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

FORM 10-K/A
Amendment No. 1

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

For the fiscal year ended April 30, 2014

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

NUVILEX, INC.
(Exact name of registrant as specified in its charter)

Nevada	**62-1772151**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

12510 Prosperity Drive, Suite 310, Silver Spring, MD 20904
(Address of principal executive offices)

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

Securities registered under Section 12(b) of the Act:	None
Securities registered under Section 12(g) of the Act:	None

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

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

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

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

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

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

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

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

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of October 31, 2013: $64,379,703.

As of August 1, 2014, the registrant had 709,256,214 outstanding shares of common stock.

DOCUMENTS INCORPORATED BY REFERENCE

None.

Explanatory Note

We are filing this amendment to our annual report on Form 10-K for the year ended April 30, 2014 ("10-K") to amend Part I, Item 1 - Business and Part III, Item 13 Certain Relationships and Related Transactions, and Director Independence, in the original 10-K filed with the Securities and Exchange Commission ("SEC"), in response to comments from the staff of the SEC. Except as aforesaid, the information in this Form 10-K/A has not been updated to reflect events that occurred after August 4, 2014, the filing date of the original 10-K. Accordingly, this Form 10-K/A should be read in conjunction with the 10-K and our filings made with the SEC subsequent thereto. Except as set forth above, all other information in the 10-K remains unchanged. The Company has included as exhibits to this Form 10-K/A an updated certification from the Company's Principal Executive and Financial Officer pursuant to Sections 302 and 906 of the Sarbanes Oxley Act of 2002 and certain additional exhibits pursuant to comments from the staff of the SEC.

Forward-Looking Statements

This Amendment No. 1 to the Annual Report on Form 10-K/A ("Report") includes "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended ("Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended ("Exchange Act"). All statements other than statements of historical fact are "forward-looking statements" for purposes of this Report, including any projections of earnings, revenue or other financial items, any statements regarding the plans and objectives of management for future operations, any statements concerning proposed new products or services, any statements regarding future economic conditions or performance, any statements regarding expected benefits from any transactions and any statements of assumptions underlying any of the foregoing. In some cases, forward-looking statements can be identified by the use of terminology such as "may," "will," "expects," "plans," "anticipates," "estimates," "potential" or "continue," or the negative thereof or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements contained in this Report are reasonable, there can be no assurance that such expectations or any of the forward-looking statements will prove to be correct, and actual results could differ materially from those projected or assumed in the forward-looking statements. Thus, investors should refer to and carefully review information in future documents the Company files with the Securities and Exchange Commission ("SEC"). 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" in the original 10-K filed with the SEC and for the reasons described elsewhere in this Report. All forward looking statements and reasons why results may differ included in this Report are made as of the date hereof, and we do not intend to update any forward-looking statements except as required by law or applicable regulations. Except where the context otherwise requires, in this Report, the "Company," "Nuvilex," "we," "us" and "our" refer to Nuvilex, Inc., a Nevada corporation, and, where appropriate, its subsidiaries.

PART I

ITEM 1 - BUSINESS

Overview

We are dedicated to bringing to market scientifically derived products designed to improve the health, condition and well-being of those who use them. The Company is utilizing a cellulose-based live cell encapsulation technology, we refer to in this Report as "Cell in-a-Box®," to develop treatments for pancreatic cancer, breast cancer, brain cancer and diabetes. The Company is currently preparing for a Phase 2b clinical trial with its pancreatic cancer treatment in patients with advanced, inoperable pancreatic cancer that will be conducted in Australia and preclinical studies and clinical trials of that same pancreatic cancer treatment to study its effects on major symptoms associated with pancreatic cancer. These latter studies and trials will be conducted in the United States.

The Company operates independently and through wholly-owned subsidiaries. The Company has three distinct segments. The first of these includes the cellulose-based live cell encapsulation technology and all of its associated licenses. The second pertains to the work of our subsidiary, Medical Marijuana Sciences, Inc. ("MMS"). MMS focuses on ways to exploit the benefits of the live cell encapsulation technology in optimizing the anticancer effectiveness of constituents of *Cannabis*, known as cannabinoids, against cancers while minimizing or outright eliminating the debilitating side effects usually associated with cancer treatments. The third segment consists of the Company's nutraceutical formulations and their associated product names and information technology. The plan for this segment is to sell its names, nutraceutical formulations and associated information technology to one or more third parties. The Company's current strategy is to focus on developing and marketing products it believes have potential for long-term corporate growth solely in the area of biotechnology.

Cancer Treatments

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

Inno Biologics Sdn. Bhd. ("Inno Biologics") in Malaysia was first contracted to do the initial cloning of the cells that will be encapsulated using the Cell-in-a-Box® technology and then used together with ifosfamide as the Company's pancreatic cancer treatment. We have a proposal, dated August 20, 2013, pursuant to which Inno Biologics has been performing services for us. Under the terms of the proposal, we have agreed to pay Inno Biologics approximately $51,670 for generating up to 100 individual clones from the 22P1G cell lines (the cells that express the CYP2B1 isoform of cytochrome P450 that converts ifosfamide into its cancer-killing form) and DNA extraction from each of the clones. Together with us, Inno Biologics will select the 10 most suitable clones to be maintained and tested using Southern Blotting and Resorufin assays. A 30% "up-front" payment required to be paid upon acceptance of the proposal was rendered by Nuvilex to Inno Biologics. The remainder of the proposal amount is due and payable upon completion of the work. The goal was to produce up to 100 clones from which the 5-10 best would be selected for use in the encapsulation process. These clones were then to be used for expanding (propagating) the cells to obtain the large numbers that needed for the preclinical studies and clinical trials. The encapsulated cells were to have been stored for safekeeping around the globe or used for other purposes. Due to a "potential" problem that occurred during the initial cloning process and which, upon rigorous inspection, turned out not to be a problem at all, the Company decided that it was prudent for Inno Biologics to begin the cloning process again but on a much smaller scale. In order that a "fail-safe" mechanism for the cloning process be instituted, ViruSure GmbH ("ViruSure") in Vienna, Austria has been contracted to prepare a limited number of clones that can be stored for possible future expansion should there be any "real" problems at Inno Biologics. ViruSure was also engaged to expand the clones of cells obtained from Inno Biologics into a Master Cell Bank ("MCB") and from that into a Working Cell Bank ("WCB") to supply the large numbers of cells needed for the preclinical studies, clinical trials and other purposes. Nuvilex has entered into a Master Services Agreement with ViruSure to develop the MCB and the WCB pursuant to which ViruSure was engaged to conduct individual studies and provide consultation as defined in protocols and statements of work provided by us. Under our current protocol, ViruSure has been engaged to develop and expand the clones of cells obtained from Inno Biologics into a Master Cell Bank ("MCB") and from that into a Working Cell Bank ("WCB") to supply the large numbers of cells needed for our preclinical studies, clinical trials and other purposes. The MCB is to be used as a "safe" repository of the selected clone and the WCB is to be used as a source of cells for the production of the large numbers of cells that will ultimately be needed for encapsulation using the Cell-in-a-Box® technology for our future clinical trials and other studies. Compensation to ViruSure is set forth in separate agreements, and the price, fees and payment schedule depends upon the particular study.

The principal developers of the Cell-in-a-Box® cellulose-based live cell encapsulation technology are Prof. Dr. Walter H. Günzburg ("Dr. Günzburg") and Dr. Brian Salmons ("Dr. Salmons"). Both are officers of SG Austria Pte Ltd ("SG Austria") and/or its wholly-owned subsidiary, Austrianova Singapore Pte Ltd ("Austrianova Singapore"). The Company owns a 14.5% equity interest in SG Austria and has contractual relationships governing its relationship with Austrianova Singapore. The success of SG Austria/Austrianova Singapore and the Company are co-dependent in almost every respect. By way of elaboration, SG Austria and Austrianova Singapore benefit from the success of the Company. As the Company reaches certain "milestones" in the progression of the Cell-in-a-Box® cellulose-based live cell encapsulation technology towards the development of treatments for cancer and diabetes, substantial payments will be made by the Company to SG Austria or Austrianova Singapore. Accordingly, the more success that the Company has in developing such treatments, the more lucrative it becomes for SG Austria and Austrianova Singapore. Contracts covering such payments have already been disclosed. In turn, the Company is dependent upon SG Austria and Austrianova Singapore because of their knowledge and expertise in the Cell-in-a-Box® technology. This technology serves as the basis for all of the Company's efforts in developing treatments for both cancer and diabetes. In addition, the Company owns 14.5% of the shares of SG Austria. Thus, in our opinion, the two companies are indeed co-dependent.

Dr. Günzburg and Dr. Salmons are intimately involved in the scientific endeavors underway and being planned by the Company having commenced work on the Company's behalf at the beginning of 2014 pursuant to an oral agreement providing for their services as consultants to the Company being compensated at arms-length economic terms through their consulting company, Vin-de-Bona Trading Company Pte Ltd ("Vin-de-Bona"). This arrangement was later formalized as of April 1, 2014, with the execution of a written Consulting Agreement between the Company and Vin-de-Bona. The Consulting Agreement has an initial term of 12 months, with additional terms of 12 months automatically occurring unless either party terminates an additional term upon 30 days' prior written notice. The professional services rendered to the Company by Drs. Günzburg and Salmons are charged at a negotiated and confidential hourly rate. During the fiscal year ended April 30, 2014, this is the only relationship between the Company and Drs. Günzburg and Salmons. Pursuant to the terms of the Consulting Agreement, Drs. Günzburg and Salmons must not disclose or use our confidential information for any purpose (except for performing services under the Consulting Agreement) without our prior written consent. In addition, during the term of the Consulting Agreement and for a period of twelve months after termination or expiration of the Consulting Agreement, Drs. Günzburg and Salmons shall not solicit any of our customers, employees, suppliers or other persons with whom they had dealings during the tenure of their consultancy with the Company.

These endeavors include work associated with the preclinical studies and clinical trials to be conducted in the United States on behalf of the Company by Translational Drug Development ("TD2"), one of the leading Contract Research Organizations ("CRO") in the United States specializing in oncology. These studies and trials involve determining the effectiveness of our pancreatic cancer treatment in ameliorating the virtually untreatable and unbearable pain associated with advanced pancreatic cancer and the effects of the treatment on the rate of accumulation of fluid in the abdomen, known as "Malignant Ascites", because it contains cancer cells that could "seed" and form new tumors in the body. Malignant Ascites occurs in patients with pancreatic cancer and other cancer tumors in the abdomen. In addition, Dr. Günzburg and Dr. Salmons will be intimately involved in the Company's Phase 2b clinical trial that will be conducted in Australia by one of the foremost CROs in that country, Clinical Network Services (CNS) Pty Ltd ("CNS"). This Phase 2b clinical trial, which can be viewed as "mini" Phase 3 trial, will compare the Company's treatment "head to head" with the best available therapy which is currently Celgene's drug Abraxane® in combination with gemcitabine (this was the first drug approved by the FDA to treat pancreatic cancer; the trade name of gemcitabine is "Gemzar®") to treat advanced, inoperable pancreatic cancer. The participation of Dr. Günzburg and Dr. Salmons is fortunate for the Company because, in addition to being architects of the Cell-in-a-Box® technology and of Nuvilex's pancreatic cancer treatment, they: (i) were intimately involved in the original Phase 1/2 clinical trials in advanced, inoperable pancreatic cancer that were carried out several years ago in Europe; and (ii) are exceedingly familiar with CNS and the personnel that will be involved in the Company's Phase 2b clinical trial.

Dr. Matthias Löhr ("Dr. Löhr"), a renowned European gastroenterologist/oncologist, will also play a major role in the development of the Company's pancreatic cancer treatment. Dr. Löhr, currently with the Karolinska Institute in Stockholm, Sweden, served as Principal Investigator of the Phase 1/2 clinical trials of the combination of CapCell® (now known as Cell-in-a-Box®) with low-dose ifosfamide in patients with advanced, inoperable pancreatic cancer. Dr. Löhr is exceedingly familiar with the use of this combination treatment in a clinical setting and believes in the combination as a possible "first-line" treatment (i.e. the initial treatment of choice) for the disease. Dr. Löhr is integrally involved in planning every aspect of the Phase 2b clinical trial and will oversee the trial that will be conducted in Australia by CNS.

Diabetes Studies

Diabetes is a major problem throughout the world. Approximately 382 million cases have been diagnosed world-wide. It is estimated that this number will rise to 592 million by 2035. Approximately 175 million have diabetes and do not know it. Diabetes caused 5.1 million deaths in 2013; every six seconds a person dies from the complications caused by diabetes. Treatments for diabetes and its complications caused at least $580 billion in health care expenditure in 2013. In 2013, more than 21 million live births were affected by diabetes during pregnancy.

Diabetes is caused by insufficient availability of, or resistance to, the hormone insulin. Insulin is produced by the islet cells of the pancreas. Its function is to assist in the transport of glucose (sugar) in the blood to the inside of most types of cells in the body where it is used as a source of energy for those cells. In Type 1 diabetes, which usually begins at a young age, the islet cells of the pancreas have been destroyed, usually by an autoimmune reaction. Type 1 diabetics require daily insulin administration through injection or through the use of an insulin pump. Type 2 diabetes, which is more prevalent than Type 1, can be controlled by diet and exercise in its early stages. As time goes by, it may be necessary to use antidiabetic drugs to control the diabetes. However, over time these too may lose their effectiveness. Thus, even Type 2 diabetics may eventually need insulin administration.

Dr. Günzburg and Dr. Salmons are also fulfilling a major role in the development of the Company's treatment for diabetes that is based on the Cell-in-a-Box® technology. Dr. Günzburg and Dr. Salmons have introduced the Company to the participants and potential participants in the Company's diabetes program in an attempt to develop a medical breakthrough in how diabetes will be treated in the future throughout the world. Researchers at a major university in Australia have developed insulin-producing cells from a human hepatocellular carcinoma cell line. These cells have been exhaustively tested *in vitro* and found to be capable of producing insulin in direct correlation to the amount of glucose in their surroundings. Nuvilex and that university have entered into an exclusive, worldwide license to use these insulin-producing cells in combination with the Cell-in-a-Box® technology in developing a product for the treatment of insulin-dependent diabetes. The insulin-producing cells will be undergoing a tumorigenicity test that will be conducted by the University of Veterinary Medicine Vienna ("UVMV") where Dr. Günzburg is a professor in the Department of Virology. He will coordinate all of the work for the Company being done by UVMV. This test will show whether or not these particular cells have the capacity to form tumors because they were developed from a liver cancer cell line. If they do not, then preclinical animal studies will first be done with these cells. If the studies are successful, they will lead to clinical trials. In the event that the cells are tumorigenic, then it will be necessary to develop another insulin-producing cell line for encapsulation.

Since Dr. Günzburg and Dr. Salmons have previously worked with these insulin-producing cells and have them in frozen storage at Austrianova Singapore, the Australian university was approached to obtain permission for these stored cells to be used for the tumorigenicity testing. Written authorization from the Australian university has been obtained for the use of these insulin-producing cells for this testing. Since the tumorigenicity of the cells will be determined at the UVMV, a Collaborative Research Agreement ("CRA") between the Company and the UVMV has been entered into regarding the use of cellulose sulphate encapsulated Melligen cells in the treatment of diabetes to be carried out at the facilities of UVMV.

In the majority of diabetes animal models used by others, the diabetic condition is induced by employing drugs to destroy the normal insulin-producing capability of the pancreas in those animals. The University of Munich ("UOM") in Germany operates a €5-million animal farm that houses animals for research purposes. Scientists at the UOM have developed unique transgenic mouse and pig models of diabetes. Through the use of gene transfer technologies, mice and pigs that are diabetic at birth have been developed. These model systems more closely mimic Type 1 diabetes in humans than any other model systems available world-wide. Through introductions by Dr. Günzburg and Dr. Salmons, the investigators at UOM have agreed to join the Nuvilex team in its efforts to develop a treatment for diabetes based on the Cell-in-a-Box® technology. The Company plans to enter into a research agreement with the UOM in the near term. However, no assurance can be made that such an agreement will be entered into between the Company and the UOM.

The Company is in the process of developing a diabetes consortium consisting of major universities, renowned scientists and physicians and CNS ("Diabetes Consortium"). Executive officers of Nuvilex and the institutions identified above have already explored the possibility of joining the Diabetes Consortium. These institutions will be part of the Diabetes Consortium, as will Dr. Gunzburg and Dr. Salmons through their consulting company, Vin-de-Bona Trading Co. Pte Ltd ("Vin-de-Bona"). The consensus among individuals that could be involved is that the formation of the Diabetes Consortium would be beneficial to all parties and may be a way of optimizing the development of the Company's treatment for diabetes given the free flow of ideas and communication that would occur within such a consortium. Dr. Löhr has a great deal of interest and expertise in treating diabetes. Because of this, he will be assisting the Company in the development of a treatment for diabetes that will employ the Cell-in-a-Box® cellulose-based live cell encapsulation technology. If and when the Diabetes Consortium finally reaches fruition, Dr. Löhr is also expected to play a prominent role in it.

In the areas of both cancer and diabetes, Dr. Günzburg and Dr. Salmons have functioned as consultants to the Company through Vin-de-Bona. In addition, Dr. Salmons is a member of the Scientific Advisory Board of MMS, the Company's subsidiary whose initial goal is to use the Cell-in-a-Box® technology in combination with constituents of *Cannabis* to develop treatments for two of the deadliest forms of cancer - pancreatic and brain cancer.

Current Business of the Company

In the fall of 2013, the Company restructured its corporate operations in an effort to focus on its biotechnology core businesses, having been primarily a nutraceutical products company in the recent past. Of the three segments that resulted from this restructuring, the first of these that houses the cellulose-based live cell encapsulation technology is by far the most advanced, through its efforts to use this technology for the development of treatments for pancreatic cancer and diabetes. The second segment consists of MMS which focuses its efforts on ways to exploit the benefits of the Cell-in-a-Box® technology. In essence, it is developing a "green" approach to treat cancer that combines the Cell-in-a-Box® technology with constituents of *Cannabis* known as cannabinoids. MMS is targeting deadly cancers, such as those of the pancreas, brain, breast and prostate, that affect hundreds of thousands of individuals worldwide every year. It may do so in a way that optimizes the anticancer effectiveness of the cannabinoids while minimizing or outright eliminating the debilitating side effects usually associated with cancer treatments. The third segment consists of the Company's nutraceutical formulations and their associated product names and information technology. This segment is presently "in stasis," as the Company seeks to sell the names, nutraceutical formulations and associated information technology to one or more third parties.

The Company's acquisition of a 14.5% equity interest in SG Austria and a 100% interest in Bio Blue Bird AG ("Bio Blue Bird") that occurred in June 2013 were the first acquisitions related to our biotechnology company. Bio Blue Bird holds the exclusive worldwide licensing rights to the use of the cellulose-based live cell encapsulation technology for developing treatments for pancreatic cancer and diabetes. The Company is working with SG Austria to advance the clinical research, development and marketing of new biotechnologies and medical therapies in the oncology and diabetes arenas. As a result of the Bio Blue Bird acquisition, the Company is now a biotechnology company with a specialty in developing treatments that are based on its live cell encapsulation technology platform we refer to as "Cell-in-a-Box®."

The Company's approach to the development of its treatment for advanced, inoperable pancreatic cancer is somewhat different from the development of many anticancer drugs for this as well as other forms of cancer. Whereas the development of most anticancer agents is focused on the antitumor activity of the drugs, this is not the case for the Company's Cell-in-a-Box®/low-dose ifosfamide combination treatment. Not only will the direct antitumor properties of the Company's treatment be examined by the Phase 2b clinical trial to be conducted in Australia, but also the effects of the treatment on symptoms associated with the disease will be examined by virtue of the preclinical studies and subsequent clinical trials to be done by TD2 in the United States. These latter studies and trials will, initially, examine the effectiveness of this treatment on two of the most debilitating and dangerous symptoms associated with pancreatic cancer - namely the unbearable, virtually untreatable pain and the accumulation of Malignant Ascites in the abdomen.

Strategy

As one of our primary goals, we have worked closely with the senior executives of SG Austria and Austrianova Singapore in a number of critical areas. The senior executives of Nuvilex and SG Austria/Austrianova Singapore have succeeded in creating mechanisms and processes to advance the interests of their respective companies, regardless of the economic conditions and challenges. The strong collaboration between our companies is expected to remain since we have a 14.5% ownership interest in SG Austria and Austrianova Singapore will be carrying out the cGMP manufacturing of encapsulated live cells for the Company in the areas of pancreatic cancer and diabetes. In addition, the senior executives of SG Austria and Austrianova Singapore will be working with us to develop new areas for the use of the live cell encapsulation technology, one example being the development of a "breakthrough" treatment for breast cancer.

The Company's first vision is to ensure that the success engendered in the previous Phase 1/2 pancreatic cancer clinical trials can be built upon and advanced. This occurred with our acquisition of Bio Blue Bird. This acquisition enabled the Company to advance itself as a biotechnology company. Due to the Company's extensive array of product candidates already in-house, Nuvilex exists as a biotechnology company with a broad base - much like that of larger biotechnology or pharmaceutical companies after years of in-house advances, the purchasing of products from third parties and even the acquisition of entire companies. Thus, with an overall goal of long-term growth, management believes the Company is poised to be thrust into a very different position from that of one year ago, particularly as a result of the stabilization of its financial condition that has been occurring over the past year.

Management believes its objective is to have the Company become an industry-leading biotechnology company, with a multi-part, laser-focused strategy. Like those of larger pharmaceutical companies, this strategy is expected to strengthen the Company's position in both the short and long term. The Company will seek to raise capital to fund growth opportunities and provide for its working capital needs as the strategy of the Company is executed. The Company's efforts to achieve financial stability and to enable it to carry out the strategy of the Company include several primary components:

- The completion of the preparations for the Phase 2b clinical trial in advanced, inoperable pancreatic cancer to be carried out in Australia;
- The conducting of preclinical studies and clinical trials that will examine the effectiveness of the Company's pancreatic cancer treatment in ameliorating the pain and accumulation of Malignant Ascites fluid in the abdomen that are characteristic of pancreatic cancer. These studies and trials will be conducted by TD2 in the United States;
- The enhancement of the Company's ability to expand into the biotechnology arena through further research and partnering;
- The acquisition of new contracts and revenue utilizing both in-house products and the newly acquired biotechnology licensing rights;
- The further development of uses of the Cell-in-a-Box® technology platform through contracts, licensing agreements and joint ventures with other companies; and
- The completion of testing, expansion and marketing of existing and newly derived product candidates.

Cell Therapy Product Development

The Company is pursuing the development of the Cell-in-a-Box® cellulose-based live cell encapsulation for use in creating treatments for patients suffering from a number of diseases. Initially, focus will be placed on the preparations for a Phase 2b pancreatic cancer clinical trial. These preparations will include the live cell encapsulation of cancer prodrug-activating cells. For the Phase 2b clinical trial, as in the earlier Phase 1/2 clinical trials, cells expressing a cytochrome P450 isozyme (CYP2B1) for use in cancer therapy will be utilized. These cells were used earlier in Phase 1/2 clinical trials in patients with advanced, inoperable pancreatic cancer. These particular cells were developed so that they converted the cancer prodrug ifosfamide into its active cancer-killing form. When the encapsulated cells were placed in close proximity to the pancreas (and hence in close proximity to the cancerous tumor) and then low-doses (one-third of normal) of the well-known anticancer prodrug ifosfamide were administered, the passage of the ifosfamide through the capsules created an elevated local concentration of active drug capable of stopping the growth of or killing the cancer cells. The results of this "targeted chemotherapy" are discussed in detail below.

These same encapsulated drug-converting cells may also play a significant role in the treatment of breast cancer. Recently, the results of a veterinary Phase 1/2 clinical trial in dogs with spontaneously occurring mammary tumors were published. In this veterinary clinical trial, the same CYP2B1-expressing cells as those that are part of the Company's pancreatic cancer treatment were encapsulated using the Cell-in-a-Box® technology. However, in this clinical trial, ifosfamide was replaced by its "sister" prodrug cyclophosphamide because the latter is often used to treat breast cancer. In fact, according to the American Cancer Society, cyclophosphamide is a component of 9 of 10 commonly used combination chemotherapies for breast cancer. Cyclophosphamide is activated in the exact same way as ifosfamide.

The Cell-in-a-Box® live cell encapsulation technology can be viewed as the equivalent to a modern computer operating system. We have created the hardware and operating platform to envelop or encapsulate our own or other company's "software products," or cells. These cells are then packaged in our live cell encapsulation "operating system."

Estimates indicate that, in approximately 25% of pancreatic cancer patients, the cancer is too advanced for any treatment due to late diagnosis and resulting short survival times. In addition, the disease is typically operable in approximately only 10% of patients. Therefore, we believe the market for the Company's product equates to approximately 68% of the incidence rate in industrialized countries or about 85,000 patients per year. Due to the "unmet medical need" status of pancreatic cancer, the biotechnology and pharmaceutical sectors have been working to discover a treatment for this disease and have invested significant levels of funding required for clinical discovery. The Company believes there is no treatment comparable to the Cell-in-a-Box® live cell encapsulation-based treatment when survival rates and patients' quality of life are compared, increasing the potential that the Company's product candidate will be of value to the oncology community and to pancreatic cancer patients in particular.

Over the past year, the Company contracted with ViruSure, a professional cell growing and adventitious agent (bacteria, mycoplasma, viruses and prions) testing company that has had extensive experience with these CYP2B1-expressing cells, in order to recover them proficiently from frozen stocks and regenerate new stocks for use by the Company going forward. ViruSure has already stored new cell stocks ready for our future work.

The Cell-in-a-Box® encapsulation technology enables living cells to be used as miniature factories. The technology results in the formation of pin-head sized cellulose-based capsules in which cells can be grown and maintained. In the laboratory setting, which involves the large scale amplification and production of useful biotech products outside the body of a person or animal, the proprietary live cell encapsulation technology creates a micro-environment in which delicate cells survive and are protected from environmental challenges, such as the sheer forces associated with bioreactors, enabling greater growth and production of the end product.

The aim is for production of biological products inside the body of a person or an animal after the encapsulated live cells have been strategically placed there**.** The Company's technology enables cells to survive in the human host and function like any other living cell in the body. Since the capsule structure is permeable, small molecules (such as nutrients, oxygen, and waste products) pass through the pores of the capsules enabling the encapsulated therapeutic cells to 'live' in the body, thereby behaving like new miniature organs of the body.

We believe the live cell encapsulation technology brings significant new advantages and opportunities to market for the Company in the following ways:

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

Market Opportunity and the Competitive Landscape

There is intense competition for the use of the product candidates being developed by the Company for treating pancreatic cancer patients due to the number of drugs already available and those in the pipelines of pharmaceutical companies worldwide, not the least of which is the combination of the drugs gemcitabine and Abraxane®. This is the primary FDA approved combination of drugs for treating pancreatic cancer. Some of the Company's competitive strengths include the patents and licensing agreements described in this Report which protect the ability to utilize encapsulated cells as part of the driving force for the Company's cancer and diabetes treatments being developed. Many of our competitors have substantially greater financial and marketing resources than the Company, stronger name recognition, brand loyalty and long-standing relationships with customers. The Company's future success will be dependent upon the Company's ability to compete. Its failure to do so could adversely affect the Company's success. In many ways, the advantage of a smaller and more nimble company is its ability to change quickly as and when needed, therefore providing the Company a competitive position in the biotechnology sector that larger and well-funded biotechnology companies may not have.

Live Cell Encapsulation

Every year in the United States, an estimated 45,220 patients will be diagnosed with pancreatic cancer and over 38,460 will pass away from the disease. In our effort to bring potential treatments to bear on this and other diseases, the Company acquired Bio Blue Bird. This subsidiary holds exclusive worldwide licenses to our unique cellulose-based live cell encapsulation technology for use in oncology and diabetes. The capsules are comprised of cotton's natural component, bio-inert cellulose. Other materials used by competitors include alginate, collagen, chitosan, gelatin and agarose. Cellulose appears to be the most robust of these. This inherent strength provides the Cell-in-a-Box® capsules with advantages over the competition. For example, the Cell-in-a-Box® capsules have remained intact for more than 2 years in humans and for several months in animals during preclinical studies and clinical trials with no evidence of rupture, damage, degradation or an immune response of any kind. In addition, the cells within the capsules remained alive during the course of the studies and trials. Other encapsulating materials degrade over time in the human body. Immune response damage to surrounding tissues has also been reported to occur over time with such materials.

The two areas the Company is currently developing for live cell encapsulation-based treatments are cancer and diabetes. The field of diabetes cell therapy development is competitive. There are a number of companies developing cell based therapies for diabetes. These competitors include Living Cell Technologies, Viacyte, Cellmed, Microislet Sciences, Cerco Medical and BetaCell to name a few. Although competition exists, we believe these other companies are developing live cell encapsulation-based treatments using encapsulation materials and methodologies to produce capsules far less robust than the cellulose-based capsules that the Company is using.

The Cell-in-a-Box® based cancer therapy has already shown promise through the completion of two Phase 1/2 clinical trials in advanced, inoperable pancreatic cancer and the diabetes cell therapy has completed research studies which demonstrated positive responses in animal models. The Company believes it is in a strong competitive position in light of its manufacturing contract with Austrianova Singapore which will provide for cGMP manufacturing of the ifosfamide-converting encapsulated cells to be used in its clinical trials in advanced, inoperable pancreatic cancer to be conducted in Australia and the United States.

The two earlier Phase 1/2 clinical trials referred to above were carried out in Europe in the late 1990s-early 2000s and employed the combination of the cellulose-based live cell encapsulation technology with low doses of the anticancer drug ifosfamide. The results of the first of the two studies have appeared in the peer-reviewed scientific literature, but the report of the second has yet to be published. Accordingly, the discussion below relates to the single clinical trial which has appeared in the scientific literature.

Dates of Trial and Location

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

Identity of Trial Sponsors

The trial was sponsored by Bavarian Nordic GmbH ("Bavarian Nordic").

Trial Design

The trial was an open-label, prospective, single-arm and single center study.

Patient Information

A total of 17 patients were enrolled in the 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 trial and had to be treated by other means. For the other patient, an angiography was not successful, causing the patient to be disqualified from the trial.

Trial Criteria

Criteria for entering the study included inoperable pancreatic adenocarcinoma stage III-IV (IUCC) as determined by histology and measured by CAT scan and with no prior chemotherapy.

Duration of Treatment and Dosage Information

On day 0, celiac angiography was performed and 300 (in 13 patients, 250 in one) of the capsules containing the ifosfamide-activating cells were placed by supraselective catheterization of an artery leading to the tumor. Each capsule (~0.8 mm in diameter) contained about 10,000 cells. The cells overexpressed an enzyme, CYP2B1 (a variant of the cytochrome P450 system), which catalyzed the conversion of the anticancer drug ifosfamide (Holoxan®, Ifex®) into its "cancer-killing" form.

On day 1, patients were monitored for evidence of any clinically relevant adverse reactions, e.g. allergy and/or pancreatitis.

On days 2-4, each patient received low-dose (1 g/m^2 body surface area) ifosfamide in 250 ml of normal saline was administered systemically as a 1-hour infusion. This was accompanied by a 60% dose equivalent of the uroprotector MESNA given as three intravenous injections. This regimen was repeated on days 23-25 for all but two patients who received only one round of ifosfamide. A total of two treatments with ifosfamide were given.

Specific Clinical Endpoints

Median survival time from the time of diagnosis, the percentage of patients who survived one year or more and quality of life were examined in the trial.

Observational Metrics Utilized and Actual Results Observed

Standard NCI criteria for evaluating tumor growth were used to assess stable disease ("SD"; tumors 50-125% of initial size), partial remission ("PR"; more than 50% reduction in tumor volume) and minor response ("MR"; tumor reduction of between 25% and 50%).

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

Toxicity was measured based on WHO/NCI guidelines on common toxicity criteria. The World Health Organization ("WHO") and the National Cancer Institute ("NCI") use standardized classifications of the adverse events associated with the use of cancer drugs. In cancer clinical trials, these are used to determine if a particular drug or treatment causes unwanted side effects (adverse events) when used under specific conditions. For example, the most commonly used classification is known as the "Common Terminology Criteria for Adverse Events" (CTCAE v. 4.0) developed by the NCI in the United States. Most clinical trials carried out in the United States and the United Kingdom code their adverse event results according to this system which consists of five grades; these are: 1 = mild; 2 = moderate; 3 = severe; 4 = life-threatening; 5 = death. In the studies reported for the CapCell® plus low-dose ifosfamide combination in pancreatic cancer patients, the study investigators noted 11 serious adverse events in 7 patients, none of which were believed to be treatment-related.

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

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

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

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

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

The chemotherapy regimen was well tolerated with no toxicity beyond Grade 2 being detected in any of the 14 patients; thus, there were no obvious specific treatment-related risks.

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

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

Only one adverse event (increased lipase activity on day 15 after installation of the capsules) "may" have been linked to capsule administration.

If a "clinical benefit" is considered to be either no increase or a decrease in pain intensity, then 10 of 14 experienced such a benefit. For 7 of the patients, this was confirmed by their analgesic consumption. None of these "benefited" patients registered an increase analgesic usage both in terms of dosage or WHO levels.

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

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

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

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

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

Comparisons to Standard of Care

At the time that the clinical trial was conducted, only one FDA-approved treatment for advanced, inoperable pancreatic cancer was available; that was gemcitabine, an Eli Lilly drug first approved by the FDA in 1996.

An examination of the prescribing information for gemcitabine reveals that the median survival seen in the pivotal (Phase 3) pancreatic cancer clinical trial for that drug was approximately 23 weeks (5.7 months). The percentage of one-year survivors was approximately 18%. In addition, in the pivotal (Phase 3) clinical trial of Celgene's Abraxane® plus gemcitabine combination that was approved by the FDA in September 2013 for the treatment of patients with advanced inoperable pancreatic cancer, the median survival time for patients was about 8.5 months and the percentage of one-year survivors was approximately 35%. By comparison, corresponding values from the Phase 1/2 reported clinical trial of the CapCell® (now known as Cell-in-a-Box®) plus ifosfamide combination were 39 weeks (approximately 9.8 months) and 36%, respectively.

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

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

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

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

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

Conclusions

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

In the Phase1/2 trial only a small number of patients were evaluable. As a result, statistical parameters were not used in the published reports of the Phase 1/2 trial to validate the anticancer efficacy of the Cell-in-a-Box®/low-dose ifosfamide combination in patients with advanced, inoperable pancreatic cancer. In the opinion of the investigators, the results indicate a trend towards efficacy, so the results should not be viewed as absolute numbers. It should be noted, however, that because the results were not statistically significant, any observations of efficacy must be weighed against the possibility that the results were due to chance alone. The purpose of the trials was not to obtain data so that we could seek marketing approval from regulatory authorities, but rather the trials allowed us to determine whether the Cell-in-a- Box/low-dose ifosfamide combination holds promise as a treatment for pancreatic cancer. In the cancer arena, Phase 1/2 trials are used to first establish the safety of drug or treatment being investigated and second to determine if a trend towards efficacy exists. In accordance with FDA guidance, as well as similar guidance from other regulatory authorities in countries other than the United States, we fully realize that a large, multicenter, randomized, comparative study with statistically powerful findings would need to be conducted and the results from such a trial would have to confirm those from the previous Phase 1/2 trial before an application for marketing approval would be made for the Cell-in-a-Box/low-dose ifosfamide combination as a treatment for advanced, inoperable pancreatic cancer.

If the cancer treatment were approved by the Regulatory Agencies (defined below), it could provide a significant benefit to those with this devastating and deadly disease, not only in terms of life-span but also in terms of increased quality of life. In addition, success of the live cell encapsulation technology in the pancreatic cancer setting may lead to its successful use in developing treatments for other forms of cancer after preclinical studies and clinical trials dealing with each form.

Manufacturing

The Company is outsourcing all cell growth, processing and encapsulation services needed in connection with its future clinical trials of the ifosfamide-converting encapsulated cell cancer treatment pursuant to our Manufacturing Framework Agreement with Austrianova Singapore.

Medical Marijuana

The Company formed MMS in early 2013. With 23 states and the District of Columbia approving the use of marijuana, commonly referred to in the scientific community as "*Cannabis*" for medicinal purposes, a plethora of medical marijuana companies have emerged. Most of these involve production and distribution of *Cannabis* in its various forms, such as liquid extracts and pills, as well as *Cannabis* delivery systems - such as vapor pens. Very few are focused on using constituents of *Cannabis* for the treatment of specific diseases.

The Company's major competitors for the development of *Cannabis*-based treatments for cancer are Cannabis Science, Inc. ("CSI"), GW Pharmaceuticals ("GWP") and Medical Marijuana, Inc. ("MMI"). CSI plans to use complex extracts of *Cannabis* to develop treatments for basal and squamous cell (skin) carcinomas and Kaposi's sarcoma. GWP is developing a product portfolio of cannabinoid prescription medicines. MMI is a company that has proprietary cannabinoid delivery methods. It is also a source for some of the 108 identified cannabinoids, one of the most important being cannabidiol or CBD.

In contrast to the work being done by these companies, Nuvilex plans to develop treatments for two of the deadliest forms of cancer - brain and the pancreatic - rather than Kaposi's sarcoma and skin cancer. Nuvilex also plans to focus initially on developing specific treatments based on carefully chosen molecules rather than using complex *Cannabis* extracts. Targeted cannabinoid-based chemotherapy utilizing Cell-in-a-Box® cellulose-based live cell encapsulation technology offers a "green" approach to treating solid-tumor malignancies. *Cannabis* has provided a sustainable source of fiber, food, energy and medicine for thousands of years. The plant's constituents, such as Δ^9-tetrahdyrocannabinol and cannabidiol, have been well-documented to have broad anti-inflammatory, antioxidant, analgesic, nerve protecting and antineoplastic abilities, among many other therapeutic properties. An understanding of the chemical and biochemical processes involved in the interaction of substances derived from *Cannabis* with live cell encapsulation provides the opportunity to develop "green" approaches to treating cancers (pancreatic, brain, breast and prostate to name a few) that affect hundreds of thousands of individuals worldwide every year. The Company believes that MMS is in a unique position among medical marijuana and pharmaceutical companies to develop cannabinoid-based therapies utilizing our proprietary live cell encapsulation technology as the platform.

The Company has entered into a Research Agreement with the State of Colorado, acting on behalf of the Board of Trustees of the University of Northern Colorado. The goal of the current study is to develop methods for the identification, separation and quantification of constituents (pro-drugs) of *Cannabis* that may be used in combination with the Company's Cell-in-a-Box® technology. Initial studies have been undertaken using non-cannabinoid model compounds to identify the appropriate cell type that can convert the selected cannabinoid pro-drugs into metabolites with antineoplastic activity. Once identified, the selected cells or cells transfected with the gene(s) for the appropriate enzyme(s) will be encapsulated using the Company's Cell-in-a-Box® technology. The encapsulated cells and cannabinoid pro-drugs identified by these studies will then be combined and used for future studies to evaluate their antineoplastic effectiveness.

Government Regulations

The United States' Food and Drug Administration ("FDA"), Europe's European Medicines Agency ("EMA"), Australia's Therapeutic Goods Administration ("TGA") and other country specific regulatory agencies around the world (collectively "Regulatory Agencies") ensure the safety of the entire community through their regulations pertaining to new drugs. Regulation by governmental authorities plays a significant factor in the manufacture and marketing of pharmaceuticals and in our ongoing research and development activities. Our therapeutic products require regulatory approval by the Regulatory Agencies. Human therapeutic products are subject to rigorous preclinical testing and clinical trials and other pre-marketing and post-marketing approval requirements of the Regulatory Agencies. In the United States, various federal and, in some cases, state statutes and regulations also govern or impact the manufacturing, testing for safety and effectiveness, labeling, storage, record-keeping and marketing of such products. The lengthy process of seeking required approvals and the continuing need for compliance with applicable statutes and regulations require the expenditure of substantial resources. Regulatory approval, if and when obtained, may be limited in scope which may significantly limit the uses for which a product may be placed into the market. Further, approved drugs, as well as their manufacturers, are subject to ongoing post-marketing review, inspection and discovery of previously unknown problems with such products or the manufacturing or quality control procedures used in their production, which may result in restrictions on their manufacture, sale or use or in their withdrawal from the market. Any failure or delay by us, our suppliers of manufactured drug product, collaborators or licensees in obtaining regulatory approvals could adversely affect the marketing of our products and our ability to receive product revenue, license revenue or profit sharing payments. For more information, see Item 1A. "Risk Factors."

Clinical Development

Before a product may be administered to human subjects, it must undergo preclinical testing. Preclinical tests include laboratory evaluation of a product candidate's chemistry and biological activities and animal studies to assess potential safety and efficacy. The results of these studies must be submitted to the Regulatory Agencies as part of an Investigational New Drug ("IND") application which must be reviewed by the Regulatory Agencies for safety and other considerations before clinical trials in humans can begin.

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

Phase 1 Clinical Trials: Phase 1 clinical trials begin when regulatory agencies allow initiation of clinical investigation of a new drug or product candidate. The clinical trials study a drug's safety profile and may include a preliminary determination of a drug or product candidate's safe dosage range. The Phase I clinical trial also determines how a drug is absorbed, distributed, metabolized and excreted by the body and, therefore, the potential duration of its action. Phase 1 clinical trials generally take from one to three years to complete.

Phase 2 Clinical Trials: Phase 2 clinical trials are conducted on a limited number of subjects with the targeted disease. An initial evaluation of the drug's effectiveness on subjects is performed and additional information on the drug's safety and dosage range is obtained. For many diseases, Phase 2 clinical trials normally include up to several hundred subjects and may take as many as two to three years to complete.

Phase 3 Clinical Trials: Phase 3 clinical trials are typically controlled multi-center trials that involve a larger target patient population that can consist of from several hundred to thousands of subjects to ensure that study results are statistically significant. During Phase 3 clinical trials, physicians monitor subjects to determine efficacy and to gather further information on safety. These trials are designed to generate all of the clinical data necessary to submit an application for marketing approval to regulatory agencies. Phase 3 testing varies by disease state, but can often last from two to four years or more.

Regulatory Review: If a product candidate successfully completes Phase 3 clinical trials and is submitted to governmental regulators, such as the FDA in the United States and the EMA in Europe, the time to final marketing approval can vary from six months to several years, depending on a number of variables. These variables can include such things as the disease type, the strength and complexity of the data presented, the novelty of the target or compound, risk-management approval and whether multiple rounds of review are required for the agency to evaluate the submission. There is no guarantee that a potential treatment will receive marketing approval or that decisions on marketing approvals or treatment indications will be consistent across geographic areas. In some cases, further studies beyond the three-phase clinical trial process described above are required as a condition for approval of a New Drug Application ("NDA"), a Marketing Authorization Application ("MAA") or a Biologics License Application ("BLA"). The Regulatory Agencies require monitoring of all aspects of clinical trials and reports of all adverse events must be made. The Regulatory Agencies may also require the conduct of pediatric studies for the drug and indication either before or after submission of a NDA or a BLA.

Review and Approval by Regulatory Agencies

The results of the preclinical testing, production parameters, and clinical trials are submitted to the Regulatory Agencies as part of a NDA or a BLA for evaluation to determine if there is substantial evidence that the product is sufficiently safe and effective to warrant approval. In responding to a NDA or a BLA, the Regulatory Agencies may grant marketing approval, deny approval or request additional information, including data from new required clinical trials.

Expedited Programs for Serious Conditions

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

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

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

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

Orphan Drug Status

In accordance with laws and regulations pertaining to the Regulatory Agencies, a sponsor may request that the Regulatory Agencies designate a drug intended to treat a "rare disease or condition" as an "orphan drug." For example, in the United States a "rare disease or condition" is defined as one which affects less than 200,000 people in the United States, or which affects more than 200,000 people but for which the cost of developing and making available the product is not expected to be recovered from sales of the product in the United States. Upon the approval of the first NDA or BLA for a drug designated as an orphan drug for a specified indication, the sponsor of that NDA or BLA is entitled to seven years of exclusive marketing rights in the United States unless the sponsor cannot assure the availability of sufficient quantities to meet the needs of persons with the disease. In Europe this exclusivity is 10 years, and in Australia it is 5 years. However, orphan drug status is particular to the approved indication and does not prevent another company from seeking approval of an off-patent drug that has other labeled indications that are not under orphan or other exclusivities. Orphan drugs may also be eligible for federal income tax credits for costs associated with such as the disease state, the strength and complexity of the data presented, the novelty of the target or compound, risk-management approval and whether multiple rounds of review are required for the agency to evaluate the submission. There is no guarantee that a potential treatment will receive marketing approval or that decisions on marketing approvals or treatment indications will be consistent across geographic areas.

Patents, Intellectual Property and Trade Secrets

We have determined that intellectual property ("IP") and patent protection are of paramount importance to our business. Although the Company believes it takes reasonable measures to protect its IP, the Company cannot guarantee it will be able to protect and enforce its IP or obtain international patent protection for its products as needed. Nuvilex and its subsidiaries license patents and trademarks and have exclusive worldwide licensing rights to numerous patents in multiple countries over three technical areas: (i) live cell encapsulation; (ii) treatment of solid tumors, including pancreatic cancer; and (iii) encapsulation of cells for producing retroviral particles for gene therapy. In addition, Nuvilex and its subsidiaries collectively have exclusive worldwide licensing rights to patents, trademarks and know-how using Cell-in-a-Box ®technology in the diabetes field. Litigation may be required to enforce the Company's products, IP rights, trade secrets or determine the validity and scope of the proprietary rights of others. Maintenance of these utilizes financial and operational resources. In addition, the possibility exists that the Company's IP could be discovered to be owned by others, be invalid or be unenforceable, potentially bringing unforeseen challenges to the Company.

Patents and Intellectual Property Agreements

The following patents and agreements constitute the material IP of the Company:

- License Agreement Relating to Encapsulated Cells Producing Viral Particles and Encapsulated Cells Expressing Biomolecules ("Bavarian Nordic/GSF License"). The licensors are Bavarian Nordic and GSF – Forschungszentrum fur Umwelt u. Gesundheit GmbH. The licensee is Bio Blue Bird. The License Agreement was signed in July 2005. The Licensors have rights to terminate the license in the event that the annuity and upkeep fees are not paid to Bavarian Nordic, there is not proper reporting or there is not a clearly documented effort to commercialize this technology;

- The Bavarian Nordic/GSF License relates to the patent US 6893634 B1 that claims "A capsule comprising a porous membrane formed by a polyelectrolyte complex which encapsulates cells which express cytochrome P450 as a cell membrane bound protein, wherein the porous membrane of the capsule is permeable to prodrug molecules and the cells are retained within the capsule" and further claims based on this;

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

- Third Addendum to Asset Purchase Agreement between the Company and SG Austria effective as of June 25, 2013 ("Third Addendum"). The Third Addendum resulted in the Company acquiring 100% ownership of Bio Blue Bird, the licensee of the patents identified above; and

- Licensing Agreement between the Company and Austrianova Singapore effective as of June 25, 2013 relating to diabetes. The Company has an exclusive license world-wide to use the Cell-in-a-Box® technology with genetically modified or non-modified non-stem cell lines and IPS stem cells specifically designed to produce insulin or other critical components for the treatment of diabetes. The Company must enter into a research program involving European academic research partners providing a total funding of at least US$400,000 within three years of June 25, 2013 and must enter clinical trials within 7 years of June 25, 2013 to retain the exclusive world-wide license.

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

Our royalty payments commence on the date of the first commercial sale of the licensed product in a particular country and continue on a country by country basis until expiration of the last valid claim within the licensed patent rights in such country. The territories where such commercial sales are anticipated are in the U.S., Europe and Japan. The patents expire starting in 2014 through 2018.

Third Addendum to Asset Purchase Agreement with SG Austria

On May 26, 2011, the Company entered into an Asset Purchase Agreement with SG Austria ("SG Austria APA"). As a result, Austrianova Singapore and Bio Blue Bird were to become wholly owned subsidiaries of the Company on the condition that the Company pay SG Austria $2.5 million and 100,000,000 shares of the Company's common stock and for the Company to receive 100,000 shares of Austrianova Singapore's common stock and nine Bio Blue Bird bearer shares.

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

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

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

The Third Addendum requires the Company to make the following payments for the purchased assets, which payments were timely made in full under the payment deadlines set forth in the Third Addendum:

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

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

The Third Addendum requires the Company to pay SG Austria, pursuant to a manufacturing agreement between the parties, a one-time manufacturing setup fee in the amount of $633,144.05 of which 50% is required to be paid on the signing of the manufacturing agreement and 50% is required to be paid three months later. In addition, the Third Addendum requires the Company to pay a fee for producing the final encapsulated cell product of $633.14 per vial of 300 capsules after production with a minimum purchased batch size of 400 vials of any Cell-in-a-Box® product.

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

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

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

Diabetes Licensing Agreement

The Company acquired from Austrianova Singapore the exclusive license worldwide to use the cellulose-based live cell encapsulation technology for the development of a treatment for diabetes and the use of Austrianova Singapore's "Cell-in-a-Box ®" trademark for this technology with a right to sublicense. The licensed rights pertain to genetically modified or non-modified non-stem cell lines and certain stem cells specifically designed to produce insulin or other critical components for the treatment of diabetes.

Under its Licensing Agreement with Austrianova Singapore ("Diabetes Licensing Agreement"), the Company is required to make a payment of $2,000,000 in two equal payments of $1,000,000 each. The Company made its first $1,000,000 payment on October 30, 2013. The second payment of $1,000,000 was made on February 25, 2014.

The Diabetes Licensing Agreement requires the Company to pay Austrianova Singapore, pursuant to a manufacturing agreement between the parties, a one-time manufacturing setup fee in the amount of $633,144, of which 50% is required to be paid on the signing of a manufacturing agreement and 50% is required to be paid three months later. In addition, the Diabetes Licensing Agreement requires the Company to pay a fee for producing the final encapsulated cell product of $633.14 per vial of 300 capsules after production with a minimum purchased batch size of 400 vials of any Cell-in-a-Box® product.

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

- Ten percent royalty of the gross sale of all products sold by the Company;
- Twenty percent royalty of the amount actually received by the Company from sub-licensees on sub-licensees' gross sales value; and
- Milestone payments of $100,000 within 30 days of beginning the first pre-clinical experiments using the encapsulated cells; $500,000 within 30 days after enrollment of the first human patient in the first clinical trial; $800,000 within 30 days after enrollment of the first human patient in the first Phase 3 clinical trial; and $1,000,000 due 60 days after having a NDA or a BLA approved at the FDA or a MAA approved in Europe or its equivalent based on the country in which it is accepted for each product.

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

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

Set forth in the table below is information regarding the relevant Intellectual Property described above:

Encapsulated Cells Producing Cytochrome P450 (for treating solid tumors, e.g. pancreatic cancer)

Claims cover capsules encapsulating a cell expressing cytochrome P450 and treatment methods using same.

There are no contested proceedings or third party claims known to the Company.

All major countries provide for patent term extension.

The Company has an exclusive license from joint patent owners Bavarian Nordic/GSF.

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

Encapsulated Cells Producing Retroviral Particles

Claims cover capsules which have walls that are permeable to retroviral particles, methods for producing same and methods of using same for gene therapy in countries where this protection is available.

There are no contested proceedings or third party claims known to the Company.

All major countries provide for patent term extension.

The Company has an exclusive license from joint patent owners Bavarian Nordic/GSF.

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

Sources and Availability of Raw Materials

As for the encapsulation and the cells for the oncology and diabetes based treatment, the entire encapsulation process is to be carried out by Austrianova Singapore. They are responsible for acquiring the necessary raw materials including the cellulose sulfate necessary for encapsulating the live cells. In 2012, as part of our pre-planning, we had the cells, a critical raw material, contracted through SG Austria to have the initial production, by ViruSure, of cells for future use. Thus, since all raw materials in our products could at any time in the future be difficult to obtain in large quantities, this could have a potential negative impact on the Company and or its subsidiaries.

Employees

As of April 30, 2014, the Company had four full-time employees. The Company primarily utilizes independent contractors in their respective capacities as scientists and physicians and in the areas of finance, accounting and technical support.

Available Information

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports, as well as other documents we file with the SEC, are available free of charge through the Investor Relations section of our web site (http://client.irwebkit.com/Nuvilex) as soon as reasonably practicable after such material is electronically filed with or furnished to the SEC. The public can obtain documents that we file with the SEC at www.sec.gov. This Report includes trademarks, service marks and trade names owned by us or other companies. All trademarks, service marks and trade names included in this Report are the property of their respective owners.

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

The Company had the following related party transactions:

As of April 30, 2014 and 2013, the Company owed Berkshire Capital $0 and $393,158, respectively, for operating expenses. Berkshire Capital was, at certain times when such amounts were outstanding, the holder of more than 5% of our outstanding shares of common stock. The highest amount outstanding during the fiscal year ended April 30, 2013 was $393,158 and during the fiscal year ended April 30, 2014 was $471,011. All loans bear interest at 6% and were due within one to three years. During the fiscal year ended April 30, 2013, the Company did not make any payments in respect of principal or interest on these loans. During the fiscal year ended April 30, 2014, the Company repaid $471,011 of principal and $30,195 in accrued interest with the issuance of 26 million shares of common stock.

As of April 30, 2014 and 2013, the Company owed directors and a shareholder $0 and $26,425; respectively, the loan bears interest at 8% and is due on demand. The highest amount outstanding during the fiscal year ended April 30, 2013 was $261,862.

As of April 30, 2013, the Company owed Dr. Robert F. Ryan, our former Chief Scientific Officer, $186,262 of principal and$20,171 of accrued interest on a loan that is due on demand and accruing interest at 8% per year. The highest amount outstanding during the fiscal year ended April 30, 2013 was $261,862. No additional funds were loaned to the Company by Dr. Ryan during the fiscal year ended April 30, 2014. During the year ended April 30, 2013, the Company made principal payments totaling $95,600 and no interest payments in respect of this loan. During the year ended April 30, 2014, the Company repaid $20,000 of principal in cash and converted $25,920 of principal to common stock. No payments were made towards accrued interest. As of April 30, 2014, the balance on this loan was $140,143 of principal and $33,960 of accrued interest. Subsequent to April 30, 2014, the Company repaid an additional $20,000 of principal.

The Board has determined that none of the Company's directors satisfies the definition of “Independent Director” as established in the NASDAQ Marketplace Rules.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

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

Exhibit No.	Description	Location
2.1	Asset Purchase Agreement, dated August 24, 2005, between the Company and Mark Taggatz.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on August 30, 2005.
2.2	Share Purchase Agreement, dated August 31, 2005, between the Company and Dr. Richard Goldfarb.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on September 7, 2005.
2.3	Addendum to Share Purchase Agreement, dated August 31, 2005, between the Company and Dr. Richard Goldfarb.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on September 7, 2005.
2.4	Share Exchange Agreement, dated January 12, 2009, between the Company and Freedom2 Holdings, Inc.	Incorporated by reference from the Company's Current Report on Form 10-K filed with the SEC on August 13, 2009.
2.5	Share Exchange Agreement, dated May 26, 2011 between the Company and SG Austria Private Limited.	Incorporated by reference from the Company's Current Report on Form 10-Q filed with the SEC on September 14, 2011.
2.6	Third Addendum, dated June 25, 2013 between the Company and SG Austria Private Limited.	Incorporated by reference from the Company's Report on Form 8-K filed with the SEC on July 17, 2013.
2.7	Licensing Agreement, dated June 25, 2013 between the Company and Austrianova Singapore Private Limited.	Incorporated by reference from the Company's Report on Form 8-K filed with the SEC on July 17, 2013.
3.1	Articles of Incorporation of DJH International, Inc. dated October 25, 1996.	Incorporated by reference from the Company's Registration Statement on Form SB-2 (File No. 333-68008) filed with the SEC on August 20, 2001.
3.2	Certificate of Amendment of Articles of Incorporation of DJH International, Inc. dated October 20, 2000.	Incorporated by reference from the Company's Registration Statement on Form SB-2 (File No. 333-68008) filed with the SEC on August 20, 2001.
3.3	Certificate of Amendment of Articles of Incorporation dated November 14, 2003.	Incorporated by reference from the Company's Registration Statement on Form.

Exhibit No.	Description	Location
3.4	Certificate of Amendment of Articles of Incorporation dated June 30, 2008.	Incorporated by reference from the Company's Registration Statement on Form.
3.5	Certificate of Amendment of Articles of Incorporation dated January 22, 2009.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on March 26, 2009.
3.6	Corporate Bylaws.	Incorporated by reference from the Company's Registration Statement on Form SB-2 (File No. 333-68008) filed with the SEC on August 20, 2001.
3.7	Certificate of Designations, Preferences and Rights of Series E Convertible Preferred Stock dated December 20, 2007.	Incorporated by reference from the Company's Current Report on Form 10-K filed with the SEC on August 13, 2009.
3.8	Certificate of Designations, Preferences and Rights of Series E Convertible Preferred Stock, dated April 29, 2008.	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the SEC on August 13, 2009.
3.9	Amendment No. One to the Bylaws of Nuvilex, Inc.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on September 25, 2014.
3.10	Amendment No. Two to the Bylaws of Nuvilex, Inc.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on October 3, 2014.
4.1	Reference is made to Exhibits 3.1, 3.2 and 3.3.	
4.2	Form of Common Stock Certificate.	Incorporated by reference from the Company's Registration Statement on Form SB-2 (File No. 333-68008) filed with the SEC on August 20, 2001.
4.3	Mutual Termination and Release Agreement dated as of May 28, 2014 between Lincoln Park Capital Fund, LLC and the Registrant.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on May 29, 2014.
10.1	License Agreement Relating to Encapsulated Cells Producing Viral Particles and Encapsulated Cells Expressing Biomolecules between and among Bavarian Nordic A/S, GSF – Forschungszentrum für Umwelt u. Gesundheit GmbH and Bio Blue Bird AG dated June [ ] 2005.	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the SEC on August 4, 2014.**
10.2	Amendment to License Agreement Relating to Encapsulated Cells Producing Viral Particles and Encapsulated Cells Expressing Biomolecules between and among Bavarian Nordic A/S, GSF – Forschungszentrum für Umwelt u. Gesundheit GmbH and Bio Blue Bird AG dated December 20, 2005.	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the SEC on August 4, 2014.**
10.3	Manufacturing Framework Agreement between Austrianova Singapore Pte. Ltd. and Registrant dated March 20, 2014.	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the SEC on August 4, 2014.
10.4	Master Services Agreement between ViruSure GmbH and Registrant dated April 7, 2014.	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the SEC on August 4, 2014.

Exhibit No.	Description	Location
10.5	Licensing Agreement between the Company and Austrianova Singapore dated June 25, 2013.	Incorporated by reference from the Company's Report on Form 8-K filed with the SEC on July 18, 2013.
10.6	Consulting Agreement between Vin-de-Bona Trading Company Pte. Ltd. and Registrant effective as of April 1, 2014.	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the SEC on August 4, 2014.**
10.7	Master Consultancy Agreement between BB Biotech Consulting GmbH and Registrant dated as of April 15, 2014.	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the SEC on August 4, 2014.**
10.8	Financial Advisory, Offering and At the Market Offering Engagement Letter between Chardan Capital Markets, LLC and the registrant dated May 28, 2014.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on May 29, 2014.
10.9	Memorandum of Understanding dated as of January 31, 2011 between the Company and Robert F. Ryan, M.S., Ph.D.	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the SEC on August 4, 2014.
10.10	Employment Agreement made the 31st day of January 2012 between the Company and Robert F. Ryan, M.S., Ph.D.	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the SEC on August 4, 2014.
10.11	Collaborative Research Agreement between University of Veterinary Medicine Vienna and the Company effective as of July 1, 2014.	Filed herewith.**
10.12	Licence Agreement between University of Technology, Sydney and Nuvilex Australia Pty Ltd effective as of October 13, 2014.	Filed herewith.**
10.13	Master Services Agreement between ViruSure GmbH and the Company effective as of August 23, 2014.	Filed herewith.**
10.14	Settlement Agreement dated as of September 19, 2014, by and between Nuvilex, Inc. and Robert F. Ryan, M.S., Ph.D.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on September 25, 2014.
10.15	Asset Purchase Agreement dated as of September 19, 2014, by and between Nuvilex, Inc. and Robert F. Ryan, M.S., Ph.D.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on September 25, 2014.
10.16	Consulting Agreement, dated September 29, 2014, between Nuvilex, Inc. and Patricia Gruden.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on October 3, 2014.
10.17	Stock Option Agreement, dated September 29, 2014, between Nuvilex, Inc. and Patricia Gruden.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on October 3, 2014.
10.18	Consulting Agreement, dated September 29, 2014, between Nuvilex, Inc. and Timothy Matula.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on October 3, 2014.
10.19	Stock Option Agreement, dated September 29, 2014, between Nuvilex, Inc. and Timothy Matula.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on October 3, 2014.
10.20	Consulting Agreement, dated September 29, 2014, between Nuvilex, Inc. and Richard M. Goldfarb.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on October 3, 2014.
10.21	Stock Option Agreement, dated September 29, 2014, between Nuvilex, Inc. and Richard M. Goldfarb.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on October 3, 2014.
14.1	Nuvilex, 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.
21.1	List of Subsidiaries.	Filed herewith.
31.1	Certification of Chief Executive and Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under Sarbanes-Oxley Act of 1934, as amended.	Filed herewith.
32.1	Certification of Chief Executive and Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002*.	Filed herewith.
101	Interactive Data Files for Nuvilex, Inc. Form 10-K for the period ended April 30, 2014	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the SEC on August 4, 2014.

*Exhibit 32.1 is being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, 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 of 1933, as amended, or the Securities Exchange Act, as amended, except as otherwise stated in such filing.

** Confidential treatment has been requested. Confidential material has been redacted and separately filed with the SEC.

SIGNATURES

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

NUVILEX, INC

October 16, 2014 By: /s/ Kenneth L. Waggoner
Kenneth L. Waggoner, JD
Chief Executive Officer and President
(Principal Executive Officer and Principal Financial Officer On behalf of the Registrant)

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

October 16, 2014 By: /s/ Richard Goldfarb
Richard Goldfarb, MD, FACS, Director

October 16, 2014 By: /s/ Gerald W. Crabtree
Gerald W. Crabtree, PhD, Director

October 16, 2014 By: /s/ Kenneth L. Waggoner
Kenneth L. Waggoner, Director

Exhibit 10.11

Collaborative Research Agreement

between

University of Veterinary Medicine Vienna

and

Nuvilex, Inc.

*** Certain confidential information contained in this document, marked by brackets, has been omitted and filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Article 1 Parties

A. University of Veterinary Medicine Vienna, VeterinŠrplatz 1, A-1210 Vienna, according to Section 27 para 1 University Act 2002 represented by the head ofepartment for Pathobiology, Prof. Saalmueller (hereinafter also referred to as "University").

B. Nuvilex, Inc., 12510 Prosperity Drive, Suite 310, Silver Spring, Maryland 20904 USA, represented by its Chief Executive Officer, Dr. Kenneth L. Waggoner (hereinafter also referred to as "Nuvilex").

University and Nuvilex are collectively referred to in this Collaborative Research Agreement (hereinafter also referred to as "Agreement") as "Parties" and individually as "Party").

Responsibility of scientific carrying out of the research program:

On the part of University:
Name: o.Prof. Dr. Walter H. Gunzburg
Phone: +43.1-25077-2330
Email: Gunzburg@onlymyemail.com
(hereinafter also referred to as "University´s Principal Investigator")

as substitute: Mag. Helga Petznek
Phone: +43.1-25077-2331
Email: Helga.petznek@vetmeduni.ac.at

On the part of Nuvilex:
Name: Dr. Gerald W. Crabtree
Phone: + 1.860.448.1393
Fax: + 1.917.595.2851
Email:gcrabtree@nuvilex.com
(hereinafter also referred to as "Nuvilex´s Principal Investigator")

as substitute: Dr. Matthias Löhr
Phone: +46 70.283.0181
Fax: +46 8.585.82340
Email: matthias.loehr@me.com

Article 2 Subject-Matter of the Agreement (Research Program)

University and Nuvilex desire to perform certain research work and are willing to have certain employees directly collaborate on a research project on diabetes.

NOW THEREFORE, in consideration of the premises and mutual covenants contained, in this Agreement, University and Nuvilex agree as follows:

Article 3 Definitions

As used in this Agreement, capitalised terms have the meanings given them below or elsewhere in this Agreement:

3.1. "Research Materials" means those experimental materials, including information and data, one party may provide the other in connection with and as stated in the Research Program.

3.2. "Research Program" means the Research Program set forth in Annex A to this Agreement.

3.3. "Research Program Invention" means any invention, discovery, work of authorship, software, information or data, patentable or unpatentable that is conceived, discovered and reduced to practice in performance of the Research Program.

*** Certain confidential information contained in this document, marked by brackets, has been omitted and filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

3.4. "Background IP" means any information, techniques, know-how, intellectual property, software and materials that are provided by one Party to the other for use in the Research Program, which has been developed prior to the date of this Agreement or that is independently developed by the Parties outside the Research Program after the date of this Agreement.

Article 4 Effective Date of Agreement

This Agreement is effective as of 1st July, 2014 ("Effective Date") and shall continue in effect until the Research Program has been completed as set forth in Article 13.

Article 5 Research Program

5.1. Research Efforts. The Parties will perform all their obligations under this Agreement and use their reasonable efforts to conduct those activities for which each Party is responsible under the Research Program.

5.2. Use of Research Materials. Any Research Materials of one Party transferred to the other in connection with the Research Program may only be used as stated in the Research Program. Unless the Parties agree otherwise, Research Materials are to be considered as "Confidential Information" of the Party providing them and marked in writing as "Confidential."

5.3. No Human Use. The Parties agree that the activities under the Research Program may encompass animal and in vitro use; treatment of human subjects is explicitly excluded from any such activities.

5.4. Reporting. The Parties will generally keep one another informed of the results of the work performed in connection with the Research Program, principally through their respective Principal Investigators. In addition, the Parties' respective Principal Investigators will meet and provide reports as stated in the Research Program.

5.5. Changes to the Research Program. During the course of the Research Program, either or both of the Principal Investigators may find it advantageous to modify the Research Program. Any modifications will be documented and formalized in a written amendment to this Agreement. Any such amendment will become effective only if signed by an authorized representative of both Parties to this Agreement.

5.6. University Purposes.

5.6.1 Use of Facilities. University agrees to make available adequate laboratory, animal house and office facilities and to allow shared use of these facilities to Nuvilex for the purpose of the Research Program

5,6,2 No Guarantee of Results. Nuvilex acknowledges that the primary mission of University is education and the advancement of knowledge; accordingly, the Research Program will be performed in an appropriate manner to carry out that mission.

5.7. Similar Research. Nothing in this Agreement will be construed to limit the freedom of University or its researchers who are participants under this Agreement from engaging in similar research made under other grants, contracts or research agreements with parties other than Nuvilex.

*** Certain confidential information contained in this document, marked by brackets, has been omitted and filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Article 6 Consideration

6.1. As consideration for carrying out the Research Program, University shall be paid by Nuvilex an amount of [**********], with an option of a further payment of up to [**********] if the two in-vivo diabetic mouse models ([**********] per model) are carried out at the University. The amount stated above shall include: (i) office expenses and cost of materials; (ii) reimbursement of expenses for acquisition and operation of the equipment required for the Research Program; (iii) reimbursement of expenses for University staff to be directly or indirectly employed by University, including taxes and social security contributions resulting there from, if any; and (iv) indirect costs of University. The expenses for travels of University staff required in connection with the Research Program, if any, as well as any other cash disbursements and out-of-pocket expenses which are not listed under items (i) to (iv) of this Article 6.1 shall be approved in advance and borne by Nuvilex and shall be invoiced separately.

6.2. The consideration of Euro **[**********]** shall be paid in advance at the start of the Agreement. The additional Euro [**********] per in-vivo mouse model for diabetes will be paid in advance as soon as the decision to implement the model at the University has been made.

6.3. [**********] Where University does not receive payment on the due date for payment, interest shall accrue thereafter on the sum due and owing at the rate of [**********] over the base rate from time to time of European Central Bank interest to accrue on a day to day basis.

6.4. The subject-matter of this Agreement is academic research work, which is, in principle, exempt from VAT according to Section 2 para 3 UStG [Value-Added Tax Act]. If it turns out subsequently that the services or parts of the services rendered by University arising out of or related to the Research Program are subject to VAT nevertheless, University shall be entitled to subsequently invoice VAT which Nuvilex hereby agrees to pay.

Article 7 Confidential Information

7.1 Confidential Information. "Confidential Information" with respect to a Party ("Disclosing Party") shall be marked confidential and shall include all confidential technical, business and financial information, including, but not limited to, all information, data, patent disclosures, patent applications, structures, models, techniques, processes, samples, compositions, compounds and apparatus relating to the same that are disclosed by the Disclosing Party to the other Party to this Agreement ("Receiving Party"). Confidential Information of a Disclosing Party may include information of an affiliate, collaborator or other third party disclosed by or through the Disclosing Party to the Receiving Party.

7.2 Nondisclosure. The Receiving Party shall not use any of the Confidential Information of the Disclosing Party at any time except for the purposes of this Agreement, including, but not limited to, performing the Research Program described in Annex A attached to this Agreement. The Receiving Party shall not disclose any of the Confidential Information of the Disclosing Party other than on a need-to-know basis, as reasonably necessary to carry out its obligation under this Agreement or the Research Program, to its directors, officers, managers, members, employees, attorneys, accountants, bankers, financial advisors, subcontractors or consultants (collectively, "Representatives") who are bound by obligations of confidentiality to the Receiving Party at least as stringent as those imposed by the terms of this Agreement.

*** Certain confidential information contained in this document, marked by brackets, has been omitted and filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

7.3 Exceptions. The Receiving Party's non-use and nondisclosure obligations above shall not apply to such information as the Receiving Party can establish by written documentation: (i) was publicly known prior to disclosure of the Disclosing Party of such information to the Receiving Party; (ii) becomes publicly known, without breach of this Agreement by the Receiving Party or any of its Representatives, after disclosure of such information by the Disclosing Party to the Receiving Party; (iii) was received by the Receiving Party without obligation of confidentiality or limitation on use at any time from a source other than the Disclosing Party lawfully having possession of and the right to disclose such information; (iv) was otherwise known by the Receiving Party prior to disclosure by the Disclosing Party; or (v) was independently developed by or for the Receiving Party without use of such information.

7.4 Compelled Disclosure. Notwithstanding the foregoing provisions of this Article 7, the Receiving Party shall have the right to disclose Confidential Information of the Disclosing Party to the extent required by applicable law or regulation, provided that the Receiving Party gives the Disclosing Party prompt written notice of such requirement and sufficient opportunity, at Disclosing Party's own expense, to file a motion or otherwise seek protection against such use or disclosure of the Confidential Information.

7.5 Representatives. Except as required by applicable law or regulation, neither Party shall disclose the terms of this Agreement or anything about the Research Program, other than to its Representatives on a need to know basis.

7.6 Disclaimer. The Receiving Party's use of the Confidential Information of the Disclosing Party shall be at its own risk. All Confidential Information is provided "AS IS" and without any warranties whatsoever, express or implied.

7.7 Return of Confidential Information. Upon the written request of the Disclosing Party, the Receiving Party shall promptly return or destroy all tangible items relating to Confidential Information of the Disclosing Party, including all written material, photographs, models, samples, compounds, compositions and the like made available or supplied by the Disclosing Party to the Receiving Party, and all copies thereof; provided, however, that the Receiving Party may retain one (1) copy for its files.

7.8 Confidentiality Term. The Parties agree to maintain Confidential Information received from each other in confidence for three (3) years from date of receipt of such Confidential Information, unless a shorter period of time is agreed to in writing between the Parties.

Article 8 Publicity

Neither Party will identify the other in any products, publicity, promotion, promotional advertising, or other promotional materials to be disseminated to the public, or use any trademark, service mark, trade name, logo, or symbol that is representative of a Party or its entities, whether registered or not, or use the name, title, likeness, or statement of the other party's faculty member, employee, or student, without other Parties prior written consent. Any use of a Party's name shall be limited to statements of fact and shall not imply endorsement of products or services.

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Article 9 Publication

9.1. The basic objective of research activities at University is the generation of new knowledge and its expeditious dissemination for the public's benefit. Nuvilex will provide all reasonable cooperation with University in meeting this objective.

9.2. The Parties mutually acknowledge that it is important for investigators to publish the results of their research in scientific and medical publications and, to the extent possible, each Party shall cooperate with the other and the Principal Investigators to facilitate such publication. However, the Parties and the Principal Investigators agree to confer and consult prior to the publication of information to assure that no proprietary information or Confidential Information is released and that patent and other rights are not jeopardized. If either Party or either of the Principal Investigators desire to publish an article, paper or other written submission, such Party or such Principal Investigator agrees to furnish the other Party and Principal Investigator with a copy of any proposed publication, including if only the submission of an abstract, at least thirty (30) days in advance of any proposed submission date to allow ample review time and for the protection of any proprietary information or Confidential Information. In no event shall any Party or either Principal Investigator publish or disclose Confidential Information of another Party without written permission from the other Party or Parties, as the case may be. Nuvilex shall not unreasonably withhold consent to publication. In particular, it shall not be allowed to delay or prevent the preparation, completion and evaluation of diploma, master's or doctoral theses.

9.3. Proper acknowledgement will be made for the contributions of each Party to the results of the Research Program being published.

Article 10 Intellectual Property Rights

10.1. Ownership of Research Program Inventions. Research Program Inventions conceived, discovered and reduced to practice by University only, i.e. solely by its employees, agents or students, will be owned by University. Research Program Inventions conceived, discovered and reduced to practice by Nuvilex only, i.e. by its employees or agents, will be owned by Nuvilex (collectively, "Sole Inventions"). Neither Party shall make any claim to the other Party's Sole Inventions. Research Program Inventions conceived, discovered and reduced to practice by at least one employee, agent or student of each of University and Nuvilex will be jointly owned by University and Nuvilex, ("Joint Inventions"). In the event the Parties generate any Joint Invention, the Parties agree to negotiate a co-ownership agreement, which shall specify the rights each Party shall have to protect, use and exploit the Joint Invention. Unless and until the terms of such co-ownership agreement are agreed, neither Party shall grant a third party any right of license under the Joint Invention without first obtaining the prior written agreement of the other Party.

10.2. License to Use Results of Research Program. Both Parties will have a non-exclusive world-wide royalty-free license with respect to the results of the Research Program, including Research Program Inventions, for non-commercial internal research and educational purposes. Nuvilex will have a non-exclusive world-wide royalty-free license to use the results of the Research Program for any and all commercial purposes.

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10.3. Patent and Other Intellectual Property Protection. Nuvilex and University will immediately advise the other of any Research Program Inventions and will offer reasonable assistance in applying for and obtaining relevant patent or other intellectual property protection. Nuvilex shall have the exclusive right to obtain an exclusive license for University Sole Inventions and the University´s shares in Joint Inventions at market conditions to be agreed on a case-by-case basis. The option shall expire eight (8) weeks after Nuvilex's receipt of the notification of creation of the invention and may be renewed once for a period of eight (8) weeks at Nuvilex's written request. The option shall be exercised by registered letter to University. If Nuvilex declares that it waives its right, or if Nuvilex fails to respond within eight (8) weeks of receipt of the information about University Sole Inventions, University shall be free to decide whether it will exploit the invention itself, co-operate with third parties in exploiting the invention or whether University will release the same to the inventor. This shall also apply in the event that the option has not been exercised or if no licence agreement has been concluded and the option period has not been renewed. Notwithstanding conclusion of a licence agreement, University shall continue to be entitled to use Sole Inventions for research and teaching purposes for no consideration.

10.4 Background IP. All Background IP used in connection with the Research Program shall remain the property of the Party introducing the same. Except to the limited extent required to perform a party's obligations under this Agreement, neither Party receives any right, title, or interest in or to any of the other Party's Background IP.

Article 11 Indemnification

Each Party ("Indemnifying Party") agrees during and after the term of this Agreement to indemnify and keep indemnified the other Party ("Indemnified Party") from and against all liabilities, loss, damage, cost or expenses which may result from the Indemnifying Party's use of the results of the Research Program, Research Materials, Research Program Inventions and the other Party's Background IP, except where such liability, loss, damage, cost or expenses are the result of the gross negligence or wilful misconduct by the Indemnified Party, its employees or agents.

Article 12 Representations, Warranties, Liability Limits

12.1. No Warranties. The Parties acknowledge that the Research Program is of an experimental nature. As a result, any result of the Research Program and any Research Materials are provided "as is" and without warranty of merchantability or fitness for a particular purpose. Neither Party makes any representations or warranties express or implied, as to any matter whatsoever that: (i) any Background IP, advice or information provided by it or any of its employees, agents or students in connection with the Research Program is accurate or works; (ii) the content of use of any results of the Research Program, Research Materials, Research Program Inventions and the other Party's Background IP will not constitute or result in any infringement of third party rights; and (iii) any particular outcome including, but not limited to, results of the Research Program, Research Program Inventions, process or products, whether tangible or intangible outcome will be achieved.

12.2. No Damages. Apart from wilful misconduct or gross negligence, neither Party shall be liable to the other Party for any direct, consequential or other damages arising from the use of the results of the Research Program, Research Materials, Research Program Inventions or the other Party's Background IP. The Parties acknowledge and agree that this exclusion and limitation is reasonable considering the experimental nature of the Research Program and the nature and terms of the Parties´ relationship.

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Article 13 Term and Termination

13.1. Term. This Agreement will remain in effect from the Effective Date and expire upon finalizing the Research Program ("Term"), unless sooner terminated in accordance with this Agreement.

13.2. Termination. Either party may terminate this Agreement upon sixty (60) days prior written notice.

13.3. Effect of Termination. Expiration of the Term or termination of this Agreement by written notice has the effect that the Parties will discontinue use of any Research Materials received from the other under this Agreement and will, upon the direction of the owning Party, either return or destroy such Research Material. Upon termination of this Agreement, Nuvilex shall reimburse University for all amounts due and non-cancellable commitments incurred to date in the performance of the Research Program, such reimbursement not to exceed the total amount contemplated upon for this Research Program. These non-cancellable commitments include the salary of the Senior Postdoc associated with the project for twenty-four (24) months. The obligations and rights contained in Articles 3, 7, 8, 9, 10, 11, 12 and this Section 13.3. shall survive the expiration of the Term or termination of this Agreement.

Article 14 Dispute Resolution

Any controversy, claim or other dispute arising out of this Agreement or relating to the subject matter of this Agreement hereof will be decided by binding arbitration in accordance with the Arbitration Rules of The World Intellectual Property Organization before one or more arbitrators appointed in accordance with those Rules. Any arbitration will take place in Vienna, Austria, or at any other mutually agreeable location.

Article 15 General

15.1. Binding Effect; Assignment. Neither Party may assign or delegate its rights or obligations under this Agreement without the express written consent of the other Party.

15.2. Entire Agreement. This Agreement constitutes the entire agreement between the Parties relating to the Research Program, and any and all prior or contemporaneous negotiations, representations, agreements and understandings are superseded hereby. No amendment or change to this Agreement may be made except by means of a written document signed by duly authorized representatives of the Parties.

15.3. Notices. Any notice or communication required or permitted to be given under this Agreement ("Notice") shall be in writing and, except as otherwise expressly provided in this Agreement, shall be deemed given and effective: (i) when delivered personally or by fax; or (ii) when received if sent by email, overnight courier or mail:

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To University: Univ.Prof. Dr. Walter Günzburg University of Veterinary Medicine Vienna VeterinŠrplatz 1 A-1210 Vienna Tel: +43. 1.25077.2330 Tel: +43. 664.9108.672 Tel: +65. 9108. 6742 Tel: +66. 847.298.873 Email: Gunzburg@onlymyemail.com	To Nuvilex: Dr. Kenneth L. Waggoner Nuvilex, Inc 12510 Prosperity Drive, Suite 310, Silver Spring, Maryland 20904 USA Tel: + 1.917.595.2850 Fax: + 1.917.595.2851 Email: kwaggoner@nuvilex.com

15.4. Applicable Law. This Agreement will be construed and enforced in accordance with the laws of Austria, without regard to any choice or conflict of laws, rule or principle that would result in the application of the laws of any other jurisdiction.

15.5. Headings. Headings included herein are for convenience only and will not be used to construe this Agreement.

15.6. Relationship of Parties. For the purposes of this Agreement and all services to be provided hereunder, each Party will be, and will be deemed to be, an independent contractor and not an agent or employee of the other Party. Neither Party will have authority to make any statements, representations or commitments of any kind, or to take any action that is binding on the other Parties, except as explicitly provided for herein or authorized in writing.

15.7. Severability. If any provision of this Agreement is found by a court of competent jurisdiction to be void, invalid or unenforceable, the same will either be reformed to comply with applicable law or stricken if not so conformable, so as not to affect the validity or enforceability of this Agreement.

15.8. Force Majeure. Neither Party will be liable for any failure to perform as required by this Agreement, if the failure to perform is caused by circumstances reasonably beyond such Party's control, such as labor disturbances or labor disputes of any kind, accidents, failure of any governmental approval required for full performance, civil disorders or commotions, acts of aggression, acts of God, energy or other conservation measures, explosions, failure of utilities, mechanical breakdowns, material shortages, disease, thefts, or other such occurrences.

Article 16 Annex

The following Annex A is attached to this Agreement and constitutes an integral part thereof: Annex A: Research Program. Annex A shall specify the work, timeline, Research Materials and reporting obligation (incl. final report).

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IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorised representatives.

University of Veterinary Medicine Vienna

By: _____

Name: Univ. Prof. Dr. Armin Saalmüller

Title: Head of Department of Pathobiology

Date: _____

By: _____

Name: Otto Doblhoff-Dier

Title: Vice-Rector for Research and International Affairs

Date: _____

Nuvilex, Inc.

By: /s/ Kenneth L. Waggoner

Name: Dr. Kenneth L. Waggoner

Title: Chief Executive Officer

Date: 23 August 2014

Principal Investigators acknowledge that they have read this Agreement in its entirety and will use reasonable efforts to uphold their obligations and responsibilities set forth in this Agreement:

University's Principal Investigator

Signature: /s/ Walter H. Gunzburg

Name: O. Prof. Dr. Walter H. Gunzburg

Date: 1st August 2014

Collaborator's Principal Investigator

Signature: /s/ Gerald W. Crabtree

Name: Dr. Gerald W. Crabtree

Date:

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Annex A: Research Program

1.1. Research and Objectives

The current proposal aims to make a substantial contribution towards the success of beta cell replacement becoming a viable treatment option for type 1 diabetes ("T1D") patients. T1D is an auto-immune disease which results in the destruction of insulin producing beta cells in the pancreas. As a consequence, patients suffer from diabetes and depend on frequent insulin injections to stay alive. They need to monitor their blood sugar levels and dose their insulin injections accordingly. The dosing is, however, based on an approximation and does not lead to ideal normalisation of blood sugar levels. Even with the best possible dosing regimen, patients are at risk of hypoglycaemic episodes, which can be life threatening, as well as chronic hyperglycaemia, which leads to eye and kidney disease, nerve damage and an increased risk of cardiovascular disease. To date the only possibility to cure T1D is beta cell replacement. This involves transplantation of the entire pancreas or of its insulin producing cells. The downside of this treatment is the severity of detrimental side effects of the immune suppressive medication necessary to avoid transplant rejection. Having said that, the need for immune suppression can be circumvented by encapsulation of the transplanted cells. Thereby, transplanted cells are surrounded by a porous capsule, typically made of alginate, which allows them not only to survive but also to exchange small molecules such as glucose and insulin with their environment all the while shielding them from cells of the immune system[1]. Efforts to translate this concept into a clinical product have been plagued by poor survival of the transplanted beta cells. Within the capsules, oxygen supply is often sub-optimal and pro-inflammatory cytokines can lead to death of sensitive cells, thus compromising the long term effect and success of this so called bio-artificial pancreas.

The current proposal suggests the combination of two major advancements: a novel source of surrogate beta cells, termed Melligen cells, which are resistant to pro-inflammatory cytokines involved in beta cell death[1]. Melligen cells are derived from a liver cell line and are capable of controlled insulin release[2]. Since the liver originates from the cell germ cell layer as the pancreas, its cells have certain similarities to pancreatic beta cells but are more robust due to the liver's function as a detoxification organ. Melligen cells hold great promise to survive for a long time in a transplant scenario. The current proposal comprises the first *in-vivo* experiments with Melligen cells in animal models of diabetes. The other advancement lies in the choice of encapsulation material. Cellulose sulphate will be used as a novel material for beta cell encapsulation. It has excellent biocompatibility in contrast to alginate, which is despite its shortcomings (such as pericapsular fibrotic overgrowth)[3], the most broadly accepted encapsulation material to date. Clinical data with cellulose sulphate encapsulated cells for treatment of pancreatic cancer[4-5] indicate that this material does not cause inflammation or immune- and sever foreign body-reaction to the transplant and, as a consequence, has the potential to significantly improve graft survival and efficacy. Up to now, cellulose sulphate has mainly been used as encapsulation material for cell-based cancer therapies[4,6-18]. There is, however, no reason why it should not serve well for beta cell encapsulation.

In combination, these two advancements will bring new momentum into the field of beta cell replacement and will, hopefully, overcome the remaining hurdles on the way to bioartificial pancreases in the clinic.

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1.2 Research Activities

The aim of the proposed Research Project is to use the encapsulation of insulin producing cells to tackle the following challenges in cell-based therapy of diabetes: shortage of human donor organs for islet cell transplantation, bio-compatibility issues of commonly used encapsulation materials, and poor graft survival.

Cell encapsulation is the immobilisation of cells inside a bead or hollow sphere, which is defined by a semi-permeable membrane. Such capsules have pores that are large enough to allow molecules like nutrients, oxygen, waste products and biomolecules to diffuse in and out but small enough to keep the encapsulated cells separate from the cells around the capsules, namely from immune cells in the body into which the capsule is implanted[1]. In other words, cell encapsulation enables the transplantation of allogeneic or even xenogeneic cells into the body and eliminates the need for immune suppression. Furthermore, the capsules hold the cells in place at the site where they are needed, which is important in certain applications[15].

1.3 State of the Art

The history of islet cell transplantation began in the late 1960s and early 1970s when islets of Langerhans were successfully isolated from animals[19] and shown to confer insulin independence in formerly diabetic animals[20]. When the same concept was applied to human patients, the results were disappointing. Only occasionally did a recipient become insulin-independent for a few days or, at best, weeks. This started to change when in 1988 an advanced protocol for the isolation of islets from donor pancreatic was developed[21]. Despite improvement in graft survival, the success rate of islet transplantation was no higher than 12% of recipients remaining off insulin for one year after treatment. In 2000, the Edmonton protocol yielded the long awaited break-through in islet transplantation[22]. The group at University of Alberta in Edmonton, Canada, achieved 100% success in seven patients, all of which were insulin-independent for one year post-transplantation. Despite its dramatically improved success rate, islet transplantation comes at a high price due to the detrimental effects of immune suppressive drugs which put the patients at high risk of infection and neoplasia, and have a number of undesired side effects including liver dysfunction, bleeding, mouth ulcers and hypercholesterolaemia, which may force patients to cease treatment. Due to this ambiguous risk versus benefit ratio, less than 1000 people with T1D have been allografted with human islets worldwide. This translates to 1 in around 20,000 T1D patients.

Numerous efforts have been made to come up with immunoprotective devices for islet cells in order to eliminate the need for immunosuppressive medication and tip this balance in favour of the benefit of islet transplantation making it widespread applicable. These immunoprotective devices come in different shapes and sizes, which groups them into intra- and extra-vascular devices and the later into micro- and macro-capsules. Despite initial success in animal models[23-24], intra-vascular devices turned out to have severe issues, rendering them inappropriate for clinical use. Extra-vascular macro-capsules come as tubular and planar diffusion chambers and have the advantage that they are easily retrievable. Tubular diffusion chambers exert good biocompatibility and excellent graft survival[25] but suffer from the susceptibility to rupture and the requirement of large islet numbers to achieve normoglycemia[26]. Planar diffusion chambers are more stable compared to tubular ones but cause extensive foreign body reactions, resulting in fibrotic overgrowth of the chamber and subsequent graft failure[27]. A technology called TheraCyte™ has shown promising results in animal models[28] but is yet to prove itself in the clinic.

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The most extensively researched immunoprotective strategy however are micro-capsules. The reasons for this are many. Micro-capsules are mechanically stable, have a favourable surface to volume ratio, which results in good diffusion characteristics. They are relatively simple to manufacture, can be implanted into the body without major surgery and, depending in the encapsulation material, microencapsulated cells can be cryopreserved[29]. Characteristics of the capsule membrane like thickness and pose size can be adjusted according to the intended use. In most techniques, micro-capsules are made of hydrogel formed by electrostatic interaction of a polyanion with a polycation. Capsule formation is a three step process: First, the cells are mixed with the polyanionic solution. Next, small droplets are formed with the help of a drop forming device. Finally, the droplets fall into a hardening bath consisting of the polycation. This is where the electrostatic interaction occurs and the droplets solidify into beads or hollow spheres. Due to the cytotoxic nature of the polycation in its non-complexed state, any cells that protrude from the capsule surface get eliminated. This ensures that there are no intact cells at the capsule surface, which could later grow out of the capsule.

Microencapsulated islet cells made had lines in 1994 when the first diabetic patient remained insulin-independent for 9 months after receiving islets encapsulated in alginate[30]. This patient had previously received a kidney graft and was therefore on immunosuppressive medication. After 18 years and numerous clinical trials later, there are still no reports of long—term insulin-independence in non-immunosuppressed diabetic patients receiving encapsulated islet transplants. Clinical trials by different groups3,31-32 showed similar outcomes. In the initial days after transplantation, C-peptide (showing that insulin was produced) could be detected, indicating graft function. The clinical benefit for the patients was, however, modest and insulin injection had to be resumed. The fact that the same approach that worked so well in an immunosuppressed patient did not work in non-immunosuppressed patients is a first hint that alginate encapsulated islets might elicit an immune response. Despite a great deal of work aimed at solving this problem[33] 36, this issue still persists today[37-38]. So much so that alginate is even used to enhance immune responses in vaccination approaches[39]. One of the major drawbacks seems to be the occurrence of a severe foreign body reaction called peri-capsular fibrotic overgrowth[3], which leads to severe hypoxia inside the capsules, ultimately leading to failing of the graft. The proposed project will overcome this problem by introducing a more robust type of surrogate beta cells and employing an encapsulation material with superior biocompatibility.

Should islet cell transplantation ever become the treatment of choice for T1D patients, the world will face an acute shortage of donor organs. Statistics from the UK reveal that there is only 1 donor pancreas for every 625 T1D patients. To make matters worse, 2-4 donor pancreases per recipient are required to achieve insulin-independence[22]. The search is, thus, on for surrogate beta cells.

- Xenotransplantation: Researchers have been looking into xenotransplantation as an alternative. Porcine islets have shown much promise since porcine insulin is functional in humans and does not elicit an immune response. However, the manufacturing of porcine islet production is very difficult and expensive compared to insulin producing cell lines. There are concerns about the transmission of pig endogenous retroviruses ("PERVs") to humans, creating a possible pandemic[40]. There is, however, no evidence yet of PERV infection in patients transplanted with porcine islets[41]. These findings results in the reactivation of efforts to alleviate severe cases of T1D using encapsulated neonatal porcine islets. Living Cell Technologies ("LCT), a company with bases in Australia and New Zealand, reported the first results of their clinical phase 2 trial at a meeting of the International Pancreas and Islet Transplant Association ("IPITA") in June 2011[42]. The frequency of unaware hypoglycaemic episodes was reduced despite only modest reduction in insulin dose and little change in high blood glucose related data. Insulin-independence, and thus a cure of the disease, could not be achieved. Somewhat surprisingly, higher doses of encapsulated porcine islets did not result in improved efficacy. LCT is using alginate as encapsulation material.

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- Stem Cells: Much progress has been made towards the differentiation of human embryonic stem cells ("hESCs") into functional beta cells but the different protocols still have flaws, such as the fact that the final step from mature pancreatic progenitors to glucose-responsive insulin secreting cells can so far only be achieved inside the body of the recipient[43-44]. This is a major safety concern. hESC derived surrogate beta cells are projected to reach the clinic in the 2020s[43]. Efforts to replace islet cells with adult stem cells and induced pluripotent stem ("iPS") cells by companies like Regentech and Osiris Therapeutics are ongoing but they are still a long way off the clinic.

1.4 Research Partners

University of Technology, Sydney

A novel genetically engineered cell line capable of controlled insulin release was developed by the team around Prof. Simpson at the University of Technology, Sydney ("UTS"). The so called 'Melligen' cells are HuH-7 cells (hepato-carcinoma cell line) genetically engineered to express human insulin and glucokinase. Melligen cells produce, properly process, store and secrete insulin in a physiological manner[2]. Moreover, Melligen cells can be readily grown in culture and hence are available in unlimited supply. Compared to native beta cells, they are much more resistant to pro-inflammatory cytokines involved in beta cell death[1]. This makes them the ideal candidate cell line for beta cell replacement therapy with the prospect to achieve long-term graft function. Melligen cells have been encapsulated by Austrianova Singapore in a pilot study and show excellent long-term survival in cellulose sulphate capsules (non-published data). The current proposal comprises the first *in-vivo* experiments with Melligen cells in animal models of diabetes.

University of Veterinary Medicine, Vienna

The group of O. Prof. Dr. Walter H. Gunzburg at the Institute of Virology at the University of Veterinary Medicine, Vienna, will coordinate the programme and conduct cell biology, molecular biology and animal studies to evaluate the insulin producing potential, viability and tumorigenicity of the Melligen cells. Melligen cells are derived from a hepatocellular carcinoma cell line. As such, the prospect of developing a clinical product requires an initial tumorigenicity study with Melligen cells. Should they turn out to be tumorigenic, strategies to ensure the safety of this cell line (e.g. suicide gene) will be devised or another cell line will be substituted. Pericapsular fibrotic overgrowth will be assessed after intraperitonial and subcutaneous implantation of encapsulated Melligen cells into immune competent mice. Histological methods similar to the ones used in Tuch *et. al.*[3] will be applied to assess the amount of pericapsular fibrotic overgrowth. Labroscopic intervention[3] is not needed since the mice will be sacrificed.

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Nuvilex Inc.

Nuvilex Inc., will provide encapsulated Melligen cells. Encapsulated will be performed using Austrianova Singapore's "Cell-in-a-Box®" technology which involves the use of cellulose sulphate as encapsulation material. Cellulose sulphate is an encapsulation material derived from cotton and has a proven safety record in patients [4-5]. It has been used successfully in clinical trials in patients suffering from inoperable pancreatic cancer, as well as clinical trials on dog patients of a veterinary clinic suffering from mammary cancer (published[18] and unpublished data by Winiarczyk et al.,). Not only did the trials result in a remarkable clinical success in terms of survival of the patients but also in terms of quality of life, safety of the treatment and biocompatibility of the capsules[4-5,9]. Potential reasons for the superior characteristics of cellulose sulphate capsules are the composition of the material (no protein contaminations) and the anatomy of the capsules. When the capsules form, they develop a solid membrane on the outside and a less dense core in the middle which allows cells to divide and grow inside the capsules until the available space is filled[2]. In contrast, alginate forms homogenous beads, and there is no space for the cells to divide inside. As a result, high cell densities are required for alginate encapsulation, whereas cellulose sulphate encapsulation can be done at low cell densities with a maturation step for the cells to populate the capsules from within. The low cell density upon encapsulation leads to a low incidence of dead cells being trapped within the membrane and protruding on the surface of the cellulose sulphate capsule, lowering the potential to give rise to an immune and inflammatory response.

Ludwig-Maximillian-University, Munich

The groups of O. Prof. Dr. Eckhart Wolff and O. Univ.-Prof. Dr. Rüdiger Wanke at the Ludwig-Maximillian-University, Munich have established mouse models of diabetes[45-48], as well as transgenic pig models of diabetes which closely resemble the situation in patients[49-50]. They have extensive experience with these animal models.

1.5. Work Plan

1.5.1 *In-vivo* mouse testing

- Tumorigenicity testing of Melligen cells to determine the Tumour Producing Dose at 50% endpoint ("TPD_{50}") in mice: Tumorigenicity studies will be an indispensable part of the pre-clinical data, necessary to obtain permission for clinical trials. Different amounts of cells will be injected subcutaneously into nude mice, and the tumour growth will be assessed by palpating the subcutaneous tumours and measuring them with a calliper. The distress for the animals will be kept at a minimum. TPD_{50} assay = first half of 1st year.

- Biocompatibility study: Implantation of encapsulated islet cells into immune- competent mice and subsequent histological analysis. Read out: signs of inflammation and immune response to the capsules, fibrosis and state of the encapsulated cells (alive or necrotic, insulin production). A total of three animals per group should suffice because the data are qualitative, like the data in Tuch *et. al.*[3]. The read out of the experiments will be done post mortem. Preparation and conduction of the animal experiments and subsequent histological analysis of the harvested tissue (capsules and surrounding tissue) for different implantation sites (subcutaneously and intraperitoneally) and at different time points after capsule implantation = 1st year.

*** Certain confidential information contained in this document, marked by brackets, has been omitted and filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

1.5.2 *In-vivo* diabetic mouse testing

Reversal of diabetes in diabetic mouse models (GIPR^{dn} & Munich *Ins2*^{C95S})$^{45-48}$ using encapsulated insulin-producing cells: This will be done in collaboration with the Ludwig-Maximillian-University, Munich. Capsules will be implanted into diabetic mice by the researcher with the assistance of the Institute of Virology team at the University of Veterinary Medicine, Vienna. Follow up by monitoring of blood glucose levels and C-peptide (showing that insulin is produced) levels throughout the study period will be done by the collaborator's team. Blood samples will be taken from the tail vein. Periodically, capsules will be explanted and the blood glucose and C-peptide levels of animals after explantation of capsules will be monitored. We expect diabetes symptoms to recur after removal of encapsulated cells. Viability and insulin secretion of explanted capsules will also be analysed. Due to the clear phenotype[45-48], 25 animals per study should suffice (5 control animals and 20 treated animals). Preparation and conduction of the studies together with subsequent statistical data analysis = second half of 1st year & first half of 2nd year.

1.5.3 *In-vivo* diabetic pig testing

Reversal of diabetes in diabetic pig models (GIPR^{dn} & *INS*^{C4rS})$^{49-50}$ using encapsulated insulin-producing cells: This will be done in collaboration with the Ludwig-Maximillian-University, Munich. Capsules will be implanted into diabetic mice by the researcher with the assistance of the Institute of Virology team at the University of Veterinary Medicine, Vienna. Follow up by monitoring of blood glucose levels and C-peptide (showing that insulin is produced) levels throughout the study period will be done by the collaborator's team. Periodically, capsules will be explanted and the blood glucose and C-peptide levels of animals after explantation of capsules will be monitored. We expect diabetes symptoms to recur after removal of encapsulated cells. Viability and insulin secretion of explanted capsules will also be analysed. Due to the clear phenotype[49-50], 25 animals per study should suffice (5 control animals and 20 treated animals). Preparation and conduction of the studies together with subsequent statistical data analysis = 2nd year.

1.6 Budget

1.6.1 Requested Personnel

The proposed project is initially planned for a two year period for one senior postdoctoral fellow (Constantine Konstantoulas) who will dedicate 100% of his time to the project. Dr Konstantoulas will be based at the Institute of Virology, University of Veterinary Medicine, Vienna and will be responsible for managing and coordinating the research activities at the Institute of Virology and the LudwigMaximillian-University, Munich, to ensure the successful running of the project. He will also undertake the molecular and cellular biological analysis at the Institute of Virology, University of Veterinary Medicine, Vienna. He will be responsible for the preparation of scientific manuscripts and progress reports, as well as preparation of publications at scientific meetings. Salary is also requested for two research assistants at the Institute of Virology, University of Veterinary Medicine, Vienna. It is estimated that A. Spasic, who is responsible for housing and feeding of animals at the Institute of Virology, University of Veterinary Medicine, Vienna, will dedicate a total of 24 hours to the project. Mag. H. Petznek, who will conduct the animal studies at the Institute of Virology, University of Veterinary Medicine, Vienna, will dedicate approximately 60 hours to the proposed project. The personnel costs requested are the FWF's (the Austrian government agency for research funding) standard salaries, and represents the industry standard in Austria (http://www.fwf.ac.at/de/projects/personalkostensaetze.html).

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1.6.2 Non-personnel costs

All the equipment required to conduct the proposed project is available, so no additional pieces of equipment are required. Material is requested for the initial two year period. Costs per annum have been estimated based on the experience of previous years and are based on stringent calculations, including discounts for large scale orders on behalf of the Universities.

1.6.3 Breakdown of costs

Budget:

	year 1	**year 2**
Salary (Senior Postdoc - C Konstantoulas)	[**********]	[**********]
Salary (Research Assistant - A Spasic)	[**********]	[**********]
Salary (Research Assistant - H Petznek)	[**********]	[**********]
Consumables	[**********]	[**********]
Travel costs	[**********]	[**********]
Management activities	[**********]	[**********]
Overheads	[**********]	[**********]
Equipment	[**********]	[**********]
Maintenance of Equipment	[**********]	[**********]
Publishing costs	[**********]	[**********]
Literature	[**********]	[**********]
Histology 60 samples x €200/sample	[**********]	[**********]
In-vivo diabetic mouse testing ($GIPR^{dn}$ mice)	[**********]	[**********]
In-vivo diabetic mouse testing ($Ins2^{C95S}$ mice)	[**********]	[**********]
Total	[**********]	[**********]
Overhead Uni & Inst (20%)	[**********]	[**********]
Grand Total	[**********]	[**********]

Notes:

In-vivo diabetic mouse testing will be carried out either in Vienna or Munich (at the University of Munich). Depending on where the work is carried out, the costs (and associated overhead of 20%) will be allocated to that institution. So if all in-vivo diabetic mouse testing is carried out in Munich, the budget will be reduced by Euro 32,794.12.

1.7 References

1. Lawandi, J. (2010). Resistance of Melligen cells to pro-inflammatory cytokines involved in beta cell death. Australian Digital Thesis Program (ADT), Thesis.

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2. Stadlbauer, V., *et al.* Morphological and functional characterization of a pancreatic beta-cell line microencapsulated in sodium cellulose sulfate/ poly (diallyl-dimethylammonium chloride). *Xenotransplantation* **13**, 337-344 (2006).

3. Tuch, B.E., *et al.* Safety and viability of microencapsulated human islets transplanted into diabetic humans. *Diabetes Care* **32**, 1887-1889 (2009).

4. Lohr, M., *et al.* Microencapsulated cell-mediated treatment of inoperable pancreatic carcinoma. *Lancet* **357**, 1591-1592 (2001).

5. Matthias Lšhr, J.-C.K., Anne Hoffmeyer, Mathias Freund, Johannes Hain, Albrecht Holle, Wolfram T Knšfel, Stefan Liebe, Horst Nizze, Matthias Renner, Robert Saller, Petra MŸller, Thomas Wagner, Karlheinz Hauenstein, Brian Salmons, Walter H Günzburg. Safety, feasibility and clinical benefit of localized chemotherapy using microencapsulated cells for inoperable pancreatic carcinoma in a phase I/II trial. *Cancer Therapy* **1**, 121-131 (2003).

6. Günzburg, W.H. & Salmons, B. Use of cell therapy as a means of targeting chemotherapy to inoperable pancreatic cancer. *Acta Biochim Pol* **52**, 601-607 (2005).

7. Günzburg, W.H. & Salmons, B. Novel clinical strategies for the treatment of pancreatic carcinoma. *Trends Mol Med* **7**, 30-37 (2001).

8. Kammertoens, T., *et al.* Combined chemotherapy of murine mammary tumors by local activation of the prodrugs ifosfamide and 5-fluorocytosine. *Cancer Gene Ther* **7**, 629- 636 (2000).

9. Kroger, J.C., *et al.* Intra-arterial instillation of microencapsulated, Ifosfamide-activating cells in the pig pancreas for chemotherapeutic targeting. *Pancreatology* **3**, 55-63 (2003).

10. Kroger, J.C., *et al.* Intraarterial instillation of microencapsulated cells in the pancreatic arteries in pig. *Ann N Y Acad Sci* **880**, 374-378 (1999).

11. Lohr, J.M., Saller, R., Salmons, B. & Gunzburg, W.H. Microencapsulation of genetically engineered cells for cancer therapy. *Methods Enzymol* **346**, 603-618 (2002).

12. Lohr, M., *et al.* Cell therapy using microencapsulated 293 cells transfected with a gene construct expressing CYP2B1, an ifosfamide converting enzyme, instilled intraarterially in patients with advanced-stage pancreatic carcinoma: a phase I/II study. *J Mol Med (Berl)* **77**, 393-398 (1999).

13. Lohr, M., *et al.* Targeted chemotherapy by intratumour injection of encapsulated cells engineered to produce CYP2B1, an ifosfamide activating cytochrome P450. *Gene Ther* **5**, 1070-1078 (1998).

14. Lohr, M., *et al.* Microencapsulated, CYP2B1-transfected cells activating ifosfamide at the site of the tumor: the magic bullets of the 21st century. *Cancer Chemother Pharmacol* **49 Suppl 1**, S21-24 (2002).

*** Certain confidential information contained in this document, marked by brackets, has been omitted and filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

15. Salmons, B., *et al.* Encapsulated cells to focus the metabolic activation of anticancer drugs. *Curr Opin Mol Ther* **12**, 450-460 (2010).

16. Salmons, B. & Gunzburg, W.H. Therapeutic application of cell microencapsulation in cancer. *Adv Exp Med Biol* **670**, 92-103 (2010).

17. Salmons, B., Lohr, M. & Gunzburg, W.H. Treatment of inoperable pancreatic carcinoma using a cell-based local chemotherapy: results of a phase I/II clinical trial. *J Gastroenterol* **38 Suppl 15**, 78-84 (2003).

18. Winiarczyk, S., *et al.* A clinical protocol for treatment of canine mammary tumors using encapsulated, cytochrome P450 synthesizing cells activating cyclophosphamide: a phase I/II study. *J Mol Med (Berl)* **80**, 610-614 (2002).

19. Lacy, P.E. & Kostianovsky, M. Method for the isolation of intact islets of Langerhans from the rat pancreas. *Diabetes* **16**, 35-39 (1967).

20. Reckard, C.R., Ziegler, M.M. & Barker, C.F. Physiological and immunological consequences of transplanting isolated pancreatic islets. *Surgery* **74**, 91-99 (1973).

21. Ricordi, C., Lacy, P.E., Finke, E.H., Olack, B.J. & Scharp, D.W. Automated method for isolation of human pancreatic islets. *Diabetes* **37**, 413-420 (1988).

22. Shapiro, A.M., *et al.* Islet transplantation in seven patients with type 1 diabetes mellitus using a glucocorticoid-free immunosuppressive regimen. *N Engl J Med* **343**, 230-238 (2000).

23. Sun, A.M., Parisius, W., Healy, G.M., Vacek, I. & Macmorine, H.G. The use, in diabetic rats and monkeys, of artificial capillary units containing cultured islets of Langerhans (artificial endocrine pancreas). *Diabetes* **26**, 1136-1139 (1977).

24. Maki, T., *et al.* Treatment of severe diabetes mellitus for more than one year using a vascularized hybrid artificial pancreas. *Transplantation* **55**, 713-717; discussion 717- 718 (1993).

25. Scharp, D.W., *et al.* Protection of encapsulated human islets implanted without immunosuppression in patients with type I or type II diabetes and in nondiabetic control subjects. *Diabetes* **43**, 1167-1170 (1994).

26. Colton, C.K. Implantable biohybrid artificial organs. *Cell Transplant* **4**, 415-436 (1995).

27. Brauker, J., Martinson, L.A., Young, S.K. & Johnson, R.C. Local inflammatory response around diffusion chambers containing xenografts. Nonspecific destruction of tissues and decreased local vascularization. *Transplantation* **61**, 1671-1677 (1996).

*** Certain confidential information contained in this document, marked by brackets, has been omitted and filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

28. Sweet, I.R., *et al.* Treatment of diabetic rats with encapsulated islets. *J Cell Mol Med* **12**, 2644-2650 (2008).

29. Stiegler, P.B., *et al.* Cryopreservation of insulin-producing cells microencapsulated in sodium cellulose sulfate. *Transplant Proc* **38**, 3026-3030 (2006).

30. Soon-Shiong, P., *et al.* Insulin independence in a type 1 diabetic patient after encapsulated islet transplantation. *Lancet* **343**, 950-951 (1994).

31. Calafiore, R., *et al.* Microencapsulated pancreatic islet allografts into nonimmunosuppressed patients with type 1 diabetes: first two cases. *Diabetes Care* **29**, 137-138 (2006).

32. Basta, G., *et al.* Long-term metabolic and immunological follow-up of nonimmunosuppressed patients with type 1 diabetes treated with microencapsulated islet allografts: four cases. *Diabetes Care* **34**, 2406-2409 (2011).

33. De Vos, P., De Haan, B. & Van Schilfgaarde, R. Effect of the alginate composition on the biocompatibility of alginate-polylysine microcapsules. *Biomaterials* **18**, 273-278 (1997).

34. Otterlei, M., *et al.* Induction of cytokine production from human monocytes stimulated with alginate. *J Immunother (1991)* **10**, 286-291 (1991).

35. Menard, M., *et al.* Role of protein contaminants in the immunogenicity of alginates. *J Biomed Mater Res B Appl Biomater* **93**, 333-340 (2010).

36. Liu, X.Y., Nothias, J.M., Scavone, A., Garfinkel, M. & Millis, J.M. Biocompatibility investigation of polyethylene glycol and alginate-poly-L-lysine for islet encapsulation. *ASAIO J* **56**, 241-245 (2010).

37. Tam, S.K., *et al.* Factors influencing alginate gel biocompatibility. *J Biomed Mater Res A* **98**, 40-52 (2011).

38. de Vos, P., Spasojevic, M., de Haan, B.J. & Faas, M.M. The association between in vivo physicochemical changes and inflammatory responses against alginate based microcapsules. *Biomaterials* **33**, 5552-5559 (2012).

39. Mata, E., Igartua, M., Patarroyo, M.E., Pedraz, J.L. & Hernandez, R.M. Enhancing immunogenicity to PLGA microparticulate systems by incorporation of alginate and RGD-modified alginate. *Eur J Pharm Sci* **44**, 32-40 (2011).

40. Gunzburg, W.H. & Salmons, B. Xenotransplantation: is the risk of viral infection as great as we thought? *Mol Med Today* **6**, 199-208 (2000).

41. Heneine, W., *et al.* No evidence of infection with porcine endogenous retrovirus in recipients of porcine islet-cell xenografts. *Lancet* **352**, 695-699 (1998).

*** Certain confidential information contained in this document, marked by brackets, has been omitted and filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

42. Elliot, R.B. Microencapsulated Neonatal Porcine Islet Implants Alleviate Unaware Hypoglycaemia without Immune Suppression. *IPITA World Congress* (2011).

43. Tuch, B.E., Hughes, T.C. & Evans, M.D. Encapsulated pancreatic progenitors derived from human embryonic stem cells as a therapy for insulin-dependent diabetes. *Diabetes Metab Res Rev* **27**, 928-932 (2011).

44. Naujok, O., Burns, C., Jones, P.M. & Lenzen, S. Insulin-producing surrogate beta-cells from embryonic stem cells: are we there yet? *Mol Ther* **19**, 1759-1768 (2011).

45. Herbach, N.*, et al.* Overexpression of a dominant negative GIP receptor in transgenic mice results in disturbed postnatal pancreatic islet and beta-cell development. *Regul Pept* **125**, 103-117 (2005).

46. Herbach, N.*, et al.* Dominant-negative effects of a novel mutated Ins2 allele causes early-onset diabetes and severe beta-cell loss in Munich Ins2C95S mutant mice. *Diabetes* **56**, 1268-1276 (2007).

47. Herbach, N., Bergmayr, M., Goke, B., Wolf, E. & Wanke, R. Postnatal development of numbers and mean sizes of pancreatic islets and beta-cells in healthy mice and GIPR(dn) transgenic diabetic mice. *PLoS One* **6**, e22814 (2011).

48. Kautz, S.*, et al.* Early insulin therapy prevents beta cell loss in a mouse model for permanent neonatal diabetes (Munich Ins2(C95S)). *Diabetologia* **55**, 382-391 (2012).

49. Renner, S.*, et al.* Glucose intolerance and reduced proliferation of pancreatic beta-cells in transgenic pigs with impaired glucose-dependent insulinotropic polypeptide function. *Diabetes* **59**, 1228-1238 (2010).

50. Renner, S.*, et al.* Permanent neonatal diabetes in INS(C94Y) transgenic pigs. *Diabetes* **62**, 1505-1511 (2013).

LICENCE AGREEMENT

UNIVERSITY OF TECHNOLOGY, SYDNEY

and

NUVILEX AUSTRALIA PTY LTD

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REFERENCE SCHEDULE

Item 1	Effective Date of Agreement	13 October 2014
Item 2	Licensee	Nuvilex Australia Pty Ltd
Item 3	Ownership of Intellectual Property	Solely owned by University
Item 4	Licensed Intellectual Property	Patent/s: Cells Genetically Modified to Comprise Pancreatic Islet Glucokinase and Uses Thereof Filing details: · Patent applications derived from PCT/AU2008/001160 o Australia: 2007904310 o United States: 14/185716 o Europe: 08782908.1 Trademarks: N/A Copyright: N/A Plant Breeders Rights: N/A Knowhow: Data and knowhow related the Patent or Patent Applications
Item 5	Territory	Worldwide
Item 6	Exclusivity	Exclusive rights to Licensed Intellectual Property, except Knowhow.
		Non-Exclusive rights to Knowhow.
Item 7	Field	Treatment of Diabetes using the Licensed Intellectual Property
Item 8	Patent Administration Fee	[**] on all amounts paid by University to prosecute and maintain patents related to Licensed Intellectual Property
Item 9	Royalty	[**] Gross Exploitation Revenue on Product Sales
Item 10	Term	20 years (or the remainder of any term on the Licensed Intellectual Property)
Item 11	Milestone Payments	Successful conclusion of: · [**********] · [**********] · [**********] · [**********]

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Item 12	Product /Service	Use of Melligen cell line to treat diabetes.
Item 13	Sub Licensee Royalty	[**] gross revenues
Item 14	Existing publications and disclosures for the Technology	Ann M. Simpson, M. Anne Swan, Guo Jun Liu, Chang Tao, Bronwyn A O'Brien, Edwin Ch'ng, Leticia M. Castro, Julia Ting, Zehra Elgundi, Tony An, Mark Lutherborrow, Fraser Torpy, Donald K. Martin, Bernard E. Tuch and Graham M. Nicholson (2013). Insulin Trafficking in a Glucose Responsive Engineered Human Liver Cell Line is Regulated by the Interaction of ATP-Sensitive Potassium Channels and Voltage-Gated Calcium Channels, Gene Therapy -Tools and Potential Applications, Dr. Francisco Martin (Ed.), ISBN: 978-953-51-1014-9, **InTech**, DOI: 10.5772/52839. Available from: http://www.intechopen.com/books/gene-therapy-tools-and-potential-applications/ insulin-trafficking-in-a-glucose-responsive -engineered-human-liver-cell-line -is-regulated-by-the-int Tuch *et al.*, (2003). "Function of a genetically modified human liver cell line that stores, processes and secretes insulin". **Gene Therapy**. Vol. 10 (6), pp490-503. Tabiin *et al*., (2001). "Susceptibility of Insulin-Secreting Hepatocytes to the Toxicity of Pro- inflammatory Cytokines". **Journal of Autoimmunity**. Vol. 17 (3), pp229-242. Simpson *et al.,* (1997). "Gene therapy of diabetes: glucose-stimulated insulin secretion in a human hepatoma cell line (HEP G2ins/g)". **Gene Therapy**. Vol. 4 (11), pp1202-14. Simpson *et al.,* (1995). "Functional expression of the human insulin gene in a human hepatoma cell line (HEP G2)". **Gene Therapy**. Vol. 2 (3), pp223-231.
Item 15	Interest rate amounts on overdue amounts	[**] per annum

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Item 16	Contact details for Licensee	Chief Executive Officer of Nuvilex Australia Pty Ltd 12510 Prosperity Drive Suite 310 Silver Spring, Maryland 20904 USA Telephone:+917.595.2850 Facsimile: +917.595.2851 Email: kwaggoner@nuvilex.com
Item 17	Contact details for University	Director, Research & Innovation Office Level 14, Building 1 University of Technology, Sydney 15 BROADWAY NSW 2007 Telephone: 02 9514 9861 Facsimile: 02 9514 1244 Email: patents@uts.edu.au
Item 18	Period Objectionable Material not to be published	12 months

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LICENCE AGREEMENT

THIS LICENSE AGREEMENT is made on the 10 day of October 2014
("Agreement")

BETWEEN	**UNIVERSITY OF TECHNOLOGY, SYDNEY** (ABN 77 257 686 961), a body corporate constituted pursuant to the provisions of the *University of Technology, Sydney Act 1989* (NSW) of 15 Broadway, ULTIMO NSW 2007 ("**University**")
AND	**NUVILEX AUSTRALIA PTY LTD (**ACN 600 316 621) of Level 15, 300 Queen Street, Brisbane, QLD 4001("**Licensee**")

BACKGROUND

A The University owns the Intellectual Property.

B The University has agreed to grant a licence to the Licensee to Commercialise the Intellectual Property.

THIS AGREEMENT PROVIDES

1. DEFINITIONS AND INTERPRETATION

1.1 Definitions

In this Agreement:

Abandonment Event means the Licensee fails to Commercialise the Intellectual Property for a period of 2 years.

Agreement means this Agreement and any appendices to it.

BIP means Intellectual Property owned, acquired or licensed by the University that is described in a Research Agreement between the Licensee and the University as being Intellectual Property that the University has made available for a research project.

Business Day means:

(a) in relation to the doing of any act or the receipt of any notice by the University, a day (other than a Saturday or Sunday) upon which banks are ordinarily open for business in Sydney, Australia; or

(b) in relation to the doing of any act or the receipt of any notice by Licensee, a day (other than a Saturday or Sunday) upon which banks are ordinarily open for business in Sydney, Australia.

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Commercialise or Commercialisation means:

(a) in relation to a product that uses or incorporates part or all of the Intellectual Property to use, make, manufacture, have made or manufactured, sell, advertise, promote, distribute, hire, or otherwise dispose of the product, or to keep it for the purpose of doing any of those things;

(b) in relation to a method or process that uses or incorporates part or all of the Intellectual Property, to use the method or process or do any act referred to above in respect of a product resulting from such use; or

(c) to research, develop or test a product or process that uses or incorporates part or all of the Intellectual Property.

Confidential Information of a party ("**Discloser"**) means, in respect of the other party ("**Recipient"**), any or all information and data of any nature:

(a) disclosed by the Discloser to the Recipient in connection with this Agreement; or

(b) obtained by the Recipient where the Recipient knows or suspects, or ought reasonably to have known or suspected, that the information was obtained, whether directly or indirectly, from the Discloser and the Discloser would treat such information as confidential, whether before or after the Effective Date of this Agreement.

Defence Trade Controls Law means any Australian law restricting or regulating the export, transfer or trading of specified defence-related or weapons-related goods, services or technologies, including each of the Defence Trade Controls Act 2012 (Cth), Customs Act 1901 (Cth), Weapons of Mass Destruction (Prevention of Proliferation) Act 1995 (Cth), Nuclear Non-Proliferation (Safeguards) Act 1987 (Cth) and Chemical Weapons (Prohibition) Act 1994 (Cth).

Effective Date means the date of this Agreement as specified at **Item 1** of the reference schedule.

Field means the field as specified at **Item 7** of the reference schedule.

Improvements means all developments of, improvements to, additions to or alterations to the Licensed Intellectual Property (after the Effective Date).

Insolvency Event means:

(a) a winding up order is made;

(b) a resolution is made for winding up (other than for the purpose of reconstruction);

(c) a provisional liquidator or administrator is appointed;

(d) an official manager, a receiver, a receiver and manager or similar officer is appointed and that appointment is not stayed or revoked within 14 days of such appointment;

(e) ceasing to carry on business; or

(f) any proposal to enter into a scheme of arrangement or composition for the benefit of creditors (except for the purpose of reconstruction).

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Intellectual Property means:

(a) the Licensed Intellectual Property;

(b) all Patent Applications (including foreign applications) that are filed or may later be filed based on or corresponding to the Licensed Intellectual Property in paragraph (a) above;

(c) all divisional and continuation, in whole or in part, applications and reissue applications based on any of the foregoing Licensed Intellectual Property or Patent Applications;

(d) all issued and unexpired patents resulting from any application in paragraph (a), (b) or (c) above;

(e) all issued and unexpired reissue, re-examination, renewal, or extension patents that may be based on any patents referred to in paragraph (d) above; and

(f) Improvements.

Licensed Intellectual Property means that intellectual property described at **Item 4** of the Reference Schedule.

Non-Commercial Research means research that is not funded in whole or part by a for-profit entity and in respect of which a for-profit entity does not obtain a right to Commercialise or otherwise exploit the outcome of the research.

Party or **Parties** means a party or the parties to this Agreement.

Patent means a patent granted that encompasses any part of the Intellectual Property.

Patent Application means any new patent application filed after the Effective Date which is either related to the Licensed Intellectual Property or arisen separately from it but still within the Field and of potential commercial interest to the Licensor.

Product means each product:

(a) the manufacture, use, or sale of which infringes (or which would, but for the licence granted under this Agreement, infringe), uses, or employs any part of the Intellectual Property; or

(b) that is derived from the Intellectual Property.

Proposed Publication means:

(a) a manuscript or abstract intended for publication;

(b) a paper or abstract intended to be orally presented;

(c) any poster presentation; or

(d) any other public disclosure that relates to any matter concerning the Intellectual Property but excludes a student thesis

Public Domain means the general store of knowledge that is known or generally available and ascertainable by members of the community.

*** Certain confidential information contained in this document, marked by brackets, has been omitted and filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Royalty means the figure or percentage at **Item 9** of the Reference Schedule.

Term means the period defined at **Item 10** of the Reference Schedule.

Territory means that region or regions described at **Item 5** of the Reference Schedule where the Licensee may Commercialise the Intellectual Property.

1.2 Interpretation

(a) A reference to a Party to this Agreement includes a reference to that Party's executor, administrator, heirs, successors, permitted assignees, guardian, and trustee in bankruptcy, all of whom, respectively, are bound by the provisions of this Agreement.

(b) Headings in this Agreement are inserted for guidance only and shall not affect the meaning and interpretation of the remaining provisions of this Agreement.

(c) Words in this Agreement importing the singular number or plural number shall include the plural number and singular number respectively.

(d) Words in this Agreement importing persons include all persons, entities and associations, including companies, trusts, bodies corporate, statutory bodies, partnerships, and joint ventures.

(e) Where a word or phrase is given a particular meaning in this Agreement, other parts of speech and grammatical forms of that word or phrase have corresponding meanings.

(f) Where a party to this Agreement is more than one person the covenants and obligations on their part contained in this Agreement are binding upon each of them jointly and severally.

(g) The word "including" is not a word of limitation.

(h) If something must be done on a day that is not a Business Day, it may be done on the next day that is a Business Day.

(i) A reference to any statute is a reference to that statute, as amended and in force from time to time.

1.3 Currency

(a) A reference to an amount of money is a reference to that amount in Australian dollars.

(b) All amounts payable pursuant to this Agreement shall be paid in Australian dollars.

2. TERM

The term of this Agreement ("**Term**") in each country shall be the period commencing upon the Effective Date and ending:

(a) where a Patent encompassing any of the Intellectual Property has been granted in that country – on the date of expiration of the last to expire Patent granted in that country;

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(b) where a Patent encompassing any of the Intellectual Property has not been granted in that country – on the date of expiration of the last to expire Patent granted in any country; or

(c) where no Patent encompassing any of the Intellectual Property has been granted in any country - on the expiration of the period at **Item 10** of the Reference Schedule from the Effective Date,

unless this Agreement is terminated earlier in accordance with Clause 14.

3. GRANT OF LICENCE

3.1 Grant of Licence to Licensee

The University grants to the Licensee a licence in accordance with the exclusivity terms at **Item 6** of the Reference Schedule in the Territory to Commercialise the Intellectual Property within the Field.

3.2 Not Used

3.3 Grant of Sub-Licences

Licensee may grant a sub-licence to Commercialise the Intellectual Property without the prior written consent of the University.

3.4 Operation of Section 145 of the Australian Patents Act 1990

This Agreement operates as a separate agreement in relation to:

(a) each Patent in each country; and

(b) such that the Intellectual Property that never becomes the subject of a patent,

to the intent and purpose that if a party terminates this Agreement pursuant to section 145 of the Australian Patents Act 1990 (or any similar or corresponding provision of the law of any country), that termination shall operate with respect to the Patent that ceased to be in force, without affecting the continued operation of this Agreement in relation to:

i. all remaining Patents; and

ii. such of the Intellectual Property that never becomes the subject of a patent.

3.5 Recording of Licence

(a) Licensee may apply to the Commissioner of Patents in Australia (and any other similar official or functionary in the Territory) to note on the Patents register (or any similar register in any other country) particulars of Licensee's entitlement as licensee to an interest in the Patents pursuant to this Agreement.

(b) The University must assist, at Licensee's expense, and consent to the application referred to in paragraph (a) of this Clause 3.5 and must procure the consent and assistance of the University to that application.

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3.6 Reservation of Right to Research

Notwithstanding any other provision in this Agreement, the University reserves the right to undertake internal Non-Commercial Research in relation to the Intellectual Property. Any research undertaken pursuant to this Clause 3.6 must be on terms that comply with Clauses 8 and 9 of this Agreement.

3.7 University to Disclose Improvements to Licensee

The University must promptly disclose Improvements to Licensee.

3.8 Assistance by University

The University must give to Licensee all information and reasonable assistance in its power to enable Licensee to Commercialise the Intellectual Property and the Products to the best advantage.

3.9 Referral of Enquiries

The University must promptly refer all commercially relevant enquiries it receives in relation to Products to Licensee.

3.10 Terms of Sub-Licences

(i) Subject to paragraphs 3.10 (ii) to(iv) inclusive, the University acknowledges that the terms of a sub-license agreement are a matter for Licensee to determine; however the non-economic terms of any sub-license should be similar to those in this Agreement, specifically including Clauses 5, 8, 10 and 12 .

(ii) The Licensee agrees that it cannot accept non-cash consideration from a sub-licensee without the prior written consent of the University.

(iii) As partial consideration for the license granted to the Licensee under this Agreement, the Licensee shall pay the University the Sub Licensee Royalty (Item 13) in relation to a sub-license of the Licensed Intellectual Property under this Agreement by the University.

(iv) Such Sub Licensee Royalty shall be applied to any payments made to the Licensee in relation to a sub-license of the Licensed Intellectual Property, including, but not limited to, any royalty payments paid to the Licensee on sales of any Products by the sub-licensee, initial licensing fees, milestone fees, maintenance fees and minimum royalty payments, to the extent any such payment is directly attributable to the sub-license of the Licensed Intellectual Property.

3.11 Copy of Sub-Licence Agreement to be Provided to University

Licensee must:

(a) upon execution of a sub-licence agreement; or

(b) upon execution of an agreement varying a sub-licence agreement, or effecting a variation of a sub-licence agreement in any other way; and

(c) upon receipt of a written request by the University, provide to the University:

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(d) an executed copy of a sub-licence agreement; or

(e) an executed copy of an agreement varying a sub-licence agreement; or

(f) particulars of a variation of a sub-licence agreement effected in any other way.

3.12 Not Used

3.13 Commercialisation

Without limiting the Licensee's obligations under Clause 5.4, each Party must comply with all applicable statutes, regulations, rules, ordinances, by-laws and other subordinate legislation in connection with the licencing, use and Commercialisation of the Intellectual Property contemplated by this Agreement.

4. LICENCE FEE

4.1 The Licensee must pay to the University:

(a) the Patent Administration Fee (**Item 8**); and

(b) the Royalty (**Item 9**);

(c) the Milestone Payments (**Item 11**); and

(d) the Sub-Licensee Royalty (**Item 13**).

4.2 The Royalty and Sub-Licensee Royalty must be paid to the University once every 6 months ("Half Year") throughout the Term. Each Half Year ends on 31 March and 30 September respectively. The Royalty and Sub-Licence Royalty must be paid within 30 days of the end of the Half Year and must include a written report 'Royalty and Revenue Report' with respect to the immediately completed Half Year, which details the following:

(a) the number of Products sold for that Half Year;

(b) the invoice price of each Product sold for that Half Year; and

(c) the amount of Royalty and Sub-Licensee Royalty payable to the Licensor for that Half Year.

4.3 (a) Throughout the Term (**Item 10**), the Licensee must keep proper records of sales, as well as any purchases made pursuant to any Sub-Licence Agreements, in respect of its Commercialisation of the Products ("**Books**").

(b) Throughout the Term, but not more often than once in each 6 month period, authorised representatives of the University may inspect the Books. The Licensee will provide all necessary reasonable assistance in order for the said representatives to properly carry out the inspection. The representatives may take copies of the Books. If a variation of 10% in an amount which is payable to the Licensor is revealed from the inspection of the Books, the representatives' costs will be paid by the Licensee.

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4.4 The Royalty and Sub-Licensee Royalty must be clear from all set-offs, counterclaims, charges, taxes (including withholding taxes), any other government charges, duties and other costs, and be calculated on the listed price of any Products and not on any discounted prices.

4.5 If any amounts which are owed to the Licensor under this Clause are in arrears by more than 60 days, then interest is charged at the rate, asset out in **Item 15**.

4.6 The amount referred to in Clause 4.2 is exclusive of goods and services tax.

4.7 The University shall provide to Licensee an invoice for the amount referred to in Clause 4.2; and for the goods and services tax applicable to the amount referred to in Clause 4.2, that complies with the requirements of the A New Tax System (Goods and Services Tax) Act 1999.

4.8 Licensee must pay the invoice referred to in Clause 4.7 within 30 days of Licensee's receipt of the invoice.

5. GENERAL OBLIGATIONS OF LICENSEE

5.1 Use Reasonable Efforts to Commercialise

Licensee, either on its own or through a sub-licensee or an affiliate, must use its reasonable efforts consistent with customary business practices to develop and Commercialise the Intellectual Property in a diligent manner.

5.2 Regulatory Approvals

Licensee must at its expense apply for and obtain all regulatory approvals, licences, permits and approvals from any government, government agency, or regulatory agency that may be required to Commercialise the Intellectual Property.

5.3 Use of Patent Numbers

Licensee must ensure that the Products and the packaging of the Products includes a reference to the patent/patent application numbers that relate to that Product, where the absence of that reference in any manner detrimentally affects the rights conferred by the Patent.

5.4 Compliance with Laws

Licensee must comply with all applicable laws in relation to the Commercialisation of the Intellectual Property.

5.4A If applicable and if University determines when acting reasonably and after conducting any necessary investigations, that University is or may be exposed to a risk of breaching Defence Trade Controls Law as a result of any activity in which the Licensee is or will be engaged in connection with the provision of the Licence, University may, at its absolute discretion:

(a) require the Licensee to comply with any reasonable directions issued by University in order to mitigate the risk, including a direction to cease undertaking the supply of the Commercialised Intellectual Property to a sanctioned country without a permit to export the controlled technology; or

(b) terminate this Agreement immediately without notice.

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5.5 No Misleading or Deceptive Conduct

Licensee must not engage in any misleading or deceptive conduct or conduct likely to be misleading or deceptive in Commercialising the Intellectual Property.

5.6 Licensee to Communicate Licensee's Improvements to University

Licensee must promptly disclose Improvements it makes to the Intellectual Property to the University.

5.7 Annual Reporting by Licensee

Licensee must provide to the University a written report, no more frequently than once each calendar year, within two months of the University requesting the report, and must set out in the report:

(a) the progress of research and development in relation to the Intellectual Property;

(b) the progress in Commercialising the Intellectual Property;

(c) prospective grants of sub-licenses;

(d) forecasts of sales of Products;

(e) the development or making of improvements to the Intellectual Property; and

(f) any other matter reasonably requested by the University.

6. PATENTS

6.1 What Will be Patented

Licensee, in its discretion and at its cost, may seek and maintain patent protection for all or any part of the Intellectual Property in any countries in the Territory **(Item 5**). Licensee agrees to consult with the University as to what Intellectual Property should be patented and must give due regard to the University's views and representations.

6.2 Patent Ownership

(a) All applications for provisional patents and patents in relation to the Intellectual Property will be in the name of the University.

(b) All patents in relation to the Intellectual Property will be owned by the University.

6.3 Not Used

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6.4 Patent to be Maintained

Subject to Clause 6.5, the Licensee will decide which patents shall be maintained and will pay the University a Patent Administration Fee (**Item 8**) to administer the Intellectual Property on behalf of the Licensee.

6.5 Licensee Declines to Patent

If:

(a) Licensee does not wish to protect any particular Intellectual Property, or wishes to discontinue paying any expenses in relation to any particular Intellectual Property;

(b) the University does wish to patent that Intellectual Property, or to continue to pay those expenses; and

(c) the University proceeds to do so, Licensee shall have no further rights in relation to that Intellectual Property.

7. <u>INTELLECTUAL PROPERTY</u>

7.1 Ownership

(a) The Parties acknowledge that the Intellectual Property is the property of the University

(b) Licensee must not:

(i) directly or indirectly contest or impair the University's ownership of the Intellectual Property; or

(ii) represent that it has any ownership interest in the Intellectual Property.

7.2 Infringement

If either Party shall learn or believe that:

(a) any unauthorised person has come into possession of any part of the Intellectual Property;

(b) any person has made any improper or unauthorised use of the Intellectual Property; or

(c) any unauthorised person is doing anything in contravention of rights that attach to and arise from the Intellectual Property, that Party must immediately report full particulars to the other.

7.3 Parties to Consider Acting Jointly in Relation to Infringements

As soon as practicable:

(a) after receipt of the information referred to in Clause 7.2; or

(b) after any challenge in any manner to the Intellectual Property is made by any person, the Parties must confer and decide what course should betaken.

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7.4 Parties Decide to Act Jointly

If the Parties agree, the parties shall jointly proceed with instituting or defending any proceedings concerning the Intellectual Property, and in that event:

(a) they shall jointly give all necessary instructions to legal representatives;

(b) in the event that the Parties are unable to agree upon the instructions to give to legal representatives, those instructions shall be given by Licensee;

(c) Licensee shall be responsible for all legal fees and disbursements in relation to such proceedings; and

(d) after payment of all legal expenses, Licensee shall solely retain any damages or other monies that accrue from those proceedings.

7.5 Licensee Elects to Proceed Solely

If Licensee wishes to solely institute or defend any proceedings concerning the Intellectual Property, to the extent of Licensee's rights in this Agreement:

(a) Licensee must, at the University's request, and as a precondition to the right to commence or defend any proceedings, indemnify the University with respect to any obligation or liability whatsoever that the University might be called upon to discharge, and must sign a Deed of Indemnity in such form as the University's solicitor shall reasonably require;

(b) the University must, after the provision of the indemnity referred to in paragraph (a) of this Clause 7.5, at the cost and expense of Licensee, provide to Licensee all reasonable assistance in its power with respect to the proceedings;

(c) the University must, after the provision of the indemnity referred to in paragraph (a) of this Clause 7.5, at the cost and expense of Licensee, execute a power of attorney or other authority to enable Licensee to institute or defend any proceedings;

(d) Licensee may solely give all instructions to legal representatives;

(e) Licensee shall solely be responsible for all legal fees and disbursements with respect to such proceedings; and

(f) after payment of all legal expenses, Licensee shall solely retain any damages or other monies that accrue from those proceedings.

8. CONFIDENTIAL INFORMATION

8.1 Ownership of Confidential Information

The Confidential Information is the property of the Discloser.

8.2 Use of Confidential Information

A Recipient must use the Confidential Information of the Discloser solely for the purpose for which it was disclosed and for no other purpose whatsoever, without the prior written consent of the Discloser, which the Discloser shall be at liberty to give or to decline to give in its unfettered and uncontrolled discretion.

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8.3 Non Disclosure of Confidential Information

A Recipient must keep the Confidential Information of the Discloser secret and confidential, and must not, disclose, communicate or otherwise make known to any person any part of the Confidential Information without the prior written consent of the Discloser, which the Discloser shall be at liberty to give or to decline to give in its unfettered and uncontrolled discretion, except for disclosures permitted under Clause 8.6, 8.7 or 8.8 or to the extent that the disclosure is required by law.

8.4 Relief to Recipient

The Recipient shall be relieved from the Recipient's obligations contained in Clauses 8.2 and 8.3 in respect to any Confidential Information which:

(a) the Recipient can show was in the possession of the Recipient as at the date of the disclosure and that it was not already known subject to an obligation of confidentiality;

(b) becomes part of the Public Domain other than by a breach of this Agreement; or

(c) the Recipient can show was received in good faith from a person:

(i) who is not a party to this Agreement; and

(ii) who did not receive the Confidential Information from the Discloser or any person in respect to whom the Discloser can trace the provision of the Confidential Information originating with it.

8.5 Damages Inadequate

The Recipient acknowledges that:

(a) damages may be an inadequate remedy to the Discloser in the event of any breach of Clause 8.2 or 8.3 occurring and that only injunctive relief or some other equitable remedy might be adequate to properly protect the interests of the Discloser; and

(b) the Discloser would not have entered into this Agreement but for the acknowledgment made by the Recipient in paragraph (a) of this Clause 8.5.

8.6 Disclosure to Directors and Employees

(a) The Recipient may disclose the Confidential Information of the Discloser to such of its directors and employees as is necessary to enable the Recipient to fully take advantage of the Confidential Information for the purposes of this Agreement.

(b) The Recipient warrants that each person to whom the Recipient is permitted to disclose the Confidential Information, before such disclosure is made, is subject to contractual or other duties of confidentiality to the Recipient at least to the extent imposed upon the Recipient pursuant to this Agreement.

(c) The Discloser may require that none of its Confidential Information be disclosed to a director or employee of the Recipient unless that person enters into a confidentiality undertaking upon such terms as the solicitor for the Discloser shall reasonably require.

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8.7 Not Used

8.8 Disclosure for Non-Commercial Research

(a) Without limiting this Clause 8, the University must keep any confidential information comprised in the Intellectual Property secret and confidential and must not use, disclose, communicate or otherwise make known to any person any part of that information without the prior written consent of Licensee, which Licensee shall be at liberty to give or to decline to give in its unfettered and uncontrolled discretion, except:

(i) for disclosures for the purpose of exercising its rights pursuant to Clause 3.6; or

(ii) to the extent that the disclosure is required by law.

(b) The University must ensure that its disclosure of information pursuant to paragraph (a)(i) of this Clause 8.8 is upon such terms, or is restricted to such an extent, as:

(i) protects the information from unauthorised or improper use or disclosure; and

(ii) does not prejudice any possible future patent application in relation to what is to be disclosed.

8.9 Infringement of Confidentiality

If the Recipient learns or believes that:

(a) any unauthorised person has come into possession of any part of the Confidential Information of the Discloser;

(b) any person has made any improper or unauthorised use of the Confidential Information of the Discloser; or

(c) any unauthorised person is doing anything in contravention of rights that attach to and arise from the Confidential Information of the Discloser, the Recipient must immediately report full particulars to the Discloser, and must provide to the Discloser all assistance and information it may request with respect to that information.

8.10 Public Statements

Neither Party may make any public or media statement concerning this Agreement or status or progress of Licensee without the consent of the other Party.

8.11 Survival of Obligations

The termination of this Agreement shall not affect each Party's obligations in this Agreement relating to the Confidential Information of the other set out in Clauses 8.1 to 8.10.

9. <u>PUBLICATIONS</u>

9.1 Publications to be provided to Licensee

The University must serve upon Licensee a copy of any Proposed Publication.

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9.2 Licensee may object to publication

(a) Licensee may, within 30 days of a Proposed Publication being served upon it, object to the publication of the Proposed Publication. Any objection to a Proposed Publication will specify the portions of the Proposed Publication considered objectionable ("**Objectionable Material**").

(b) On receiving notice from Licensee of Objectionable Material, the University and Licensee agree to work together to revise the Proposed Publication to remove or alter the Objectionable Material in a manner acceptable to both Licensee and the University. The University is not restricted from publishing or presenting the Proposed Publication as long as the Objectionable Material has been removed.

(c) Any Objectionable Material will not be disclosed for the period as specified at **Item 18** from the date the University delivered the Proposed Publication to Licensee, to allow for the filing of a patent application in respect of the Objectionable Material.

9.3 When University may Authorise Publication

The University may publish or authorise the publication of a Proposed Publication if:

(a) the contents of the Proposed Publication are the subject of a patent that has issued;

(b) the contents of the Proposed Publication are the subject of an application for a patent or provisional patent that has been published;

(c) the Proposed Publication was served upon Licensee in accordance with Clause 9.1 and Licensee informs the University that it does not object to its publication;

(d) the Proposed Publication was served upon Licensee in accordance with Clause 9.1, but Licensee did not object to publication within the time required by Clause 9.2; or

(e) the Proposed Publication was served upon Licensee in accordance with Clause 9.1, Licensee objects to publication within the time required by Clause 9.2 and a period of 12 calendar months elapses from the date of Licensee's objection.

9.4 Patent Applications

If paragraph (c) of Clause 9.3 applies, the Parties will use their reasonable efforts to ensure that the contents of a Proposed Publication is protected by the lodging of a provisional patent application within the time mentioned in that Clause.

9.5 Not Used

10. <u>INSURANCE</u>

10.1 Licensee to Obtain Insurance

Before Licensee or a Sub-Licensee sells any Product, Licensee must take out a product liability policy of insurance, or must ensure that the Sub-Licensee takes out a product liability policy of insurance (as applicable), covering:

(a) all usual risks covered by such policies; and

(b) any loss or damage or injury of any kind whatsoever and howsoever caused to any person or property, arising out of the Commercialisation of the Intellectual Property by Licensee or its Sub-Licensee (as the case may be) and the use of the Products for an amount no less than $10,000,000.00 per claim.

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10.2 Licensee to Obtain No Fault Compensation Clinical Trial Insurance

Before Licensee or a Sub-Licensee commences any clinical trial in relation to the Intellectual Property, Licensee must obtain, or must ensure that the Sub-Licensee obtains, a no fault compensation trial policy of insurance covering:

(a) all usual risks covered by such policies; and

(b) any loss or damage or injury or death, arising out of the clinical trial for an amount no less than $10,000,000.00 per claim.

10.3 Licensee to Maintain Insurance

Licensee must maintain, or must ensure that the Sub-Licensee maintains, the insurance policy referred to in Clauses 10.1 and 10.2 until:

(a) in the case of an event based insurance policy, the date of the last use or sale of a Product; or

(b) in the case of a claims made insurance policy, that date which is 7 years from the date of the last use or sale of a Product.

10.4 Licensee to Provide a Copy of Certificate of Insurance

Licensee must on an annual basis produce to the University for the University's inspection a certificate of currency issued by the insurer in respect to the insurance to be maintained under Clauses 10.1 and 10.2.

10.5 University May Insure if Licensee Fails to Insure

If Licensee fails to keep current the insurance policies required pursuant to Clauses 10.1 and 10.2, the University may effect such insurance and recover from Licensee all the University's expenses of doing so.

10.6 Suspension of Operation of Clauses 10.1 to 10.4

(a) The operation of Clauses 10.1 to 10.4 is suspended in relation to Licensee or a particular Sub-Licensee while the following conditions are met:

(i) Licensee or the Sub-Licensee self-insures for product liability and clinical trials;

(ii) Licensee or the Sub-Licensee’s annual gross revenues exceed US$5 billion; and

(iii) Licensee has in writing notified the University that conditions (i) and (ii) of paragraph (a) of this Clause 10.6 have been met and produced evidence demonstrating compliance with those conditions.

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(b) The operation of Clauses 10.1 to 10.5 recommences upon the conditions in paragraph (a) of this Clause 10.6 ceasing to apply.

(c) The operation of Clauses 10.1 to 10.5 remains in full force and effect for Licensee and any Sub-Licensee that does not meet the conditions in paragraph (a).

11. WARRANTIES

11.1 Commercialisation is Uncertain

Licensee acknowledges the fundamental uncertainty with respect to the Commercialisation of new technology.

11.2 Warranties by University

11.2.1 The University warrants that it is duly incorporated and validly existing under the laws of Australia.

11.2.2 The University warrants that, subject to Clause 11.2.3, it has the legal right and power to enter into this Agreement.

11.2.3 The University warrants that the execution, delivery and performance of this Agreement by the University has been duly and validly authorised by all necessary corporate action.

11.2.4 The University warrants that the execution and performance of this Agreement by the University does not violate or conflict with or result in a breach of or constitute a default under or result in the imposition of any encumbrance under the provisions of the University's governing rules (including any constitution, if applicable).

11.2.5 The University warrants that, subject to Clause 11.2.3, this Agreement is valid and binding upon it.

11.2.6 Subject to Clause 11.2.7, the University warrants to the Licensee that as at the date of this Agreement:

(a) it solely owns the Intellectual Property both legally and beneficially;

(b) it has made reasonable enquiries to establish whether it owns the Intellectual Property both legally and beneficially;

(c) the Intellectual Property is not encumbered, mortgaged, or charged in any way, nor subject to any lien;

(d) there is no litigation pending in respect to the Intellectual Property and there is no claim or demand that has been received from any person in relation to the Intellectual Property; and

(e) except as disclosed by the University to Licensee and except for this Agreement, the University has not entered into any deed, contract, arrangement or understanding dealing in any way with the Intellectual Property.

11.2.7 The warranties in paragraph (a) and (b) of Clause 11.2.6 are made by the University to the best of its actual knowledge, without having searched in every patent database in the world, and are made subject to:

(a) anything that might be discovered from such a search; and

(b) any research or other work being undertaken by any person, which may be concerned with the same subject matter as the Intellectual Property, of which it is not aware.

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11.3 Acknowledgments

Each party acknowledges that:

(a) except for such warranties on the part of the University as are expressly set out in this Agreement, there are no other terms or warranties binding upon the University or between the University and Licensee;

(b) the University has not made, nor has any person on behalf of the University made any term, warranty, undertaking, or understanding whatsoever that is not expressly set out in this Agreement;

(c) to the full extent permitted by law, there are no statutory warranties binding upon the University; and

(d) no representation or promise of any description, not expressly included in this Agreement, was made before this Agreement was entered into by the Parties.

11.4 No Other Warranties

Licensee acknowledges that the University has not made and does not make any warranty or representation whatsoever as to:

(a) the safety of the Intellectual Property or of the Products;

(b) the Commercialisation of the Intellectual Property or of the Products;

(c) the marketability of the Intellectual Property or of the Products;

(d) the profits or revenues that may result from the Commercialisation of the Intellectual Property or of the Products;

(e) the Commercialisation prospects or success of any part of the Intellectual Property or of the Products;

(f) whether any patent application may be granted, or granted with the claims sought, or any reduced claims; or

(g) whether any patent granted may be declared valid or can be registered.

12. INDEMNITIES

12.1 Indemnity by Licensee

(a) Licensee indemnifies and shall continue to indemnify the University, its officers, employees, sub-contractors and agents from and against all actions, claims, proceedings or demands (including those brought by third parties) which may be brought against it or them, whether on their own or jointly, in respect of any loss, death, injury, illness or damage (whether personal or property, and whether special, direct, indirect or consequential, including consequential financial loss) arising out of the Commercialisation or use of the Intellectual Property, and any Products derived from the Intellectual Property, to the extent that it relates to or arises from the breach of any term of this Agreement by the Licensee.

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(b) The liability of Licensee to indemnify the University, its officers, employees, sub-contractors and agents in paragraph (a) of this Clause 12.1 is reduced proportionately to the extent that the action, claim, proceeding or demand relates to or arises from the University's breach of its obligations under this Agreement (including any warranty) or from any negligent or wilful act or omission of the University.

(c) The obligation to indemnify the University, its officers, employees, sub-contractors and agents set out in paragraph (a) of this Clause 12.1 is a continuing obligation separate and independent of other obligations, and shall survive the expiration of the Term or termination of this Agreement.

12.2 Indemnity by University

(a) The University indemnifies and shall continue to indemnify Licensee its officers, employees, sub-contractors and agents from and against all actions, claims, proceedings or demands (including those brought by third parties) which may be brought against it or them, whether on their own or jointly, in respect of any loss, death, injury, illness or damage arising out of any breach of a warranty by the University in this Agreement.

(b) The obligation to indemnify Licensee and its officers, employees, sub-contractors and agents set out in paragraph (a) of this Clause 12.2 is a continuing obligation separate and independent of other obligations, and shall survive the expiration of the Term or termination of this Agreement.

12.3 Mitigation

If an event arises that may:

(a) give rise to an obligation on a Party to indemnify the other party under this Clause 12, the Party with the benefit of the indemnity; or

(b) reduce or otherwise affect a Party's obligation to indemnify the other Party under this Clause 12, the indemnifying Party, must use its reasonable endeavours to avoid or mitigate any loss, damage, cost or expense relating to or arising from that event.

13. <u>DISPUTE RESOLUTION</u>

13.1 When This Clause Applies

(a) A Party must not commence legal proceedings against another Party, unless that Party wishing to commence proceedings has complied with Clauses 13.2 to 13.5.

(b) Clauses 13.2 to 13.5 shall not apply where a Party seeks urgent interlocutory or equitable relief from a court.

13.2 Notice of Dispute

When a Party claims that a dispute has arisen under this Agreement ("**Dispute**"), that Party must serve written notice of the Dispute ("**Notice of Dispute**") to each other Party at the addresses provided at **Item 16** or **Item 17**.

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13.3 Appointment of Representative

(a) Following a Notice of Dispute, the Parties must each, within 5 Business Days of a Party's receipt of a Notice of Dispute, appoint a representative to resolve the Dispute.

(b) The representative appointed pursuant to paragraph (a) of this Clause 13.3 must have authority to resolve the Dispute in all respects and to bind the Party the person represents to any resolution of the Dispute.

(c) The representatives appointed pursuant to paragraph (a) of this Clause 13.3 must use their best endeavours to resolve the Dispute.

13.4 Mechanism for Resolution of Dispute

(a) If a Dispute has not been resolved within 10 Business Days of the first notification of the Dispute, or such further period as the Parties or the representatives appointed pursuant to Clause 13.3 shall allow, those representatives must use their best endeavours to reach agreement upon a mechanism for the resolution of the Dispute.

(b) The mechanism for resolution of a Dispute for the purposes of paragraph (a) of this Clause 13.4 may include, but need not necessarily be, further negotiations, mediation, conciliation, arbitration, litigation and expert determination.

(c) The agreement upon a mechanism for the resolution of a Dispute pursuant to paragraph (a) of this Clause 13.4 must include agreement with respect to such of the following as are applicable:

(i) a timetable for the taking of all necessary steps relating to the mechanism;

(ii) a procedure for the selection of any person to be appointed to act as a mediator, conciliator, or arbitrator;

(iii) that person's remuneration; and

(iv) who shall be responsible for the payment of that remuneration.

13.5 Commencement of Legal Proceedings

If:

(a) the Parties have not reached agreement upon a mechanism for the resolution of a Dispute within 15 Business Days after a Party receives a Notification of Dispute or any additional period agreed upon pursuant to paragraph (a) Clause 13.4;

(b) a party fails to observe the timetable referred to in paragraph (a) of Clause 13.4; or

(c) the mechanism for the resolution of the Dispute does not resolve the Dispute, any Party may commence proceedings in any court of competent jurisdiction in relation to that Dispute.

14. TERMINATION

14.1 Termination for Default

If:

(a) a Party is in default of any obligation contained in this Agreement;

(b) that default has continued for not less than 14 days or occurred more than 14 days earlier and has not been remedied;

(c) the non-defaulting Party serves upon the defaulting Party notice in writing requiring the default to be remedied within 30 days of the date of such notice, or such greater number of days as the non-defaulting Party may in its discretion allow; and

(d) the defaulting Party shall have failed to comply with the notice referred to in paragraph (c) of this Clause 14.1, the non-defaulting Party may immediately terminate this Agreement by notice in writing to the defaulting Party.

14.2 Termination for Insolvency Event

If an Insolvency Event occurs in relation to a Party, the other Party may by notice in writing terminate this Agreement immediately.

14.3 Termination for Abandonment Event

If an Abandonment Event occurs, either Party may by notice in writing to the other Party terminate this Agreement immediately.

14.4 Termination Does Not Affect Prior Rights or Obligations or Accrued Rights

(a) The termination of this Agreement by a Party shall not relieve the other Party from performing all obligations which:

(i) are due to be performed before the effective termination of this Agreement; or

(ii) are due to be performed as a result of that termination.

(b) The termination of this Agreement will not affect any rights which accrue to a Party before the termination, or which arise connected with the termination, which are preserved.

15. TERMINATION AND CONFIDENTIAL INFORMATION

15.1 Return of Confidential Information

Immediately upon the termination of this Agreement, however that arises, unless the Parties enter into a further agreement in respect to the Confidential Information, the Recipient must immediately upon being so requested in writing by the Discloser, deliver to the Discloser:

(a) all Confidential Information in its possession;

(b) all Confidential Information which it has provided to any other person;

(c) all notes, memoranda, correspondence, reports, summaries, and all other matters or things brought into existence by the party which in any manner refers to any part of the Confidential Information; and

(d) all notes, memoranda, correspondence, reports, summaries, and all other matters or things brought into existence by any person which in any manner refers to any part of the Confidential Information.

15.2 Destruction of Confidential Information

(a) Any part of the Confidential Information which cannot conveniently be returned to the Discloser by the Recipient must be completely destroyed in that manner that the Discloser directs.

(b) The Discloser shall be entitled to appoint a person to oversee and verify the performance by the Recipient of its obligations pursuant to paragraph (a) of this Clause 15.2.

(c) Upon the performance by the Recipient of its obligations contained in paragraph (a) of this Clause 15.2, the Recipient must certify in writing to the Discloser that performance has been completed.

(d) The certificate provided by the Recipient to the Discloser pursuant to paragraph (c) of this Clause 15.2 is agreed by the Parties to be a warranty by the Recipient that the Recipient has performed all the Recipient's obligations contained in paragraph (a) of this Clause 15.2.

15.3 Recipient May Keep a Copy of the Confidential Information

Notwithstanding the provisions of Clauses 15.1 and 15.2, the Recipient may keep a copy of the Confidential Information for its record keeping purposes only.

16. GOODS AND SERVICES TAX

16.1. For the purposes of this Clause 16, GST, Input Tax Credit, Recipient, Supplier, Supply, Tax Invoice and

Taxable Supply have the meanings attributed to those terms in the A New Tax System (Goods and Services Tax) Act 1999.

16.2 GST Recovery

If GST is payable by a Supplier on a Supply made under this Agreement, then, to the extent that:

(a) the consideration for that Supply is not already stated to include an amount in respect of GST; or

(b) the amount of GST stated to be included in the consideration is less than the amount of the GST liability actually incurred by the Supplier in respect of that Supply, the Supplier may increase the consideration by the applicable amount of GST and the Recipient must pay that increased amount at the same time and to the same extent as any part of the consideration is payable to the Supplier is respect of the Supply.

16.3 Reimbursable Amount

Where any expenses incurred by a Supplier are to be reimbursed by the Recipient under this Agreement, the reimbursable amount shall be determined as follows:

(a) first, any amount which the Supplier is entitled to claim as an Input Tax Credit shall be deducted from the cost to the Supplier of the expense item to arrive at an “Actual Cost”; and

(b) second, the Actual Cost shall be increased by and to the extent of the amount of GST payable by the Supplier in respect of the Supply to the Recipient for which the expense item is consideration.

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16.4 Legislative Changes

If the GST payable by the Supplier on a Taxable Supply is varied pursuant to any change in legislation, the consideration payable under this Agreement must be increased or decreased to reflect that variation of the GST.

16.5 Tax Invoice

If GST is payable, the Supplier will provide the Recipient with a Tax Invoice or a document adequate to entitle the Recipient to claim an Input Tax Credit.

17. SERVICE OF NOTICES

17.1 Manner of Service of Notices

Any notice to be given or served by a Party upon the other pursuant to this Agreement shall be sufficiently served if:

(a) sent by pre-paid post to the office of the Party appearing at **Item 16** or **Item 17** of the Reference Schedule, or to the address of the Party last known to the Party serving such notice;

(b) sent by email transmission; or

(c) delivered personally to the Party or the Party's address appearing upon this Agreement, or to the address of the Party last known to the Party serving notice.

17.2 When Service by Post is Effective

Where service is effected by prepaid post, service shall be deemed to have taken place 2 Business Days after the document to be served has been placed in a postal receptacle, and the document shall be deemed to have been received by the addressee on the day that it is deemed to have been served.

17.3 When Service by Email Transmission is Effective

Service is effected by email upon completion of the transmission of the email, unless the sender receives: (i) a report of delivery failure; (ii) a report of delivery delay; (iii) an "out of office" message; or (iv) a message from the addressee that the notice is illegible, incomplete or corrupted within 24 hours of the notice being e-mailed.

17.4 When Personal Service is Effected

Where service is effected personally, service shall be deemed to have taken place at the time of actual delivery.

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18. GENERAL

18.1 No Assignment or Subcontracting

Neither Party may assign, sub-contract or transfer any of their rights or obligations in this Agreement to any person, without the prior consent in writing of the other Party which the other Party must not unreasonably withhold.

18.2 Relationship between the Parties

(a) The relationship between the Parties is that of licensor and licensee, and nothing in this Agreement shall be construed or interpreted to make one Party the agent, partner, joint venturer or representative of the other.

(b) Neither Party may at any time, without the prior written consent of the other, act as or represent that it is the agent, partner, joint venturer or representative of the other.

18.3 Further Assurance

Each Party must, on demand by another Party, perform all such acts and execute all such agreements, assurances and other documents and instruments as that Party reasonably requires either to perfect the rights and powers afforded, created or intended to be afforded or created by this Agreement or to give full force and effect to, or facilitate the performance of, the transactions provided for in this Agreement.

18.4 Counterparts

This Agreement may be executed in separate counterparts, and all those counterparts together constitute one agreement.

18.5 Legal Costs

Each Party shall be responsible for its own legal fees and costs in connection with the preparation, negotiation and execution of this Agreement.

18.6 Warranty of Authority

Where this Agreement is signed by a person for and on behalf of a Party, that person:

(a) warrants that the person is the authorised agent of that Party with express authority to enter into and sign this Agreement for and on behalf of that Party, and thereby to bind that Party to the obligations upon that Party contained in this Agreement; and

(b) acknowledges that the other Party to this Agreement would not have entered into this Agreement but for the warranty of authority contained in paragraph (a) of this Clause 18.6.

18.7 Whole Agreement

The Parties acknowledge that solely in relation to the subject matter of this Agreement:

(a) this Agreement merges all discussions between the Parties, up to the Effective Date;

(b) the whole of the agreement between the Parties is contained in this Agreement; and

(c) there are no agreements, understandings other terms, whether express or implied, or collateral agreements in force or effect between the Parties that are not contained in this Agreement.

18.8 Variations

No variation to this Agreement shall be binding upon the Parties, unless that variation is in writing and is signed by all the Parties.

18.9 Waiver

(a) No failure or delay of any Party to exercise any right given pursuant to this Agreement or to insist on strict compliance by any other Party of any obligation in this Agreement shall constitute a waiver of any Party's rights to demand exact compliance with the terms of this Agreement.

(b) Waiver by a Party of any particular default by any other Party shall not affect or prejudice each Party's right in respect of any prior or subsequent default of the same or of a different nature.

(c) Any delay or omission by a party to exercise any right arising from any default shall not affect or prejudice that Party's right in respect to such a default or any subsequent default or the continuance of any default.

(d) Any waiver shall be an effective waiver only if the waiver is expressly set out in writing and signed by the party making the waiver.

18.10 Applicable Law

(a) The Parties agree that this Agreement is made and entered into in the State of New South Wales in Australia.

(b) The Parties agree to submit themselves to the non-exclusive jurisdiction of the laws in force for the time being in New South Wales.

(c) The Parties agree to submit themselves to the non-exclusive jurisdiction of the Courts in New South Wales.

18.11 Severance

If it is held by a court that:

(a) any part of this Agreement is or would be void, voidable, illegal or unenforceable; or

(b) the application of any part of this Agreement to any person or circumstances shall be or become invalid or unenforceable, unless any part of this Agreement were severed from this Agreement, that part shall be severable and shall not affect the continued operation of the remaining terms of this Agreement.

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SIGNATURES OF PARTIES

SIGNED	)	
for **UNIVERSITY OF TECHNOLOGY, SYDNEY**	)	
in the presence of	)	Signature
	)	
		Printed Name: Glenn Wightwick
		Signature of witness
		Printed Name:
SIGNED	)	
for **NUVILEX AUSTRALIA PTY LTD**	)	
in the presence of	)	Signature
	)	
		Printed Name: Kenneth L. Waggoner
		Signature of witness
		Printed Name: Beth Jones

Exhibit 10.13

Nuvilex, Inc.
Kenneth L. Waggoner
Chief Executive Officer and President
12510 Prosperity Drive
Suite 310
Silver Spring, Maryland 20904
USA

Date: 07 March 2014
Proposal Ref. No.: 12/0574C-0578C

Proposal for Cell Banking and Cell Line Characterization of HEK293 Master, Working and End of Production Cell Bank for a Cell Therapy Product

Dear Ken

Thank you for your request relating to a proposal for banking and characterization of a recombinant HEK 293 cell line. These cells will be encapsulated and implanted into the patient for tumour therapy. They do express a sub-class of Cytochrome P450 which is able to convert a pro-drug. We are pleased to provide you with a second revision of the proposal with the initial request dating back to 2012.

Bank (or Cells at the limit of in vitro cell age) is a key element of the safety concept for cell-derived biopharmaceutical products. The aim of the characterization of the cell banks is to exclude or at least minimize the potential risk of the introducing of adventitious agents such as bacteria, mycoplasma, fungi or viruses. These contaminants might be introduced via start materials of the biopharmaceutical production including the production cells. In addition to safety testing of cell banks and other start materials, testing is also performed at the level of the final product.

Due to the fact that we are dealing with a cell therapy product which will be implanted into the patient without further purification, extra care has to be taken on the safety testing and during GMP production. Higher air class handling will be required working in a *Class A environment with a Class B background.*

The following pages will outline our testing recommendations and banking procedures and will list the relevant guidelines for cell line characterization. The total cost will be summarized. This will be based on the current testing schema and the banking requirements.

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GLP and GMP Status and Relevant Guidelines

All work will be performed either in accordance with the principles of GLP as defined in the OECD Principles of Good Laboratory Practice as outlined in ENV/MC/CHEM(98)17, revised in 1997 or to GMP standards as defined in the Commission Directive 2003/94/EC (laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use) and also in the US FDA 21 CFR part 211: Current Good Manufacturing Practice for finished pharmaceuticals.

Study specific audits of critical phases or system audits will form an integral component of the performance of these studies.

ViruSure is a GLP and GMP certified testing facility. Copies of our certificates can be provided upon request.

The study design and study performance follows the relevant guidelines as listed below:

- ICH guidelines Q5A, Q5B and Q5D;
- CBER/FDA, Points to Consider in the Characterization of Cell Lines Used to Produce Biologicals;
- European Pharmacopoeia (EP), US Pharmacopoeia (USP) and Japanese Pharmacopoeia (JP); and
- European Regulation (EC) No 1394/2007 for Advanced Therapy Medicinal Products (ATMP´s).

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Recommended Assays for Characterizing of Recombinant Cell Banks

Assay	MCB	WCB	EPCB
Identity			
Isoenzymes	(+)[1]	(+)[1]	(+)[1]
DNA Fingerprinting by RAPD Analysis (for Identity and Genetic Stability Testing)	+	+	+
Purity			
Microbial Contaminants			
Sterility according to EP/USP/JP	+	+	+
Mycoplasma according to EP	+	+	+
Mycoplasma according to FDA PTC	+	+	+
Adventitious Viruses			
28-day *in vitro* assay for the presence of viral contamination using 3 cell lines (Vero, MRC-5 and in addition as cell of the same species as the test sample)	+		+
14-day *in vitro* assay for the presence of viral contamination using 3 cell lines (Vero, MRC-5 and in addition as cell of the same species as the test sample)		+5	
In vivo assay for the presence of adventitious agents in suckling and adult mice, embryonated eggs and *optionally* guinea pigs	+	+[5]	+
Retrovirus Tests			
Transmission electron microscopy (TEM)	+		+
Retrovirus infectivity test Extended S+L- focus assay for amphotropic and xenotropic retroviruses .	+		+
Reverse transcriptase assay using the PERT assay (FPERT) (required if TEM and infectivity test via co-cultivation is negative)	+		+ 2
Other Viruses			
Mouse antibody production test (MAP)	+6		
Hamster antibody production test (HAP)	+6		
Bovine viruses	(+)[3]		
Porcine viruses	(+)[3]		
Human viruses:			
Standard PCR package: HBV, HCV, EBV, CMV, HIV 1 & 2, HTLV I & II, HHV 6 to			
HHV8, SV40 and PB19	(+)4		
Co-cultivation test using e.g. RD cells for endogenous viruses			

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1 If RAPD (random amplified polymorphic DNA) analysis is performed for identity and genetic stability, Isoenzyme analysis for identity testing is not required if RAPD testing is included.

2 CBER recognizes that some products and reagents like avian cell substrates have RT activity that does not represent adventitious infectious retroviruses (e.g. chicken embryo fibroblasts, dermal cells and eggs). Avian cells testing positive by FPERT require other virus specific tests showing the absence of the major avian retroviruses. These include exogenous retroviruses like Avian Leukosis Virus (ALV), Reticuloendotheliosis Virus and Avian Sarcoma Virus (ALV-E or ASLV) as well as other infectious endogenous retroviruses.

3 The Requirement for porcine/bovine testing is dependent on the history of the cell line. This is to be performed if cells have been exposed to materials of bovine or porcine origin, which itself has not been adequately tested. Any animal derived raw materials should be tested prior to use.

4 Test for human viruses (standard package) is recommended for human producer cells or for a new production system which has been handled in an R&D environment to establish the cells and laid down a research bank.

5 For the first WCB, these tests should be performed on cells at the limit of in vitro cell age (EPC/PPC), generated from the WCB. Subsequent WCB"s can be tested either directly on the WCB or on cells at the limit of in vitro cell age.

6 MAP and HAP Tests are usually applicable for rodent cell lines.

Subcontracting

Part of the cell line characterization assays as well as the cell banking will be subcontracted. It is ViruSure"s policy that only qualified subcontracting CRO"s, which have been audited by the ViruSure QA team, will be used for collaboration to perform part of the safety testing. The Sponsor will be notified about each individual assay which will be subcontracted. ViruSure will take full responsibility to coordinate the work, ship the test materials and to collect the individual reports. Master Service Agreements will be in place with our Subcontract labs. The reports will be checked by our QA group and a summary of the results will be provided.

Shipment of Tests Materials

The Sponsor will be responsible for the timely shipment of test materials and growth media and supplements if required. Authenticity of the test samples must be ensured.

Any shipment costs necessary to transport samples, seed cells and cell banks or equipment either to ViruSure, to our subcontract labs or back to the Sponsor are not included in this proposal and will be covered by the Sponsor.

Project Schedule for Banking and Characterization of MCB and WCB with Expected Timelines

1.	Contract Signature	
2.	Shipment of seed cells, growth and freeze media	1 – 2 weeks
3.	Quarantine screening of cells and media (Sterility and	32 days (~ 5 weeks) Mycoplasma).

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4.	Cell banking pilot study – Establishing RCB	4 – 6 weeks
5.	GMP Banking of Master Cell Bank (MCB)	8 – 10 weeks
6.	MCB Characterization (full package)	8 – 10 weeks **R**
7.	GMP Banking of Working Cell Bank (WCB)	8 - 10 weeks **R**
8.	WCB Characterization	6 – 8 weeks
9.	Issue of Certificate of Analysis (CofA for MCB and WCB production)	2 weeks
10.	CofA´s and individual GLP reports for MCB and	2 weeks WCB characterization
11.	QA audited ViruSure summary report for MCB and	2 weeks WCB characterization
	Total	**46–57 weeks R**

R *If the timelines are critical WCB banking can already be initiated prior to completion of MCB characterization if the Sponsor is prepare to take the risk if the MCB might fail any release criteria. This can save up to 10 weeks.*

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Prices for Cell Line Characterization – Master Cell Bank (MCB)

Cell Line Characterization	Price per Test Item (in €)
Cell expansion, if required	[**********]
Isoenzyme analysis (test for 6 isoenzymes included)	[**********]
- *optional* - DNA Fingerprinting (RAPD Analysis)[1] for identity and genetic stability testing *Comparison MCB , WCB and EPCB*	[**********]
Sterility according to EP/USP/JP using direct inoculation including bacteriostasis and fungiostasis required for the first test item	[**********]
Mycoplasma (harmonized EP/USP/PTC) - culture method and indicator cells including interference test	[**********]
28-day *in vitro* assay for the presence of viral contamination using three detector cell lines (Vero, MRC-5 and third cell line of same species, e.g. Hela)	[**********]
In vivo assay for the presence of adventitious viruses using Adult and suckling mice, embryonated eggs and guinea pigs	[**********]
Transmission Electron Microscopy (TEM) - 200 cell profiles *(100 cell profiles)*	[**********]
Reverse transcriptase assay using the F-PERT assay	[**********]
Extended S^+L^- focus assay on PG-4 cells for amphotropic and xenotropic viruses	[**********]
Real Time PCR for human Viruses (CPMP package: HAV, HBV, HCV, EBV, CMV, HIV 1 & 2, HTLV I & II, HHV 6 to 8, SV40 and PB19)	[**********]
Real Time PCR for Adeno Associated Virus (AAV)	[**********]
Co-Cultivation Assay using e.g. RD cells for detection of endogenous viruses **3**	[**********]
Porcine Virus Test - via PCR (Porcine adenovirus, Porcine parvovirus, Transmissible gastroenteritis virus; Porcine hemagglutinating encephalitis virus and Porcine circovirus)	[**********]
Bovine Virus Test (9 CFR) - via PCR (Bluetongue virus; Bovine adenoviruses; Bovine parvovirus; Bovine respiratory syncytial virus; Reovirus; Rabies virus and Bovine viral diarrhoea virus**)**	[**********]
Total Price for cell line characterization of a MCB	[**********]

[1] *DNA Fingerprinting Test will be performed as an RAPD Test.*

[2] *Optional tests not included.*

[3] *This assay has not been established and validated, but the authorities might request testing for endogenous human viruses.*

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Prices for Cell Line Characterization – Working Cell Bank (WCB)

Cell Line Characterization	Price per Test Item (in €)
Cell expansion, if required	[**********]
Isoenzyme analysis (test for 6 isoenzymes included)	[**********]
- *optionally* – DNA Fingerprinting (RAPD Analysis)[1] for identity and genetic stability testing *Comparison MCB , WCB and EPCB*	[**********]
Sterility according to EP/USP/JP using direct inoculation (without bacteriostasis/fungiostasis assuming the same culture and freeze media as for MCB)	[**********]
Mycoplasma (harmonized EP/USP/PTC) - culture method and indicator cells (interference test not included assuming the same culture and freeze media as for MCB)	[**********]
14-day *in vitro* assay for the presence of viral contamination using three detector cell lines (Vero, MRC-5 and third cell line of same species, e.g. CHO)	[**********]
In vivo assay for the presence of adventitious viruses using Adult and suckling mice and embryonated eggs plus guinea pigs.	[**********]
Total Price for cell line characterization of a WCB	[**********]

[1] *DNA Fingerprinting Test will be performed as an RAPD Test.*

[2] *For the first WCB, in vitro and in vivo adventious agent tests should be performed on cells at the limit of in vitro cell age (EPCB), generated from that WCB. For WCBs subsequent to the first WCB, a single in vitro and in vivo test can be done either directly on the WCB or on the cells at the limit of in vitro cell age.*

[3] *Optional tests not included.*

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Prices for Cell Line Characterization – End of Production Cell Bank (EPCB) Prices

Cell Line Characterization	Price per Test Item (in €)
Cell expansion, if required	[**********]
Isoenzyme analysis (test for 6 isoenzymes included)	[**********]
- *optionally* – DNA Fingerprinting (RAPD Analysis)[1] for identity and genetic stability testing *Comparison MCB , WCB and EPCB*	[**********]
Sterility according to EP/USP/JP using direct inoculation (without bacteriostasis/fungiostasis assuming the same culture media as for MCB and WCB)	[**********]
Mycoplasma (harmonized EP/USP/PTC) - culture method and indicator cells (interference test not included assuming the same culture and freeze media as for MCB)	[**********]
28-day *in vitro* assay for the presence of viral contamination using three detector cell lines (Vero, MRC-5 and third cell line of same species, e.g. CHO)	[**********]
In vivo assay for the presence of adventitious viruses using Adult and suckling mice, embryonated eggs and guinea pigs	[**********]
Transmission Electron Microscopy (TEM) - 200 cell profiles *(100 cell profiles)*	[**********]
Reverse transcriptase assay using the F-PERT assay	[**********]
Extended S^+L^- focus assay on PG-4 cells for amphotropic and xenotropic viruses	[**********]
Total Price for cell line characterization of a EPCB	[**********]

[1] *DNA Fingerprinting Test will be performed as an RAPD Test.*

[2] *Optional tests not included.*

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Total Cost Summary of MCB, WCB and EPCB for Cell Bank Characterization

Contract	Project	Total Price in Euro (€)
12/0574C	**Characterization of MCB**	[**********]
12/0575C	**Characterization of WCB**	[**********]
12/0576C	**Characterization of EPCB**	[**********]
	Total Price Characterization of MCB, WCB and EPCB	[**********]

[1] *Optional tests are not included in total price.*
2 Genetic Stability testing is covered by DNA Fingerprinting (RAPD Method). This method will demonstrate identity and genetic stability by comparison of the different cell banks. This method is also listed as optional.

Validity of this Proposal

This proposal remains valid for 3 months following the date of issue.

If there is a significant delay of the project after contract signature and our subcontract partners will increase their prices in the meantime we will adjust the prices according to the price increase. The Sponsor will be notifies about this, prior to test initiation.

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GMP Cell Banking

Introduction

Cell Banking is performed in a facility well experienced in producing Master and Working Cell Banks of human and other cell species. This CMO has a special license for banking of cell therapy products and fulfills the requirement to vial the cell bank under air handling Class A with Class B background. All production steps are under a Good Manufacturing Practice (GMP) quality regime. Corresponding documentation is well established. After production and completion of release tests the banks will be stored in liquid nitrogen for up to one month prior to shipment to the Sponsor or prior to shipment to a dedicated biopository facility.

The MCB and WCB to be established shall be in a size of 200 vials with $1x10^7$ cells in each vial. HEK293 will be grown as adherent cells for the banking procedure.

This quotation is calculated with the following prerequisites:

1. Cultivation and storage in serum free medium;
2. Cultivation of cells in suspension;
3. Doubling time of the cells is in the range of 24-48h; and
4. Cells are assigned to Biosafety Level 1

Project Assumptions

The project comprises three major parts:

1. Cell Bank Pilot Study/Technology Transfer/Quarantine Testing;
2. Establishment of a Master Cell Bank (MCB); and
3. Establishment of a Working Cell Bank (WCB)

Cell Bank Pilot Study/Technology Transfer/Quarantine Testing of Medium and Seed Cells

The Sponsor will transfer detailed information and data about cultivation and freezing conditions of their cell line. Based on this information operational procedures will be generated for the establishment of the MCB and WCB. The Sponsor will send five (5) vials of the seed cells for the pilot study, for initial testing and for initiation of RCB banking. Upon reception, those cells will be tested for microbial contamination and for the absence of Mycoplasma.

During the pilot study a research bank (RCB) of about 20 vials will be laid down at the CMO.

This bank will be tested for sterility, LAL and viability as well as for virus contamination and will be the starting point for MCB banking

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In a first step (pilot study) it will be proven that the cells arrived in good conditions and are growing well in our hands. Prior to entry into the GMP facility sterility and Mycoplasma testing has to be performed for the seed cells as well as for the growth and freeze medium. If CoA´s for sterility and mycoplasma testing of the media are available, this testing can be skipped.

Service

Transfer of know-how, reception of the cells and establishment of cultivation and laying down a RCB of 20 vials, Quarantine testing for sterility and absence of Mycoplasma for media and seed cells prior to the entry into our GMP facility.

Initial Quarantine Testing	**5 weeks**
Sterility (direct inoculation) and Mycoplasma (harmonized EP/USP/PTC)	
Testing Culture Medium and Freeze Medium	(€ [**********])*
Seed Cell Testing (including cell expansion): ***** *Not require if GLP compliant test certificates for sterility and mycoplasma testing are available.*	**€** [**********]
Pilot Study with RCB Banking	
Expected time range:	**4-6 weeks**
Costs:	**€** [**********]

Establishment of a Master Cell Bank

A Master Cell Bank will be produced according to established standard operation procedures. The cell line will be handled with dedicated equipment in order to exclude the risk of a cross contamination. The procedures are thoroughly documented in a GMP compliant manner. Cell banking is performed according to the requirements of advanced therapy medical products with filling of the bank done under air handling *class A with class B background.* Our subcontract CMO got a special license from the local authorities to handle cell therapy products.

Procedure

After thawing of the vial of the research cell bank, cells will be expanded to a total cell count of at least 2.0 x 10^9, aliquoted to 200 vials, firstly frozen at –80°C and afterwards cryo-preserved at –196°C.

The organization of a later transport of parts or in whole of the MCB can be offered. Shipping costs will be transferred to the Sponsor with an additional handling surcharge of 50,- € per shipment.

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Service

Establishment of a Master Cell Bank with 200 vials (1.0 x 10^7cells per vial), batch-record and report.

Expected time range: **8-10 weeks**

Costs: **€ [**********]**

Establishment of a Working Cell Bank

A working cell bank will be produced according to established standard operation procedures after laying down a Master Cell Bank. Similar to the MCB, the cell line will be handled with dedicated equipment to exclude the risk of a cross contamination and filled under the special air handling conditions. The procedures are thoroughly documented in a GMP compliant manner. Cell banking is performed according to the requirements of advanced therapy medical products with filling of the bank done under air handling *class A with class B background.* Our subcontract CMO got a special license from the local authorities to handle cell therapy products.

Procedure

After thawing of the vial of the Master cell bank, cells will be expanded to a total cell count of at least 2.0 x 10^9, aliquoted to 200 vials, firstly frozen at –80°C and afterwards cryo-preserved at –196°C.

The organization of a later transport of parts or in whole of the WCB can be offered. Shipping costs will be transferred to the Sponsor with an additional handling surcharge of 50,- € per shipment.

Service

Establishment of a Working Cell Bank with 200 vials (1.0 x 10^7cells per vial), batch-record and report.

Expected time range: **8-10 weeks**

Costs: **€ [**********]**

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Total Cost Summary for Pilot Study, Cell Banking of MCB and WCB Banking

Contract	Project	Total Price in Euro (€)
12/0577C	**Cell Bank Pilot Study – RCB production (20 vials)** **Quarantine Testing Culture Medium and Freeze** **Medium** **Initial Quarantine Testing Seed Cells**	[**********] [**********] [**********]
12/0578C	**Cell Banking of MCB** (adherent cells) 200 vials(1.0 x 10^7cells per vial)	[**********]
12/0578C	**Cell Banking of WCB** (adherent cells) 200 vials (1.0 x 10^7cells per vial)	[**********]
	Total Price GMP Banking of MCB and WCB	**€** [**********][4]
	Special discount of **€** [*******]is offered if contract for both MCB and WCB banking will be signed together	- [**********]
	Total Discount Price GMP Banking of MCB and WCB	**€** [**********][4]

[1] *Pilot study is not required for standard CHO cell and therefore listed as optional.*

2 *Price per medium. This test is not required if test certificate for mycoplasma and sterility testing is available. These tests will be performed without bacteriostasis/fungistasis or interference test.*

3 *Not required if pre-qualified vials will be used for cell banking where ingress data are already available.*

4 *Optional tests not included.*

Validity of this Proposal

This proposal remains valid for 3 months following the date of issue.

If there is a significant delay of the project after contract signature and our subcontract partners will increase their prices in the meantime we will adjust the prices according to the price increase. The Sponsor will be notifies about this, prior to test initiation.

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Value Added Tax

All prices are calculated in Euro and exclude Austrian sales tax. According to EU law, where applicable sales or value added tax (VAT) will be added to our invoices. This is not required for clients outside Austria.

If any additional local tax has to be considered or tax at source deduction applies for Sponsors outside the EU the amount will be added to the price listed in the proposal.

General Terms

The Master Services Agreement signed and agreed on 07th April 2014 will apply to the work detailed in this proposal.

Terms of Payment

For testing:

50% upon initiation of experimental work or cell banking;

30% upon lab completion or completion of cell banking; and

20% upon delivery of cell bank and/or final audited report.

For Banking:

50% upon initiation of cell banking;

30% upon completion of cell banking; and

20% upon delivery of cell bank and final audited report.

We look forward to working together with you to perform these studies. To proceed with these studies, please sign and return a copy of the relevant contract(s) as detailed on the contract forms (last pages).

A member of our team will get back to you with an order confirmation and will finalize the timelines and discuss the sample requirements to perform this cell bank characterization.

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For any clarification on the content of this proposal please contact Dr. Ralf Klein - Manager Business Development.

With kind regards

Contact Details

Dr. Ralf Klein
ViruSure GmbH
Schnetzlerstr. 4
D-76137 Karlsruhe
Germany

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Main office: +43-126 99 120
Fax: +43-126 99 120 22
Mobile: +49-174 319 1173
Email: **ralf_klein@virusure.com**

www.virusure.com

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Contract #: 12/0574C

To:
Nuvilex, Inc.
12510 Prosperity Drive
Suite 310
Silver Spring, Maryland 20904
USA

Study: Characterization of MCB

To proceed with this study, please sign and return this contract to ViruSure. A faxed copy is acceptable and can be sent to ViruSure (Fax No.: +43 (0)1 2699 120 22). Upon receipt of the signed contract, ViruSure will contact the Sponsor to arrange a suitable slot for performing the studies.

Any change in the study design or any additional services requested by the Sponsor after contract signature not listed in this proposal may result in additional cost which will be addressed separately. Changes will be reflected in the study plan approved by the Sponsor. Additional charges will be applied at the time of invoicing.

The ViruSure standard Terms & Conditions apply when accepting this contract.

Payments for the study will be invoiced in the following stages:

50% upon initiation of experimental work;

30% upon lab completion; and

20% upon delivery of the final audited report

Total Cost of the Study: **€ [*******]**

Acceptance of the quotation:

/s/ Kenneth L. Waggoner Date: 23 August 2014
Kenneth L. Waggoner

*** Certain confidential information contained in this document, marked by brackets, has been omitted and filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Contract #: 12/0575C

To:
Nuvilex, Inc.
12510 Prosperity Drive
Suite 310
Silver Spring, Maryland 20904
USA

Study: Characterization of WCB

To proceed with this study, please sign and return this contract to ViruSure. A faxed copy is acceptable and can be sent to ViruSure (Fax No.: +43 (0)1 2699 120 22). Upon receipt of the signed contract, ViruSure will contact the Sponsor to arrange a suitable slot for performing the studies.

Any change in the study design or any additional services requested by the Sponsor after contract signature not listed in this proposal may result in additional cost which will be addressed separately. Changes will be reflected in the study plan approved by the Sponsor. Additional charges will be applied at the time of invoicing.

The ViruSure standard Terms & Conditions apply when accepting this contract

Payments for the study will be invoiced in the following stages:

50% upon initiation of experimental work;

30% upon lab completion; and

20% upon delivery of the final audited report

Total Cost of the Study: **€ [*******]**

Acceptance of the quotation:

/s/ Kenneth L. Waggoner Date: 23 August 2014
Kenneth L. Waggoner

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Contract #: 12/0575C

To:
Nuvilex, Inc.
12510 Prosperity Drive
Suite 310
Silver Spring, Maryland 20904
USA

Study: Characterization of EPCB

To proceed with this study, please sign and return this contract to ViruSure. A faxed copy is acceptable and can be sent to ViruSure (Fax No.: +43 (0)1 2699 120 22). Upon receipt of the signed contract, ViruSure will contact the Sponsor to arrange a suitable slot for performing the studies.

Any change in the study design or any additional services requested by the Sponsor after contract signature not listed in this proposal may result in additional cost which will be addressed separately. Changes will be reflected in the study plan approved by the Sponsor. Additional charges will be applied at the time of invoicing.

The ViruSure standard Terms & Conditions apply when accepting this contract.

Payments for the study will be invoiced in the following stages:

50% upon initiation of experimental work;

30% upon lab completion; and

20% upon delivery of the final audited report

Total Cost of the Study: **€ [*******]**

Acceptance of the quotation:

/s/ Kenneth L. Waggoner Date: 23 August 2014
Kenneth L. Waggoner

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Contract #: 12/0577C

To:
Nuvilex, Inc.
12510 Prosperity Drive
Suite 310
Silver Spring, Maryland 20904
USA

Study: Pilot Study and Initial Quarantine Testing

To proceed with this project, please sign and return this contract to ViruSure. A faxed copy is acceptable and can be sent to ViruSure (Fax No.: +43 (0)1 2699 120 22). Upon receipt of the signed contract, ViruSure will contact the Sponsor to arrange a suitable slot for performing the studies. Any change in the design or any additional services requested by the Sponsor after contract signature not listed in this proposal may result in additional cost which will be addressed separately. Changes will be reflected in the study plan approved by the Sponsor. Additional charges will be applied at the time of invoicing.

The ViruSure standard Terms & Conditions apply when accepting this contract

Payments for the study will be invoiced in the following stages:

50% upon initiation of experimental work;

30% upon lab completion;

20% upon delivery of the final audited report.

Cost for Pilot Study and RCB Banking:	**€ [*******]**
QC Testing of Research Bank:	**€ [*******]**
QC Test of media ***(price per medium/test material)***	**€ [*******]**

Acceptance of the quotation:

/s/ Kenneth L. Waggoner Date: 23 August 2014
Kenneth L. Waggoner

*** Certain confidential information contained in this document, marked by brackets, has been omitted and filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Contract #: 12/0578C-A

To:
Nuvilex, Inc.
12510 Prosperity Drive
Suite 310
Silver Spring, Maryland 20904
USA

Study: MCB Banking (200 Vials)

To proceed with this project, please sign and return this contract to ViruSure. A faxed copy is acceptable and can be sent to ViruSure (Fax No.: +43 (0)1 2699 120 22). Upon receipt of the signed contract, ViruSure will contact the Sponsor to arrange a suitable slot for performing the studies. Any change in the design or any additional services requested by the Sponsor after contract signature not listed in this proposal may result in additional cost which will be addressed separately. Changes will be reflected in the study plan approved by the Sponsor. Additional charges will be applied at the time of invoicing.

The ViruSure standard Terms & Conditions apply when accepting this contract.

Payments for the study will be invoiced in the following stages:

50% upon signing of contract or initiation of cell banking;

30% upon completion of cell banking; and

20% upon delivery of cell bank and final audited report

Total Cost of the Study:	**€ [*******]**
(Discount of € *******] if both MCB and WCB will be banked)	**€ [*******]**

Acceptance of the quotation:

/s/ Kenneth L. Waggoner Date: 23 August 2014
Kenneth L. Waggoner

*** Certain confidential information contained in this document, marked by brackets, has been omitted and filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Contract #: 12/0578C-B

To:
Nuvilex, Inc.
12510 Prosperity Drive
Suite 310
Silver Spring, Maryland 20904
USA

Study: WCB Banking (200 Vials)

To proceed with this project, please sign and return this contract to ViruSure. A faxed copy is acceptable and can be sent to ViruSure (Fax No.: +43 (0)1 2699 120 22). Upon receipt of the signed contract, ViruSure will contact the Sponsor to arrange a suitable slot for performing the studies. Any change in the design or any additional services requested by the Sponsor after contract signature not listed in this proposal may result in additional cost which will be addressed separately. Changes will be reflected in the study plan approved by the Sponsor. Additional charges will be applied at the time of invoicing.

The ViruSure standard Terms & Conditions apply when accepting this contract

Payments for the study will be invoiced in the following stages:

50% upon initiation of cell banking;

30% upon completion of cell banking; and

20% upon delivery of cell bank and final audited report

Total Cost of the Study:	**€ [*******]**
(Discount of € *******] if both MCB and WCB will be banked)	**€ [*******]**

Acceptance of the quotation:

/s/ Kenneth L. Waggoner Date: 23 August 2014
Kenneth L. Waggoner

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Exhibit 21.1

List of Subsidiaries

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

EXHIBIT 31.1

CERTIFICATION

I, Kenneth L. Waggoner, certify that:

1. I have reviewed this Amendment No. 1 to the Annual Report on Form 10-K/A of Nuvilex, Inc. ("Report") and its subsidiaries for the fiscal year ended April 30, 2014;

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. I am 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 my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me 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 my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States;

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

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

5. I have disclosed, based on my 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: October 16, 2014

By: /s/ Kenneth L. Waggoner
Name: Kenneth L. Waggoner
Title: Chief Executive Officer, President and Chief Financial Officer

EXHIBIT 32.1

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

In connection with Amendment No. 1 to the Annual Report of Nuvilex and its subsidiaries ("Company") on Form 10-K/A for the year ended April 30, 2014 as filed with the Securities and Exchange Commission on the date hereof ("Report"), the undersigned, Kenneth L. Waggoner, Chief Executive Officer, President and 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: October 16, 2014

By: /s/ Kenneth L. Waggoner
Name: Kenneth L. Waggoner
Title: Chief Executive Officer, President and Chief Financial Officer

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