	–	–
Unvested, April 30, 2020	6,200,000	$ 0.05

The Company recorded $338,050 and $320,178 of stock-based compensation related to the issuance of Employee Options to certain officers and directors in exchange for services during the years ended April 30, 2020 and 2019, respectively. At April 30, 2020, there remained $141,642 of unrecognized compensation expense related to unvested Employee Options granted to officers and directors, to be recognized as expense over a weighted-average period of the remaining eight months in the calendar year. The unvested options vest at 750,000 shares per month and are expected to be fully vested on December 31, 2020.

The Company recorded $41,326 and $92,171 of stock-based compensation related to the issuance of Non-Employee Options in exchange for services during the years ended April 30, 2020 and 2019, respectively. The unvested Non-Employee Options vest at 100,000 shares per month and are expected to be fully vested on June 30, 2020.

The following table summarizes the outstanding stock options by exercise price at April 30, 2020:

Exercise Price	Number of Options Outstanding	Weighted Average Remaining Contractual Life (years) of Outstanding Options	Weighted Average Exercisable Price	Number of Options Exercisable	Weighted Average Exercise Price of Exercisable Options
$ 0.063	15,600,000	0.40	$ 0.063	15,600,000	$ 0.063
$ 0.104	10,450,000	1.20	$ 0.104	10,450,000	$ 0.104
$ 0.0685	600,000	1.00	$ 0.0685	600,000	$ 0.0685
$ 0.058	2,450,000	1.62	$ 0.058	2,450,000	$ 0.058
$ 0.0734	1,200,000	2.00	$ 0.0734	1,200,000	$ 0.0734
$ 0.0729	1,800,000	2.19	$ 0.0729	1,800,000	$ 0.0729
$ 0.089	1,200,000	2.22	$ 0.089	1,200,000	$ 0.089
$ 0.0553	500,000	1.22	$ 0.0553	500,000	$ 0.0553
$ 0.0558	9,000,000	1.60	$ 0.0558	9,000,000	$ 0.0558
$ 0.0534	1,200,000	3.35	$ 0.0534	1,200,000	$ 0.0534
$ 0.0539	1,000,000	1.50	$ 0.0539	1,000,000	$ 0.0539
$ 0.0683	500,000	1.58	$ 0.0683	500,000	$ 0.0683
$ 0.0649	500,000	1.72	$ 0.0649	500,000	$ 0.0649
$ 0.0495	9,000,000	2.33	$ 0.0495	9,000,000	$ 0.0495
$ 0.0380	1,200,000	4.40	$ 0.0380	1,000,000	$ 0.0380
$ 0.0404	1,000,000	2.00	$ 0.0404	1,000,000	$ 0.0404
$ 0.0370	500,000	2.09	$ 0.0370	500,000	$ 0.0370
$ 0.0340	500,000	2.22	$ 0.0340	500,000	$ 0.0340
$ 0.0408	9,000,000	2.81	$ 0.0408	3,000,000	$ 0.0408
Total	67,200,000	1.61	$ 0.06	61,000,000	$ 0.07

The aggregate intrinsic value of outstanding options as of April 30, 2020 was zero. This represents options whose exercise price was less than the closing fair market value of the Company's common stock on April 30, 2020 of approximately $0.0245 per share.

Warrants

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

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

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

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

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

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

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

Effective June 13, 2019 the Company issued a common stock purchase warrant to Aeon for a Block Trade. The Company issued a warrant to purchase 1,338,889 shares of common stock based upon a Block Trade pursuant to the engagement agreement with Aeon dated February 22, 2018. The Company classified these warrants as equity, and the warrants have a term of five years with an exercise price of approximately $0.01 per share. Using the Black-Scholes-Merton option pricing model, the Company determined the aggregate value of these warrants to be approximately $9,000. The warrants have a cashless exercise feature.

Effective July 15, 2019 the Company issued a common stock purchase warrant to Aeon for a Block Trade. The Company issued a warrant to purchase 1,944,444 shares of common stock based upon a Block Trade pursuant to the engagement agreement with Aeon dated February 22, 2018. The Company classified these warrants as equity, and the warrants have a term of five years with an exercise price of approximately $0.01 per share. Using the Black-Scholes-Merton option pricing model, the Company determined the aggregate value of these warrants to be approximately $12,000. The warrants have a cashless exercise feature.

Effective August 7, 2019 the Company issued a common stock purchase warrant to Aeon for a Block Trade. The Company issued a warrant to purchase 3,000,000 shares of common stock based upon a Block Trade pursuant to the engagement agreement with Aeon dated February 22, 2018. The Company classified these warrants as equity, and the warrants have a term of five years with an exercise price of approximately $0.01 per share. Using the Black-Scholes-Merton option pricing model, the Company determined the aggregate value of these warrants to be approximately $10,000. The warrants have a cashless exercise feature.

Effective August 7, 2019 the Company issued a common stock purchase warrant to Aeon for a Block Trade. The Company issued a warrant to purchase 500,000 shares of common stock based upon a Block Trade pursuant to the engagement agreement with Aeon dated February 22, 2018. The Company classified these warrants as equity, and the warrants have a term of five years with an exercise price of approximately $0.01 per share. Using the Black-Scholes-Merton option pricing model, the Company determined the aggregate value of these warrants to be approximately $2,000. The warrants have a cashless exercise feature.

Effective February 24, 2020 the Company issued a common stock purchase warrant to Aeon for a Block Trade. The Company issued a warrant to purchase 1,000,000 shares of common stock based upon a Block Trade pursuant to the engagement agreement with Aeon dated February 22, 2018. The Company classified these warrants as equity, and the warrants have a term of five years with an exercise price of approximately $0.01 per share. Using the Black-Scholes-Merton option pricing model, the Company determined the aggregate value of these warrants to be approximately $3,000. The warrants have a cashless exercise feature.

Effective February 24, 2020 the Company issued a common stock purchase warrant to Aeon for a Block Trade. The Company issued a warrant to purchase 1,000,000 shares of common stock based upon a Block Trade pursuant to the engagement agreement with Aeon dated February 22, 2018. The Company classified these warrants as equity, and the warrants have a term of five years with an exercise price of approximately $0.01 per share. Using the Black-Scholes-Merton option pricing model, the Company determined the aggregate value of these warrants to be approximately $3,000. The warrants have a cashless exercise feature.

Effective March 24, 2020 the Company issued a common stock purchase warrant to Aeon for a Block Trade. The Company issued a warrant to purchase 3,500,000 shares of common stock based upon a Block Trade pursuant to the engagement agreement with Aeon dated February 22, 2018. The Company classified these warrants as equity, and the warrants have a term of five years with an exercise price of approximately $0.01 per share. Using the Black-Scholes-Merton option pricing model, the Company determined the aggregate value of these warrants to be approximately $12,000. The warrants have a cashless exercise feature.

Effective March 31, 2020 the Company issued a common stock purchase warrant to Aeon for a Block Trade. The Company issued a warrant to purchase 1,000,000 shares of common stock based upon a Block Trade pursuant to the engagement agreement with Aeon dated February 22, 2018. The Company classified these warrants as equity, and the warrants have a term of five years with an exercise price of approximately $0.01 per share. Using the Black-Scholes-Merton option pricing model, the Company determined the aggregate value of these warrants to be approximately $3,000. The warrants have a cashless exercise feature.

Effective April 7, 2020 the Company issued a common stock purchase warrant to Aeon for a Block Trade. The Company issued a warrant to purchase 2,500,000 shares of common stock based upon a Block Trade pursuant to the engagement agreement with Aeon dated February 22, 2018. The Company classified these warrants as equity, and the warrants have a term of five years with an exercise price of $0.01 per share. Using the Black-Scholes-Merton option pricing model, the Company determined the aggregate value of these warrants to be approximately $17,000. The warrants have a cashless exercise feature.

Effective April 21, 2020 the Company issued a common stock purchase warrant to Aeon for a Block Trade. The Company issued a warrant to purchase 833,333 shares of common stock based upon a Block Trade pursuant to the engagement agreement with Aeon dated February 22, 2018. The Company classified these warrants as equity, and the warrants have a term of five years with an exercise price of approximately $0.02 per share. Using the Black-Scholes-Merton option pricing model, the Company determined the aggregate value of these warrants to be approximately $9,000. The warrants have a cashless exercise feature.

A summary of the Company's warrant activity and related information for the two years ended April 30, 2020 are shown below:

	Warrants	Weighted Average Exercise Price
Outstanding, April 30, 2018	33,993,104	$ 0.10
Issued	8,084,693	–
Expired	–	–
Outstanding, April 30, 2019	42,077,797	0.09
Issued	16,666,666	–
Expired	(10,854,308)	–
Outstanding, April 30, 2020	47,890,155	–
Exercisable, April 30, 2020	47,890,155	$ 0.05

The following table summarizes additional information concerning warrants outstanding and exercisable at April 30, 2020:

Exercise Prices	Number of Warrant Shares Exercisable at April 30, 2020	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price
$0.12	17,000,000	0.69	
$0.065	769,231	1.64	
$0.0575	869,565	1.93	
$0.03	2,500,000	2.58	
$0.026	1,923,077	3.16	
$0.025	2,000,000	2.24	
$0.018	1,388,889	3.08	
$0.011	2,272,727	3.51	
$0.01	5,000,000	4.42	
$0.015	833,333	4.98	
$0.009	3,333,333	4.17	
$0.005	10,000,000	4.67	
	47,890,155	2.73	$ 0.05

NOTE 7 – LEGAL PROCEEDINGS

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

NOTE 8 – RELATED PARTY TRANSACTIONS

The Company had the following related party transactions during the years ended April 30, 2020 and 2019, respectively.

The Company owns 14.5% of the equity in SG Austria and is reported on the cost method of accounting. SG Austria has two subsidiaries: (i) Austrianova; and (ii) Austrianova Thailand. The Company purchased products and services from these subsidiaries in the approximate amounts of $153,000 and $168,000 in the years ended April 30, 2020 and 2019, respectively.

In April 2014, the Company entered the Vin-de-Bona Consulting Agreement pursuant to which it agreed to provide professional consulting services to the Company. Vin-de-Bona is owned by Prof. Günzburg and Dr. Salmons, both of whom are involved in numerous aspects of the Company's scientific endeavors relating to cancer and diabetes (Prof. Gunzburg is the Chairman of Austrianova, and Dr. Salmons is the Chief Executive Officer and President of Austrianova). The term of the agreement is for 12 months, automatically renewable for successive 12-month terms. After the initial term, either party can terminate the agreement by giving the other party 30 days' written notice before the effective date of termination. The agreement has been automatically renewed annually. The amounts incurred for the years ended April 30, 2020 and 2019 were approximately $24,000 and $18,000, respectively. In addition, during the year ended April 30, 2020 the Company issued 250,000 shares of common stock to Dr. Salmons. The Company recorded a noncash consulting expense of approximately $10,000 relating to these share issuances for the year ended April 30, 2020.

During the year ended April 30, 2020, the Company issued one share of Series A Preferred Stock to the Chief Executive Officer of the Company for $1 pursuant to a subscription agreement. The Series A Preferred Stock is described in detail in Note 12 – Preferred Stock. The Board exercised its right to have the Company redeem the one share of Series A Preferred Stock. It is no longer issued and outstanding.

NOTE 9 – COMMITMENTS AND CONTINGENCIES

The Company acquires assets still in development and enters R&D arrangements with third parties that often require milestone and royalty payments to the third-party contingent upon the occurrence of certain future events linked to the success of the asset in development. Milestone payments may be required, contingent upon the successful achievement of an important point in the development lifecycle of the pharmaceutical product (e.g., approval of the product for marketing by a regulatory agency). If required by the license agreements, the Company may have to make royalty payments based upon a percentage of the sales of the pharmaceutical products if regulatory approval for marketing is obtained.

Office Lease

Effective September 1, 2017, the Company entered into a lease for its Leased Premises in California. The term of the lease is for 24 months and expired on August 31, 2019. In May 2019, the Company entered into an additional one-year lease for the Leased Premises, commencing upon the expiration of the term of the prior lease. The term of the lease expires on August 31, 2020.

On May 28, 2020, the Company entered into an additional six-month lease of the Leased Premises, commencing on September 1, 2020. The term of the new lease expires on February 28, 2021.

Rent expenses for these offices for the years ended April 30, 2020 and 2019 were $30,964 and $34,153, respectively.

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

Years Ending April 30,	Amount
2021	$ 17,196
	$ 17,196

Material Agreements

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

Compensation Agreements

The Company entered into executive compensation agreements with its three executive officers in March 2015, each of which was amended in December 2015 and March 2017. Each agreement has a term of two years with annual extensions thereafter unless the Company or the officer provides written notification of termination at least ninety days prior to the end of the term or subsequent extensions. The Company also entered a compensation agreement with a Board member in April 2015 which continued in effect until amended in May 2017.

In May 2017, the Company amended the compensation agreement with the Board members and the terms continue in effect until a member is no longer on the Board.

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

NOTE 10 - INCOME TAXES

At April 30, 2020, the Company had federal and state net operating loss carryforwards of approximately $44,863,000 and $41,203,000, respectively, available to offset against future taxable income; these operating loss carryforwards expire in 2020 through 2038.

Current tax laws limit the amount of loss available to be offset against future taxable income when a substantial change in ownership occurs. Therefore, the amount available to offset future taxable income may be limited. Based on the assessment of all available evidence including, but not limited to, the Company's limited operating history in its core business and lack of profitability, uncertainties of the commercial viability of its technology, the impact of government regulations and healthcare reform initiatives and other risks normally associated with biotechnology companies, the Company has concluded that is more likely than not that these operating loss carryforwards will not be realized. Accordingly, 100% of the deferred tax valuation allowance has been recorded against these assets.

Deferred income taxes reflect the net effect of temporary differences between the financial reporting carrying amounts of assets and liabilities and income tax carrying amounts of assets and liabilities. The components of the Company's deferred tax assets and liabilities are as follows:

	April 30,	
	2020	**2019**
Deferred tax assets:		
Net operating loss carryforwards	$ 12,904,396	11,849,290
Stock compensation	2,494,586	2,233,230
Other	129,976	105,251
Total deferred tax assets	15,528,958	14,187,771
Valuation allowance	(15,528,958)	(14,187,771)
	$ –	$ –

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, 2020 and 2019 were increases of $1,341,187 and $952,170, 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,	
	2020	**2019**
Federal benefit at statutory rate	$ (803,646)	(854,118)
State income taxes, net of Federal taxes	(327,199)	(274,538)
Permanent differences	248,908	170,032
Provision related to change in valuation allowance	1,341,187	952,170
Net valuation allowance for state tax deductions	(402,882)	–
Other, net	(56,368)	6,454
	$ –	$ –

There have been no changes to the Company's liability for unrecognized tax benefits during the year ended April 30, 2020.

The Company files its income tax returns in the U.S. Federal jurisdiction and various state jurisdictions. As of the year ended April 30, 2020, the tax returns for 2014 through 2019 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, 2020 and 2019, the Company had accrued no interest or penalties related to uncertain tax positions.

NOTE 11 – EARNINGS PER SHARE

Basic earnings (loss) per share is computed by dividing earnings available to common stockholders by the weighted average number of shares outstanding during the period. Diluted earnings per share is computed by dividing net income by the weighted average number of shares and potentially dilutive shares of common stock outstanding during the period increased to include the number of additional shares of common stock that would be outstanding if the potentially dilutive securities had been issued. Potential shares of common stock outstanding principally include stock options and warrants. During the years ended April 30, 2020 and 2019, 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,	
	2020	**2019**
Net loss	$ (3,826,888)	$ (4,067,228)
Basic weighted average number of shares outstanding	1,355,717,271	1,100,104,338
Diluted weighted average number of shares outstanding	1,355,717,271	1,100,104,338
Basic and diluted loss per share	$ (0.00)	$ (0.00)

The table below sets forth these potentially dilutive securities:

	Years Ended April 30,	
	2020	**2019**
Excluded options	67,200,000	107,450,000
Excluded warrants	47,890,155	42,077,797
Total excluded options and warrants	115,090,155	149,527,797

NOTE 12 – PREFERRED STOCK

The Company has authorized 10,000,000 shares of preferred stock, with a par value of $0.0001, of which one share has been designated as "Series A Preferred Stock". The one share of Series A Preferred Stock was issued on October 30, 2019 and repurchased by the Company on December 3, 2019. As of April 30, 2020, there are no shares of preferred stock issued and outstanding.

The description of the Series A Preferred Stock below is qualified in its entirety by reference to the Company's Articles of Incorporation, as amended.

The Series A Preferred Stock has the following features:

- There is one share of preferred stock designated as Series A Preferred Stock;
- The Series A Preferred Stock has a number of votes at any time equal to the number of votes then held by all other shareholders of the Company having a right to vote on any matter plus one. The Certificate of Designations that designated the terms of the Series A Preferred Stock cannot be amended without the consent of the holder of the Series A Preferred Stock;
- The Company may redeem the Series A Preferred Stock at any time for a redemption price of $1.00 paid to the holder of the share of Series A Preferred Stock; and
- The Series A Preferred Stock has no rights of transfer, conversion, dividends, preferences upon liquidation or participation in any distributions to shareholders.

NOTE 13 – SUBSEQUENT EVENTS

On May 28, 2020, the Company entered into a six-month office lease extension commencing on September 1, 2020. The lease extension is for the office where the Company is currently located in Laguna Hills, California. The term of the new lease expires on February 28, 2021 and requires monthly lease payments of approximately $1,300.

From May 1, 2020 through August 11, 2020, the Company sold approximately 687 million shares of common stock using the Second S-3 structured as a Block Trade. The issuance of these shares resulted in gross proceeds to the Company of approximately $5 million. Pursuant to the Aeon Agreement, the Company is required to pay Aeon a fee of approximately $281,000 and provide warrant coverage of 5% of the number of shares of commons stock sold in the Block Trade with a five-year term for approximately 34 million warrant shares. The Company incurred additional fees of approximately $191,000 to an unrelated party.

From May 1, 2020 through August 13, 2020, the Company sold 5,339,232 shares of common stock using the Second S-3 “at-the-market” trades. The net proceeds from these sales were $131,547.

PHARMACYTE BIOTECH, INC.
SCHEDULE II — VALUATION AND QUALIFYING ACCOUNTS
Years Ended April 30, 2020 and 2019

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, 2020	$ 14,187,771	–	1,341,187	–	15,528,958
Year ended April 30, 2019	$ 13,235,601	–	952,170	–	14,187,771

EXHIBIT 21.1

List of Subsidiaries

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

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-220441) of PharmaCyte Biotech, Inc. and Subsidiaries of our report dated August 13, 2020 relating to the consolidated financial statements and consolidated financial statement schedules, which appears in this Form 10-K for the year ended April 30, 2020 listed in the accompanying index.

/s/Armanino LLP
San Jose, California

August 13, 2020

EXHIBIT 31.1

CERTIFICATION

I, Kenneth L. Waggoner, certify that:

1. I have reviewed the Annual Report on Form 10-K of PharmaCyte Biotech, Inc. ("Report") and its subsidiaries for the fiscal year ended April 30, 2020;

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

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

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

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

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

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

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

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

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

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

Dated: August 13, 2020

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

EXHIBIT 31.2

CERTIFICATION

I, Carlos A. Trujillo, certify that:

1. I have reviewed the Annual Report on Form 10-K of PharmaCyte Biotech, Inc. ("Report") and its subsidiaries for the fiscal year ended April 30, 2020;

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

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

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

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

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

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

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

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

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

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

Dated: August 13, 2020

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

EXHIBIT 32.1

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

In connection with the Annual Report of PharmaCyte Biotech, Inc. and its subsidiaries ("Company") on Form 10-K for the year ended April 30, 2019 as filed with the U.S. Securities and Exchange Commission ("Commission") on the date hereof ("Report"), the undersigned, Kenneth L. Waggoner, Chief Executive Officer of the Company, certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Dated: August 13, 2020

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

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

EXHIBIT 32.2

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

In connection with the Annual Report of PharmaCyte Biotech, Inc. and its subsidiaries ("Company") on Form 10-K for the year ended April 30, 2019 as filed with the U.S. Securities and Exchange Commission ("Commission") on the date hereof ("Report"), the undersigned, Carlos A. Trujillo, Chief Financial Officer of the Company, certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Dated: August 13, 2020

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

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