UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-K

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

For the fiscal year ended April 30, 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	☐	Smaller reporting company	☒
(Do not check if a 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.

Forward-Looking Statements

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

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. Dr. Günzburg and Dr. Salmons are intimately involved in the scientific endeavors underway and being planned by 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. Negotiations are underway between Nuvilex and that university for 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. No assurance can be made that such a license will be entered into, however. Further, the license is contingent on the insulin-producing cells passing 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, the terms and conditions of a Collaborative Research Agreement ("CRA") between the Company and the UVMV has been agreed to between the parties. The CRA is in the final stages of drafting. Once finalized and signed, the tumorigenicity studies will commence. However, no assurance can be made that the CRA will be finalized between the parties.

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.

Because only 14 patients were treated in this Phase 1/2 trial, no statistical parameters of the type used in larger clinical studies were used in determining either safety or efficacy of the CapCell® plus ifosfamide combination in this trial.

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.

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 1A. RISK FACTORS

You should carefully consider these factors that may affect future results, together with all of the other information included in this Form 10-K, in evaluating the business and the Company. The risks and uncertainties described below are those that the Company currently believes may materially affect its business and results of operations. Additional risks and uncertainties that the Company is unaware of or that it currently deems immaterial also may become important factors that affect its business and result of operations. The Company's common shares involve a high degree of risk and should be purchased only by investors who can afford a loss of their entire investment. Prospective investors should carefully consider the following risk factors concerning the Company's business before making an investment.

In addition, you should carefully consider these risks when you read "forward-looking" statements elsewhere in this Report. These are statements that relate to the Company's expectations for future events and time periods. Generally, the words "anticipate", "expect", "intend", and similar expressions identify forward-looking statements. Forward-looking statements involve risks and uncertainties, and future events and circumstances could differ significantly from those anticipated in the forward-looking statements.

Risks Related to the Company's Financial Position, Need for Additional Capital and Overall Business

The Company has a Short Operating History, a Relatively New Business Model and Has Not Produced Any Revenues in Our Current Business Model. This makes it Difficult to Evaluate Our Future Prospects and Increases the Risk that We Will Not be Successful.

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

The Company has a History of Losses from Operations which May Continue and which May Harm Our Ability to Obtain Financing and Continue Our Operations.

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

The Company is an Early Stage Company with the Generation of No Revenues.

The Company is an early stage, pre-revenue company. An investor cannot readily determine if the Company will become profitable. The Company is likely to continue to experience financial difficulties during this early revenue stage and beyond. The Company may be unable to operate profitably, even if it generates revenues. The Company may not obtain the necessary working capital to continue developing and marketing its products. Furthermore, the present products may not receive sufficient interest to generate revenues or achieve profitability.

The Company Needs Additional Capital to Continue its Business Plans.

The Company will need additional capital to continue its operations. There can be no assurance that the Company will generate revenues or obtain sufficient capital on acceptable terms, if at all. Failure to obtain such capital or generate such operating revenues would have an adverse impact on the Company's financial position, operations and ability to continue as a going concern. The Company's operating and capital requirements during the next fiscal year and thereafter will vary based on a number of factors, including the level of sales and marketing activities for its products. There can be no assurance that additional private or public financing, including debt or equity financing, will be available as needed or if available, on terms favorable to the Company. Additionally, any future equity financing may be dilutive to stockholders' present ownership levels and such additional equity securities may have rights, preferences, or privileges that are senior to those of the Company's existing common stock.

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

The Company's Future Revenues are Unpredictable Which Causes Potential Fluctuations in Operating Results.

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

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

The Company Faces Substantial Competition, Which May Result in Others Discovering, Developing or Commercializing Competing Products Before or More Successfully than the Company Does.

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

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

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

Development of Brand Awareness is Critical to the Success of the Company.

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

Any Weakness in the Company's Internal Controls Could Have a Material Adverse Effect on the Company.

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

The Success of MMS Depends on Additional States Legalizing Medical Marijuana.

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

The Alternative Medicine Industry Faces Strong Opposition.

It is believed by many that well-funded, significant businesses may have a strong economic opposition to the medical marijuana industry. Lobbying by groups within the pharmaceutical industry or changes in the regulation of marijuana-based therapies could affect MMS's ability to develop and market cannabinoid-based cancer therapies.

Marijuana Remains Illegal under Federal Law.

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

The Insurance Coverage and Reimbursement Status of Newly-Approved Products is Uncertain. Failure to Obtain or Maintain Adequate Coverage and Reimbursement for New or Current Products Could Limit Our Ability to Market those Products and Decrease the Company's Ability to Generate Revenue.

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

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

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

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

Product Liability Lawsuits against the Company Could Cause us to Incur Substantial Liabilities and to Limit Commercialization of any Products that the Company May Develop.

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

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

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

Risks Related to Regulatory Approval and The Company's Product Candidates and Other Legal Compliance Matters

If the Company is Unable to obtain, or if there Are Delays in Obtaining, Required Approval from the Regulatory Agencies, the Company Will Not be Able to Commercialize its Product Candidates and the Company's Ability to Generate Revenue Will be Materially Impaired.

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

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

Clinical Drug Development Involves a Lengthy and Expensive Process with an Uncertain Outcome. We May Incur Additional Costs or Experience Delays in Completing or be Unable to Complete the Development and Commercialization of the Company's Product Candidates.

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

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

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

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

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

We intend to conduct one or more of our clinical trials outside of the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to certain conditions imposed by the Regulatory Agencies outside of the United States. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with ethical principles. The trial population must also adequately represent the population in the country in which the clinical trial is being conducted. The data must be applicable to the United States population and medical practice in the United States in ways that the FDA deems clinically meaningful. Generally, the patient population for any clinical trials conducted outside of the United States must be representative of the population for whom we intend to seek approval in the United States. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will be dependent upon its determination that the trials also complied with all applicable United States laws and regulations. There can be no assurance that the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept the data from any of our clinical trials that we determine to conduct outside the United States, it would likely result in the need for additional trials that would be costly and time-consuming and delay or permanently halt our development of the product candidate.

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

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

If Clinical Trials of the Company's Product Candidates Fail to Demonstrate Safety and Efficacy to the Satisfaction of the Regulatory Agencies, the Company May Incur Additional Costs or Experience Delays in Completing or be Unable to Complete the Development and Commercialization of These Product Candidates.

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

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

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

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

If the Company Experiences any of a Number of Possible Unforeseen Events in Connection with Clinical Trials of Our Product Candidates, Potential Marketing Approval or Commercialization of our Product Candidates Could be Delayed or Prevented.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

If the Company Experiences Delays or Difficulties in the Enrollment of Patients in Clinical Trials, We May Not Achieve Our Clinical Development Timeline and our Receipt of Necessary Regulatory Approvals Could be Delayed or Prevented.

We may not be able to initiate or continue clinical trials for our encapsulated live cell/ifosfamide product or any other product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in clinical trials. Patient enrollment is a significant factor in the timing of clinical trials, and is affected by many factors, including:

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

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

Positive Results in Previous Clinical Trials of Our Encapsulated Live Cell/Ifosfamide Product May Not be Replicated in Future Clinical Trials Which Could Result in Development Delays or a Failure to Obtain Marketing Approval.

Positive results in the previous Phase 1/2 clinical trials of the encapsulated live cell/ifosfamide combination may not be predictive of similar results in future clinical trials. Also, interim results during a clinical trial do not necessarily predict final results. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in early-stage development. Our clinical trials may produce negative or inconclusive results and we may decide, or Regulatory Agencies may require us, to conduct additional clinical trials. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain the approval for their products by the Regulatory Agencies.

We May Request Priority Review for Our Product Candidates in the Future. The Regulatory Agencies May Not Grant Priority Review for any of Our Product Candidates. Moreover, even if the Regulatory Agencies Designated such Products for Priority Review, that Designation May Not Lead to a Faster Regulatory Review or Approval Process and, in any Event, Would Not Assure Approval by the Regulatory Agencies.

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

We Believe the Company May in Some Instances be Able to Secure Approval from the Regulatory Agencies to Use Accelerated Development Pathways. If the Company is Unable to Obtain such Approval, the Company May be Required to Conduct Additional Preclinical Studies or Clinical Trials Beyond Those That We Contemplate Which Could Increase the Expense of Obtaining and Delay the Receipt of Necessary Marketing Approvals.

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

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

We May Seek Orphan Drug Exclusivity for Some of Our Product Candidates, and the Company May be Unsuccessful.

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

Orphan Drug Exclusivity may be lost if the Regulatory Agencies determine that the request for designation was materially defective, if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Even if we obtain Orphan Drug exclusivity for a product candidate, that exclusivity may not effectively protect the product candidate from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the Regulatory Agencies can subsequently approve a different drug for the same condition if they conclude that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

A Fast Track Designation by the Regulatory Agencies, even if Granted for any of the Company's Product Candidates, May Not Lead to a Faster Development or Regulatory Review or Approval Process and Does Not Increase the Likelihood that the Company's Product Candidates Will Receive Marketing Approval.

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

A Breakthrough Therapy Designation by the Regulatory Agencies, even if Granted for any of the Company's Product Candidates, May Not Lead to a Faster Development or Regulatory Review or Approval Process and Does Not Increase the Likelihood that the Company's Product Candidates Will Receive Marketing Approval.

We do not currently have Breakthrough Therapy designation for any of our product candidates but may seek such designation. A "Breakthrough Therapy" is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as Breakthrough Therapies, interaction and communication between the Regulatory Agencies and the sponsor can help to identify the most efficient path for development.

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

Failure to Obtain Marketing Approval in International Jurisdictions Would Prevent the Company's Product Candidates from being Marketed Abroad.

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

Any Product Candidate for Which the Company Obtains Marketing Approval Will be Subject to Extensive Post-Marketing Regulatory Requirements and Could be Subject to Post-Marketing Restrictions or Withdrawal from the Market, and the Company May be Subject to Penalties if the Company Fails to Comply with Regulatory Requirements or if the Company Experiences Unanticipated Problems with its Products, when and if any of the Company's Product Candidates Are Approved.

Our product candidates and the activities associated with their development and commercialization, including their testing, manufacture, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the Regulatory Agencies. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, current good manufacturing practices ("cGMP"), requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, including periodic inspections by the Regulatory Agencies, requirements regarding the distribution of samples to physicians and recordkeeping.

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

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

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

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

The Company's Relationships with Customers and Third-Party Payors Will be Subject to Applicable Anti-Kickback, Fraud and Abuse and other Healthcare Laws and Regulations, Which Could Expose the Company to Criminal Sanctions, Civil Penalties, Contractual Damages, Reputational Harm and Diminished Profits and Future Earnings.

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

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

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

- The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; federal law requires applicable manufacturers of covered drugs to report payments and other transfers of value to physicians and teaching hospitals, which includes data collection and reporting obligations. The information is to be made publicly available on a searchable website in September 2014; and analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

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

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

Recently Enacted and Future Legislation Could Increase the Difficulty and Cost for the Company to Obtain Marketing Approval of and Commercialize our Product Candidates and Affect the Prices the Company May Obtain.

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

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

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, "PPACA"), a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Among the provisions of the PPACA of importance to our potential product candidates are the following:

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

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

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

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

Governments outside the United States Tend to Impose Strict Price Controls, which may Adversely Affect the Company's Revenues, if any.

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

Risks Related to the Commercialization of Our Product Candidates

Serious Adverse Events or Undesirable Side Effects or Other Unexpected Properties of the Company's Encapsulated Live Cell/Ifosfamide Product or any of the Company's other Product Candidates May be Identified During Development that Could Delay or Prevent the Product Candidate's Marketing Approval.

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

Even if One of the Company's Product Candidates Receives Marketing Approval, it May Fail to Achieve the Degree of Market Acceptance by Physicians, Patients, Third Party Payors and Others in the Medical Community Necessary for Commercial Success and the Market Opportunity for the Product Candidate May be Smaller than Estimated by the Company.

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

Efforts to educate the medical community and third party payors on the benefits of our product candidates may require significant resources and may not be successful. If any of our product candidates is approved but does not achieve an adequate level of market acceptance, we may not generate significant revenues and we may not become profitable. The degree of market acceptance of our encapsulated live cell/ifosfamide product or any of our other product candidates, if approved for commercial sale, will depend on a number of factors, including:

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

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

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

If any of the Company's Product Candidates Receives Marketing Approval and the Company or Others Later Discover that the Drug is Less Effective than Previously Believed or Causes Undesirable Side Effects that Were Not Previously Identified, the Company's Ability to Market the Drug Could be Compromised.

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

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

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

If the Company is Unable to Establish Sales, Marketing and Distribution Capabilities or Enter into Acceptable Sales, Marketing and Distribution Arrangements with Third Parties, the Company May Not be Successful in Commercializing any Product Candidates that it Develops if and when Those Product Candidates Are Approved.

We do not have a sales, marketing or distribution infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any approved product candidate, we must either develop a sales and marketing organization, outsource these functions to third parties or license our product candidates to others. If approved, we expect to license our encapsulated live cell/ifosfamide product to a large pharmaceutical company with greater resources and experience than us. We may not be able license our encapsulated live cell/ifosfamide product on reasonable terms, if at all. If other product candidates are approved for smaller or easily targeted markets, we expect to commercialize them in the United States directly with a small and highly focused commercialization organization. The development of sales, marketing and distribution capabilities will require substantial resources, will be time-consuming and could delay any product launch. We expect that we will commence the development of these capabilities prior to receiving approval of any of our product candidates. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing and distribution capabilities is delayed or does not occur for any reason, we could have prematurely or unnecessarily incurred these commercialization costs. Such a delay may be costly, and our investment could be lost if we cannot retain or reposition our sales and marketing personnel. In addition, we may not be able to hire or retain a sales force in the United States that is sufficient in size or has adequate expertise in the medical markets that we plan to target. If we are unable to establish or retain a sales force and marketing and distribution capabilities, our operating results may be adversely affected. If a potential partner has development or commercialization expertise that we believe is particularly relevant to one of our product candidates, then we may seek to collaborate with that potential partner even if we believe we could otherwise develop and commercialize the product independently.

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

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

Risks Related to the Company's Dependence on Third Parties

The Company Relies and Expects to Continue to Rely on Third Parties to Conduct its Preclinical Studies and Clinical Trials, and Those Third Parties May Not Perform Satisfactorily, Including Failing to Meet Deadlines for the Completion of Such Studies and Trials.

We currently rely on third party CROs to conduct our clinical trials. We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators to conduct our clinical trials. Our agreements with these third parties generally allow the third party to terminate our agreement with them at any time. If we are required to enter into alternative arrangements because of any such termination, the introduction of our product candidates to market could be delayed.

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

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

We also Expect to Rely on Other Third Parties to Store and Distribute Drug Supplies for Our Clinical Trials. Any Performance Failure on the Part of Our Distributors Could Delay Clinical Development or Marketing Approval of Our Product Candidates or Commercialization of Our Products, Producing Additional Losses and Depriving Us of Potential Product Revenue. The Company's Existing Collaboration with the University of Veterinary Medicine Vienna and Vin-de-Bona is Important to the Company's Business. If the Company is Unable to Maintain this Collaboration, or if this Collaboration is Not Successful, the Company's Business Could be Adversely Affected.

We will soon rely on the University of Veterinary Medicine Vienna for a substantial portion of our preclinical capabilities, including reliance on their employees whom we fund to conduct preclinical development of our product candidates. If there are delays or failures to perform their obligations, our product candidates would be adversely affected. If our collaboration with Vin-de-Bona is unsuccessful or is terminated, we would need to identify a new collaboration partner for our preclinical and clinical development. If we are unsuccessful or significantly delayed in identifying a new collaboration partner, or unable to reach an agreement with such a partner on commercially reasonable terms, development of our product candidates will suffer and our business would be materially harmed.

Furthermore, if Vin-de-Bona changes its strategic focus, or if external factors cause it to divert resources from our collaboration, or if it independently develops products that compete directly or indirectly with our product candidates using resources or information it acquires from our collaboration, our business and results of operations could suffer.

Future Preclinical and Clinical Development Collaborations May be Important to the Company. If the Company is Unable to Maintain these Collaborations, or if these Collaborations Are Not Successful, the Company's Business Could be Adversely Affected.

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

Future collaborations we may enter into may involve the following risks:

- Collaborators may have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- Collaborators may not perform their obligations as expected;
- Changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, may divert resources or create competing priorities;
- Collaborators may delay discovery and preclinical development, provide insufficient funding for product development of targets selected by us, stop or abandon preclinical or clinical development for a product candidate or have to repeat or conduct new preclinical and clinical development for a product candidate;
- Collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed than ours;
- Product candidates may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the development of our product candidates;
- Disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development might cause delays or termination of the preclinical or clinical development or commercialization of product candidates. This might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;

- Collaborators may not properly maintain or defend our intellectual property rights or intellectual property rights licensed to us or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;

- Collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and

- Collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of our product candidates.

Additionally, subject to its contractual obligations to us, if a collaborator of ours is involved in a business combination, the collaborator might deemphasize or terminate the development of any of our product candidates. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the business and financial communities could be adversely affected.

If we are unable to maintain our collaborations, development of our product candidates could be delayed and we may need additional resources to develop them.

We Rely on Dr. Günzburg and Dr. Salmons for the Development of Our Product Candidates. If They Decide to Terminate their Relationship with the Company, We May Not be Successful in the Development of the Company's Product Candidates.

Dr. Günzburg and Dr. Salmons are intimately involved in the scientific endeavors underway and being planned by the Company. These endeavors include preclinical and clinical studies to be conducted in the United States on behalf of the Company. These studies are designed to determine the effectiveness of the Company's pancreatic cancer treatment in ameliorating the unbearable pain that is associated with advanced pancreatic cancer and the effects of the treatment on the rate of accumulation of Malignant Ascites that occurs in patients with this disease. Also in the cancer area, Dr. Günzburg and Dr. Salmons will be intimately involved in the Company's Phase 2b clinical trial that will be conducted in Australia. In addition, they 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. Dr. Günzburg and Dr. Salmons will likewise play a prominent role in the Diabetes Consortium being formed by the Company. They provide professional consulting services to the Company through their consulting company, Vin-de-Bona, pursuant to a Consulting Agreement with us. The Consulting Agreement may be terminated for any reason at any time upon one party giving the other a written notice 30 days prior to the effective date of the termination. If that occurs, we may not be successful in the development of our product candidates which could have a material adverse effect on the Company.

The Company Contracts with Third Parties for the Manufacture of the Company's Product Candidates for Preclinical Studies and Clinical Trials and Expects to Continue to do so for Commercialization. This Reliance on Third Parties Increases the Risk that the Company will Not Have Sufficient Quantities of its Product Candidates or Such Quantities at an Acceptable Cost, Which Could Delay, Prevent or Impair the Company's Development or Commercialization Efforts.

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

Our encapsulated live cell/ifosfamide product and our other product candidates must be manufactured through complex, multi-step synthesis processes that are time-consuming and involve special conditions at certain stages. Biologics and drug substance manufacture requires high potency containment, and containment under aseptic conditions. Any performance failures on the part of our existing or future manufacturers could delay clinical development or marketing approval of our product candidates. Our agreements with our third party manufacturers can be terminated by us or such manufacturers on short notice. If any of our manufacturers should become unavailable to us for any reason, we may incur additional cost or delay in identifying or qualifying replacements. In addition, while we believe that our existing manufacturer, Austrianova Singapore, or an alternative manufacturer would be capable of continuing to produce our product candidates or products, if approved, in commercial quantities, we will also need to identify a third-party manufacturer capable of providing commercial quantities of our products. If we are unable to arrange for such a third-party manufacturing source or fail to do so on commercially reasonable terms, we may not be able to successfully produce and market our encapsulated live cell/ifosfamide product or any other product candidate or may be delayed in doing so.

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

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

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

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

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

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

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

Risks Related to the Company's Intellectual Property

If the Company is Unable to Obtain and Maintain Intellectual Property Protection for its Technology and Products, or if the Scope of the Intellectual Property Protection Obtained is Not Sufficiently Broad, the Company's Competitors Could Develop and Commercialize Technology and Products Similar or Identical to the Company's, and the Company's Ability to Commercialize Successfully its Technology and Products May be Impaired.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary technology and products. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and product candidates. Our patent portfolio includes patents and patent applications we exclusively licensed from Bavarian Nordic/GSF, SG Austria and Austrianova Singapore.

The patent prosecution and/or patent maintenance process is expensive and time-consuming, and we may not be able to file and prosecute or maintain all necessary or desirable patent applications or maintain the existing patents at a reasonable cost or in a timely manner. We may choose not to seek patent protection for certain innovations and may choose not to pursue patent protection in certain jurisdictions. Under the laws of certain jurisdictions, patents or other intellectual property rights may be unavailable or limited in scope. It is also possible that we will fail to identify patentable aspects of our discovery and preclinical development output before it is too late to obtain patent protection. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

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

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

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

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

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

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

Obtaining and Maintaining the Company's Patent Protection Depends on Compliance with Various Procedural, Document Submission, Fee Payment and other Requirements Imposed by Governmental Patent Agencies. The Company's Patent Protection Could be Reduced or Eliminated for Non-Compliance with these Requirements.

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

The Company May Become Involved in Lawsuits to Protect or Enforce the Company's Patents or other Intellectual Property, Which Could be Expensive, Time Consuming and Unsuccessful.

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

The Company May Need to License Certain Intellectual Property from Third Parties, and Such Licenses May Not be Available or May Not be Available on Commercially Reasonable Terms.

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

Third Parties May Initiate Legal Proceedings Alleging that the Company is Infringing their Intellectual Property Rights, the Outcome of Which Would be Uncertain and Could Have a Material Adverse Effect on the Success of the Company's Business.

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

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

The Company May Not be Successful in Obtaining or Maintaining Necessary Rights for its Development Pipeline through Acquisitions and Licenses from Third Parties.

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

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

If the Company is Unable to Protect the Confidentiality of its Trade Secrets, the Company's Business and Competitive Position Would be Harmed.

In addition to seeking patents for some of our technology and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We seek to protect our confidential proprietary information, in part, by entering into confidentiality and invention or patent assignment agreements with our employees and consultants; however, we cannot be certain that such agreements have been entered into with all relevant parties. Moreover, to the extent we enter into such agreements, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets to unaffiliated third parties. We may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

Risk Factors Related to the Company's Stock

The Extent to Which a Trading Market for the Company's Common Stock will Develop or How Liquid that Market Might Become is a Risk to Investors.

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

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

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

Penny Stock Rules May Have an Adverse Effect on the Company.

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

Shareholders should be aware that, according to SEC, the market for penny stocks has suffered in recent years from patterns of fraud and abuse. Such patterns include, but are not limited to:

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

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

The Company Has No Plans to Pay Dividends in the Foreseeable Future, and Investors May Not Expect a Dividend as a Return of or on Any Investment in the Company.

The Company has not paid dividends on its shares of common stock and does not anticipate paying such dividends in the foreseeable future.

The Company's Investors May Suffer Future Dilution Due to Issuances of Additional Shares of Our Common Stock for Various Reasons in the Future.

There may be substantial dilution to the Company's shareholders as a result of future decisions of our Board to issue shares without shareholder approval for cash transactions, services rendered, acquisitions, payment of debt and other permissible reasons. The Company can give investors no assurance that they will be able to sell their shares at or near the prices they ask or at all if they need money or otherwise desire to liquidate their shares.

The Price of the Company's Common Stock is Volatile, Which Substantially Increases the Risk that the Company's Investors May Not be Able to Sell Their Shares at or above the Price that the Investors Have Paid for their Shares.

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

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

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

Risks Related to Employee Matters, Managing Growth and Macroeconomic Conditions

The Company Has a Limited Number of Employees and is Highly Dependent on the Company's Chief Executive and Chief Operating Officers. The Company's Future Success Depends on the Company's Ability to Retain these Officers and other Key Executives and to Attract, Retain and Motivate Qualified Personnel.

We are an early-stage clinical development company with a limited operating history. As of April 30, 2014, we had only four employees, all of whom are executive officers. We are highly dependent on the research and development, clinical and business development expertise of the principal members of our management, scientific and clinical team. Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our discovery, preclinical and clinical development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

The Company Expects to Expand the Company's Development and Regulatory Capabilities and Potentially Implement Sales, Marketing and Distribution Capabilities. As a result, the Company May Encounter Difficulties in Managing its Growth, Which Could Disrupt its Operations.

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

Unfavorable Global Economic Conditions Could Adversely Affect the Company's Business, Financial Condition or Results of Operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, such as the recent global financial crisis, could result in a variety of risks to our business, including our ability to raise additional capital when needed on acceptable terms, if at all. This is particularly true in Europe, which is undergoing a continued severe economic crisis. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

The Company's Business and Operations Would Suffer in the Event of System Failures.

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information under this item.

ITEM 2. PROPERTIES

The Company's offices are located at 12510 Prosperity Drive, Suite 310, Silver Spring, Maryland 20904. All segments of the Company use this property in some manner.

ITEM 3. LEGAL PROCEEDINGS

The Company does not have any material pending legal proceedings as of this filing of this Report.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

PART II

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

Shares of the Company's common stock are quoted and traded on the OTC (www.otcmarkets.com; OTCQB) as a fully reporting Over-The-Counter Bulletin Board company under the classification of OTCQB utilizing the trading symbol "NVLX."

The following table sets forth the high and low bid prices for the Company's shares for each quarter during the two fiscal years ended April 30, 2014 and 2013. The prices reflect inter-dealer prices, without retail mark-up, mark-down or commission and are not intended to represent actual transactions.

Date	**Bid Price**	
FY 2014	HIGH	LOW
First Quarter	$ 0.17	$ 0.10
Second Quarter	$ 0.17	$ 0.11
Third Quarter	$ 0.20	$ 0.09
Fourth Quarter	$ 0.51	$ 0.27
FY 2013	HIGH	LOW
First Quarter	$ 0.07	$ 0.05
Second Quarter	$ 0.07	$ 0.05
Third Quarter	$ 0.04	$ 0.03
Fourth Quarter	$ 0.10	$ 0.03

At April 30, 2014, the market price of the Company's common stock was $0.29 per share.

As of April 30, 2014, there were 690,615,714 issued and outstanding shares of common stock. We are informed and believe these shares are held by 1,311 shareholders of record.

Dividend Policy

The Company has not paid and does not plan to pay cash dividends at this time. The Company's Board of Directors ("Board") will decide any future payment of dividends, depending on the Company's results of operations, financial condition, capital requirements and other relevant factors.

Issuer Purchases of Equity Securities

The Company did not repurchase any of its securities registered under Section 12 of the Exchange Act during the year ended April 30, 2014.

Securities Authorized for Issuance under Equity Compensation Plans

Name	Number of shares or units of stock that have not vested(#)	Market value of shares or units of stock that have not vested($)	Equity incentive plan awards: Number of unearned shares, units or other rights that have not vested(#)	Equity incentive plan awards: Market or payout value of unearned shares, units or other rights that have not vested ($)
Kenneth L. Waggoner	–	–	1,200,000(1)	$348,000(2)
Gerald W. Crabtree	–	–	1,200,000(3)	$348,000(4)
Robert F. Ryan	–	–	2,400,000(5)	$696,000(6)

(1) Represents the number of securities to be issued in the following fiscal year under our oral agreement with Kenneth L. Waggoner to issue him 100,000 shares of common stock each month as compensation for his services as our Chief Executive Officer, President and General Counsel and the Chief Executive Officer and General Counsel of MMS.

(2) Represents the value of the securities to be issued in the following fiscal year under our oral agreement with Kenneth L. Waggoner at the closing price of our common stock on April 30, 2014 of $.29.

(3) Represents the number of securities to be issued in the following fiscal year under our oral agreement with Gerald W. Crabtree to issue him 100,000 shares of common stock each month as compensation for his services as our Chief Operating Officer and the Chief Operating Officer of MMS.

(4) Represents the value of the securities to be issued in the following fiscal year under our oral agreement with Gerald W. Crabtree at the closing price of our common stock on April 30, 2014 of $.29.

(5) Represents the number of securities to be issued in the following fiscal year pursuant to the BOD Consent (defined below) to issue Robert F. Ryan 200,000 shares of common stock each month as compensation for his services as our Chief Executive Officer and President.

(6) Represents the value of the securities to be issued in the following fiscal year under our agreement with Robert F. Ryan at the closing price of our common stock on April 30, 2014 of $.29.

Recent Issuance of Unregistered Securities

On January 21, 2014, the Company sold 7,000,000 shares of common stock to an accredited investor for total cash proceeds of $500,000.

On January 29, 2014, the Company sold 500,000 shares of common stock to an accredited investor for total cash proceeds of $50,000.

On February 4, 2014, the Company sold 100,000 shares of common stock to an accredited investor for total cash proceeds of $10,000.

On February 14, 2014, the Company sold 8,000,000 shares of common stock to Lincoln Park Capital Fund, LLC ("Lincoln Park") for total cash proceeds of $2,000,000.

On February 18, 2014, the Company sold 1,000,000 shares of common stock to an accredited investor for total cash proceeds of $100,000.

On February 26, 2014, the Company sold 50,000 shares of common stock to an accredited investor for total cash proceeds of $5,000.

On February 28, 2014, the Company sold 10,000,000 shares of common stock to an accredited investor for total cash proceeds of $1,000,000.

On March 11, 2014, the Company sold 50,000 shares of common stock to an accredited investor for total cash proceeds of $5,000.

During February 2014, the Company converted outstanding Class A warrants into 15,204,600 shares of common stock for total cash proceeds of $1,140,345.

During March 2014, the Company converted outstanding Class A and Class B warrants into 4,045,000 shares of common stock for total cash proceeds of $359,175.

During April 2014, the Company converted outstanding Class B warrants into 528,000 shares of common stock for total cash proceeds of $63,360.

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

ITEM 6. SELECTED FINANCIAL DATA

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information under this item.

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

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

Results of Operations for the Years Ended April 30, 2014

The Company, through its acquisition of Bio Blue Bird, has successfully completed its first acquisition as a biotechnology company. The Company and the principals of SG Austria worked together for the Company to fully acquire Bio Blue Bird, the now wholly-owned subsidiary of the Company that holds the exclusive worldwide licensing rights to the use of our live cell encapsulation technology for treating pancreatic cancer.

The Company is now actively engaged with Austrianova Singapore and other entities in preparation for new clinical trials for the treatment of pancreatic and other cancers using encapsulated live cells in the previous Phase 1/2 clinical trials. We are working together to advance clinical research and development of new cellular-based therapies in the oncology arena. Due to this significant successful acquisition, the Company business is that of a biotechnology company with a specialty in live cell encapsulation. The Company's present focus is in the oncology and diabetes arenas.

Performance Indicators

As our first key performance indicator, the acquisition of our right to use the live cell encapsulation technology has enabled the company to be in a position to immediately move toward preparations for a clinical trial for treating pancreatic cancer and associated symptoms. Non-financial performance indicators used by management to manage and assess how the business is progressing will include, but are not limited to: (i) the ability to acquire appropriate funding for all aspects of the company operations; (ii) acquire and complete necessary contracts; (iii) complete activities for producing cells and having them encapsulated for the planned preclinical studies and clinical trials; (iv) have regulatory work completed to enable these studies and trials to be submitted to regulatory agencies; (v) initiate all purity and toxicology cellular assessments; and (vi) ensure completion of cGMP produced encapsulated cells ready for clinical trial use.

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

Trends, Liquidity and Capital Expenditures

Our financial statements and related disclosures have been prepared on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. Accordingly, the financial statements do not include any adjustments that might be necessary should we be unable to continue in existence. We have not generated any revenues and have not yet achieved profitable operations. There is no assurance that profitable operations, if ever achieved, could be sustained on a continuing basis. In addition, development activities, preclinical studies, clinical trials and commercialization of our product candidates will require significant additional financing. Our deficit accumulated during the development stage through April 30, 2014 was $68,700,127. Management expects to incur substantial and increasing losses in future periods. Our ability to successfully pursue our business is subject to certain risks and uncertainties, including among others, uncertainty of product development, competition from third parties, uncertainty of capital availability, uncertainty in our ability to enter into agreements with collaborative partners, dependence on third parties and dependence on key personnel. We plan to finance future operations with a combination of proceeds from the issuance of equity, debt, licensing fees, and revenues from future product sales, if any. We have not generated positive cash flows from operations, and there are no assurances that we will be successful in obtaining an adequate level of financing for the development and commercialization of our planned products. We believe that our cash and cash equivalents as of April 30, 2014, combined with our financing described below, will provide for our ability to continue to fund our operations through the end of 2015; however, there can be no assurance in this regard. Such actions primarily include raising additional capital from existing investors or securing additional external financing.

From our present assessments, we do not believe there are trends, events or uncertainties that have, or are reasonably likely to have, a material effect on short-term or long-term liquidity. Overall, the statement of cash flow is the focal point for the Company's liquidity, although the exercising of warrants at appropriate times by investors and officers of the Company will potentially have important positive effects on the liquidity of the Company. Management also believes that the relationships between changes in operating results may induce changes in liquidity, in particular material changes in working capital components as seen by both acquisition of new capital through the "At-the-Market" facility described below and conversion of warrants by present investors and officers of the Company. At present, the Company relies solely on working capital as its liquidity indicator since we do not presently have any open credit lines, although this valuable resource type may at any time become a part of the Company's mechanism(s) for maintenance of its liquidity. Further, as has often been a part of the Company's mechanism(s) to maintain overall liquidity, internal sources of liquidity from others associated with the Company may be utilized if and when needed.

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

On February 14, 2014, the Company entered into a purchase agreement ("Lincoln Park Purchase Agreement") and a registration rights agreement with Lincoln Park pursuant to which Lincoln Park purchased $2,000,000 of our common stock and the Company had the right to sell to Lincoln Park up to $25,000,000 in shares of additional common stock, subject to certain limitations.

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

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

Pursuant to the Lincoln Park Termination Agreement, Lincoln Park consented to the entry into of the Chardan Agreement, so long as there are no provisions within the Chardan Agreement that in any manner, directly or indirectly, limit Lincoln Park's ability to carry out or effect the sale of shares of common stock pursuant to a registration statement or otherwise, or in any manner, directly or indirectly, conflict with the surviving obligations under the Lincoln Park Termination Agreement. The Company has issued 1,062,500 shares of its common stock to Lincoln Park in connection with the Lincoln Park Termination Agreement.

With the proceeds received upon the sale of shares of common stock to Lincoln Park and by adjusting the Company's operations and through bridge financing being provided by new investors and existing shareholders, the Company has been able to maintain sufficient capital resources to meet projected cash flow needs. Failure by the Company to generate sufficient liquidity from operations or in raising sufficient capital resources on acceptable terms may have a materially adverse effect on the Company's business, results of operations, liquidity and financial condition.

As of April 30, 2014, we had successfully eliminated the amount of its remaining debt from prior company operations.

We have no off-balance sheet arrangements, special purpose entities, financing partnerships or guarantees

Year ended April 30, 2014 compared to year ended April 30, 2013

Revenue

The report on the revenue indicates a net loss from operations for the year ending April 30, 2014 compared to 2013, increasing $17,294,781 from $1,684,361 to $18,979,142 as a result of multiple factors. Of the expenses during the current year that contributed to the large increase in the loss from operations $768,000 was non-cash expense for stock issued to directors, $13,333,788 was non-cash expense for stock issued to officers for compensation and $3,826,521 was non-cash expense for stock issued for other services. In addition, there was no revenue generated during the year as the Company determined to commit all of the funds to maintain the Company and acquire the necessary components and personnel for its biotechnology operations going forward.

Selling, General and Administrative Expenses

The overall general and administrative expenses during the year ended April 30, 2014 compared to the year ended April 30, 2013, increased $1,624,008 to $2,241,279 from $617,271 in the prior year. The increased can be attributed to increased travel expense and stock issued for services.

Loss from Continuing Operations

For the year ended April 30, 2014, net loss increased $25,655,918 to $27,254,020 compared to $1,598,102 in the prior year. The large increase in the net loss can be attributed to the non-cash expense of stock issued for compensation and services as discussed above as well as a $5,895,000 loss on the conversion of preferred stock and a loss of $3,993,295 on the settlement of debt.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

NUVILEX, INC.
CONTENTS

ROBISON, HILL & CO.
A PROFESSIONAL
CORPORATION

Certified Public Accountants

DAVID O. SEAL, CPA
W. DALE WESTENSKOW, CPA
BARRY D. LOVELESS, CPA
STEPHEN M. HALLEY, CPA

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTANTS

To the Board of Directors and Stockholders of
Nuvilex, Inc. and Subsidiaries

We have audited the accompanying consolidated balance sheets of Nuvilex, Inc. and Subsidiaries as of April 30, 2014 and 2013, and the related consolidated statements of operations, stockholders' equity (deficit) and cash flows for the years ended April 30, 2014 and 2013. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Nuvilex, Inc. and Subsidiaries as of April 30, 2014 and 2013 and the results of its operations and its cash flows for the years ended April 30, 2014 and 2013, in conformity with accounting principles generally accepted in the United States of America.

Date: August 1, 2014

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

NUVILEX, INC.
CONSOLIDATED BALANCE SHEETS

	April 30, 2014	2013
ASSETS		
Cash	$ 3,616,470	$ 199,303
Prepaid on acquisition	–	1,520,980
Prepaid and other assets	570,106	127,870
Total Current Assets	4,186,576	1,848,153
Licenses and patents	3,549,427	–
Investment in SG Austria	1,572,193	–
Other assets	7,854	–
Settlement obligation asset (see Note 14)	–	1,028,778
Total Assets	$ 9,316,050	$ 2,876,931
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current Liabilities		
Accounts payable	$ 188,044	$ 351,996
Accrued expenses	7,803	12,300
Accrued interest, related party	33,960	52,259
Due to related parties	–	419,583
Due to an officer	143,859	201,143
Settlement obligation liabilities (see Note 14)	–	2,341,106
Loans payable	–	420,000
Total Current Liabilities	373,666	3,798,387
Long-term Liabilities		
Long-term debt, related party	–	–
Total Liabilities	373,666	3,798,387
Commitments and Contingencies		
Preferred stock, authorized 10,000,000 shares, $0.0001 par value, 0 and 8,500 shares issued, and outstanding, respectively	–	580,000
Stockholders' Equity (Deficit)		
Common stock, authorized 1,490,000,000 shares, $0.0001 par value, 690,615,714 and 482,106,348 shares issued and outstanding, respectively	69,063	48,211
Additional paid in capital	75,998,588	39,896,440
Common stock to be issued	1,574,860	–
Accumulated deficit	(68,700,127)	(41,446,107)
Total Stockholders' Equity (Deficit)	8,942,384	(1,501,456)
Total Liabilities and Stockholders' Equity (Deficit)	$ 9,316,050	$ 2,876,931

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

NUVILEX, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Years Ended April 30,	
	2014	**2013**
Revenues:		
Product sales	$ –	$ 12,160
Total revenue	–	12,160
Cost of revenues	–	9,620
Gross margin	–	2,540
Expenses:		
Sales and marketing	872,200	106,413
Compensation expense	13,609,995	678,707
Director fees	768,000	–
Legal & professional fees	1,487,668	284,510
General and administrative	2,241,279	617,271
Total operating expenses	18,979,142	1,686,901
Net loss from operations	(18,979,142)	(1,684,361)
Other income (expense):		
Gain on forgiveness of debt	1,633,380	277,085
Loss on conversion of preferred stock	(5,895,000)	
Loss on settlement of debt	(3,993,295)	(39,000)
Other income	–	2,590
Interest income	1,090	–
Interest expense, related party	(16,023)	(41,754)
Interest expense	(5,030)	(112,662)
Total other income (expense)	(8,274,878)	86,259
Net loss	$ (27,254,020)	$ (1,598,102)
Basic loss per share	$ (0.05)	$ (0.00)
Weighted average shares outstanding	583,219,665	440,954,850

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

NUVILEX, INC.
CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT)

	Common Stock Shares	Common Stock Amount	Additional Paid In Capital	Common Stock Not Yet Issued	Accumulated Deficit	Total
Balance, April 30, 2012	416,293,195	$ 41,631	$37,526,524	$ –	$ (39,848,005)	$ (2,279,850)
Shares issued for compensation	13,326,668	1,332	652,364	–	–	653,696
Shares issued for services	8,771,429	877	330,123	–	–	331,000
Shares issued for settlement of debt	3,592,656	359	143,237	–	–	143,596
Shares issued for PPM	39,622,400	3,962	1,234,242	–	–	1,238,204
Shares issued for cash	500,000	50	9,950	–	–	10,000
Net loss for the year ended April 30, 2013	–	–	–	–	(1,598,102)	(1,598,102)
Balance, April 30, 2013	482,106,348	48,211	39,896,440	–	(41,446,107)	$ (1,501,456)
Shares issued for compensation	44,370,000	4,437	13,329,351	–	–	13,333,788
Shares issued for Director fees	8,000,000	800	767,200	–	–	768,000
Shares issued for services	18,819,166	1,882	3,813,139	11,500	–	3,826,521
Shares issued for settlement of debt	28,670,600	2,868	4,780,803	–	–	4,783,671
Shares issued for cash	35,000,000	3,500	5,414,500	1,500,000	–	6,918,000
Conversion of warrants	19,649,600	1,965	1,527,555	63,360	–	1,592,880
Conversion of preferred stock	54,000,000	5,400	6,469,600	–	–	6,475,000
Net loss for the year ended April 30, 2014	–	–	–	–	(27,254,020)	(27,254,020)
Balance, April 30, 2014	690,615,714	$ 69,063	$75,998,588	$ 1,574,860	$ (68,700,127)	$ (8,942,384)

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

NUVILEX, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Years Ended April 30, 2014	2013
Cash flows from operating activities:		
Net loss	$ (27,254,020)	$ (1,598,102)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock issued for services	17,928,309	984,696
Loss on settlement of debt	3,993,295	39,000
Loss on conversion of preferred stock	5,895,000	
Gain on forgiveness of debt	(1,633,380)	(277,085)
Stock issued for interest expense	–	102,203
Net amortization of discount/premium	–	(5,695)
Change in assets and liabilities:		
(Increase) / decrease in accounts receivable	–	2,581
(Increase) / decrease in inventory	–	6,846
(Increase) / decrease in prepaid expenses	(442,236)	62,667
Increase (decrease) in accounts payable	(59,191)	97,708
Increase in accrued interest, related party	16,012	40,798
Increase in accrued expenses	1,503	153,957
Increase in other assets	(7,854)	–
Net cash used in operating activities	(1,562,562)	(390,426)
Cash flows from investing activities:		
Purchase of licenses	(3,500,000)	(646,750)
Payments towards acquisition	(51,215)	–
Net cash used by investing activities	(3,551,215)	(646,750)
Cash flows from financing activities:		
Proceeds from the sale of common stock	8,510,880	1,146,000
Proceeds from borrowings, related party	81,586	149,756
Repayment of debt, related party	(61,522)	(75,000)
Net cash provided by financing activities	8,530,944	1,220,756
Net increase in cash	3,417,167	183,580
Cash at beginning of period	199,303	15,723
Cash at end of period	$ 3,616,470	$ 199,303
Supplementary non-cash disclosures:		
Cash paid for interest	$ 4,117	$ –
Franchise and income taxes	$ –	$ –
Common stock issued for debt	$ 765,981	$ 143,596

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

NUVILEX, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 – BACKGROUND, ACQUISITION AND LIQUIDITY

Historical Overview of the Company

Past Nutraceutical Company

The Company was founded as DJH International, Inc. on October 28, 1996. It changed its name to eFoodSafety.com, Inc. following the October 16, 2000 acquisition of Global Procurement Systems, Inc. The Company acquired Ozone Safe Food, Inc. for common stock on October 29, 2003. The Company's business plan was to provide methods and products to ensure safety of marketed fruits and vegetables worldwide. On February 4, 2004, the Company registered shares of common stock with the SEC. It began publicly trading on the OTC Bulletin Board under the trading symbol EFSF.

With unrealized demand for the Company's produce sterilization methods and software tracking products, the Company changed its business plan and acquired Knock-Out Technologies, Ltd. and MedElite, Inc. in May 2004 and August 2005, respectively. Knock-Out Technologies, Ltd. was a developer of natural products using organic, non-toxic, food grade material. MedElite, Inc. was the exclusive distributor of Talsyn™-CI Scar Cream in the United States, a topical scar- reducing cream. The Company's strategy was to market nutraceutical products. The Company sold its Ozone Safe Food, Inc. operations in August 2005. In November 2006, the Company formed: (i) Cinnergen, Inc. to manufacture and market a non-prescription liquid nutritional supplement designed to promote healthy glucose metabolism; and (ii) purEffect, Inc. to manufacture and market purEffect™, a four-step non-prescription acne treatment. On March 10, 2006, the Company licensed the marketing rights for purEffect™ to Charlston Kentrist 41 Direct, Inc. ("CK41"). In July 2007, the Company formed, I-Boost to market products to support the immune system. In March 2008, Cinnechol, Inc. was formed to promote cardiovascular health. In February 2009, the Company sold the rights to the purEffect™ product to CK41 for an equity position in CK41 and future royalty compensation. In March 2009, Freedom2 Holdings, Inc. was acquired to manufacture and market products including Infinitink®, a permanent tattoo ink designed to be easily removed.

On January 20, 2009, the Company changed its name to Nuvilex, Inc. Its trading symbol on the OTC Bulletin Board® was also changed to NVLX.

Current Biotechnology Company

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

Through two addenda to the SG Austria APA, the closing dates were extended. In June 2013, the Company and SG Austria entered into a Third Addendum to the SG Austria APA ("Third Addendum"). Under the terms of the Third Addendum, the transaction contemplated by the SG Austria APA changed substantially. The Third Addendum provides that the Company is 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 is to receive nine bearer shares of Bio Blue Bird. Under the Third Addendum, the Company paid: (i) $500,000 to retire all outstanding debt of Bio Blue Bird; and (ii) $1.0 million to SG Austria. The Company also paid SG Austria $1,572,193 in 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. The licenses are pursuant to patents licensed from Bavarian Nordic A/S and GSF-Forschungszentrum fur Umwelt u. Gesundeit GmbH. These licenses enable the Company to carry out the research and development of cancer treatments that are based upon the live cell encapsulation technology known as "Cell-in-a-Box®."

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

NOTE 2 – CAPITALIZATION AND MANAGEMENT PLANS

Capitalization

The Company's financial statements are prepared using generally accepted accounting principles in the United States ("GAAP") applicable to a going concern which contemplates the realization of assets and liquidation of liabilities in the normal course of business. As of April 30, 2014, the Company has an accumulated deficit of $68,700,127 and incurred a net loss for year ended April 30, 2014 of $27,254,020.

Over the past year, funding was provided by management and investors to maintain and expand the Company and acquire Bio Blue Bird. As of April 30, 2014, new investors enabled the completion of the acquisition of Bio Blue Bird which provided the Company the ability to begin preparations toward further clinical trials in patients with advanced, inoperable pancreatic cancer. The remaining challenges, beyond the regulatory and clinical aspects, include accessing funding for the Company to cover its future cash flow needs. The Company continues to acquire additional funds through management's efforts.

The Company requires substantial additional capital to finance its planned business operations and expects to incur operating losses in future periods due to the expenses related to the Company's core businesses. The Company has not realized material revenue since it commenced doing business in the biotechnology sector, and it is not without doubt that it will be successful in generating revenues in the future in this sector. The Company believes that cash and cash equivalents as of April 30, 2014 are sufficient to fund their operations through the end of 2015.

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

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

Management Goals and Strategy

The Company has been working closely with the SG Austria to advance the Cell-in-a-Box® technology. The majority of funding over the past year has been provided to SG Austria and Austrianova Singapore and its personnel to ensure their functionality and maintain their ability to accomplish numerous goals of the Company. After substantial effort, the principals of Nuvilex and SG Austria succeeded in creating mechanisms to advance the Company's interest in the platform technology of Cell-in-a-Box® our companies regardless of the present economic conditions and challenges. Austrianova Singapore will be manufacturing the encapsulated live cells for the Company's use for its pancreatic cancer and diabetes clinical trials.

The Company's strategy is to build upon and advance the success of the previous Phase 1/2 pancreatic cancer clinical trials. The acquisition of Bio Blue Bird was the first step in this strategy. This acquisition enabled the Company to advance itself as a biotechnology company. Management believes the Company is positioned to move forward and become a significant biotech company predicated upon its platform technology, Cell-in-a-Box®. Management is committed to becoming an industry-leading biotechnology company in the treatment of cancer and diabetes.

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 consists of the following:

- The completion of the preparations for the Phase 2b clinical trial in advanced pancreatic cancer to be carried out in Australia;
- The conducting by Translational Drug Development in the United States of preclinical studies and clinical trials that 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;
- The enhancement of the Company's ability to expand into the biotechnology arena through 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 and joint ventures with other companies; and
- The completion of testing, expansion and marketing of existing and newly derived Company products and their uses.

In August 2013, the Company restructured corporate operations in an effort to focus on its biotechnology core businesses. The restructuring was precipitated by the Third Addendum to the SG Austria APA and the Company's acquisition of Bio Blue Bird. The Company restructured itself and created three new segments, two of which are biotechnology segments. The first of these houses the cellulose-based live cell encapsulation technology and all of its associated licenses in the Company. The second, Medical Marijuana Sciences, Inc. ("MMS"), focuses on ways to exploit the benefits of the Cell-in-a-Box® technology in optimizing the anticancer effectiveness of 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 all of its assets to one or more third parties.

NOTE 3 – SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

The accompanying financial statements include the accounts of the Company and its subsidiaries as of April 30, 2014: Freedom-2 Holdings, Inc., Freedom-2, Inc., MedElite, Inc., Bio Blue Bird and MMS. All significant inter-company balances and transactions have been eliminated in consolidation. See Note 4 for further discussion on consolidation.

Cash and Cash Equivalents

For purposes of the statement of cash flows, the Company considers all highly liquid debt instruments purchased with a maturity of three months or less to be cash equivalents to the extent the funds are not being held for investment purposes. There were no cash equivalents as of April 30, 2014.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Property and Equipment

Property and equipment are recorded at cost. Expenditures that increase the useful lives or capacities of the plant and equipment are capitalized. Expenditures for repairs and maintenance are charged to income as incurred. Depreciation is provided using the straight-line method over the estimated useful lives as follows:

- Computer equipment/software - 3 years
- Furniture and fixtures - 7 years
- Machinery and equipment - 7 years
- Building improvements - 15 years
- Building - 40 years

Goodwill and other Indefinite-Lived Intangibles

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

Valuation of Long-Lived Assets

The Company accounts for the valuation of long-lived assets under the FASB standard for accounting for the impairment or disposal of Long-Lived Assets. The FASB standard requires that long-lived assets and certain identifiable intangible assets be reviewed for impairment whenever events or circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of the long-lived assets is measured by a comparison of the carrying amount of the asset to future undiscounted net cash flows generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the estimated fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value, less cost to sell.

Basic and Diluted Earnings (Loss) per Share

Basic and diluted earnings per share is calculated using the weighted-average number of common shares outstanding during the period without consideration of the dilutive effect of stock warrants, convertible notes and convertible preferred shares. All outstanding warrants are convertible into 57,665,600 shares of common stock.

Fair Value of Financial Instruments

For certain of the Company’s non-derivative financial instruments, including cash and cash equivalents, receivables, accounts payable and other accrued liabilities, the carrying amount approximates fair value due to the short-term maturities of these instruments. The estimated fair value of long-term debt is based primarily on borrowing rates currently available to the Company for similar debt issues. The fair value approximates the carrying value of long-term debt.

Accounting Standards Codification ("ASC") Topic 820, “Fair Value Measurements and Disclosures,” requires disclosure of the fair value of financial instruments held by the Company. ASC Topic 825, “Financial Instruments,” defines fair value, and establishes a three-level valuation hierarchy for disclosures of fair value measurement that enhances disclosure requirements for fair value measures. The carrying amounts reported in the consolidated balance sheets for receivables and current liabilities each qualify as financial instruments and are a reasonable estimate of their fair values because of the short period of time between the origination of such instruments and their expected realization and their current market rate of interest. The three levels of valuation hierarchy are defined as follows:

- Level 1. Observable inputs such as quoted prices in active markets;
- Level 2. Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and
- Level 3. Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

The following presents the gross value of assets and liabilities that were measured and recognized at fair value as of April 30, 2014.

- Level 1: none
- Level 2: none
- Level 3: none

Effective October 1, 2008, the Company adopted ASC subtopic 820-10, Fair Value Measurements and Disclosures ("ASC 820-10") and Accounting Standards Codification subtopic 825-10, Financial Instruments ("ASC 825-10"), which permits entities to choose to measure many financial instruments and certain other items at fair value. Neither of these statements had an impact on the Company's financial position, results of operations or cash flows. The carrying value of cash, accounts payable and accrued expenses, as reflected in the balance sheets, approximate fair value because of the short-term maturity of these instruments.

Recent Accounting Pronouncements

In February 2013, the Financial Accounting Standards Board issued Accounting Standards Update (ASU) No. 2013-02, *Comprehensive Income (Topic 220): Reporting of Amounts Reclassified out of Accumulated Other Comprehensive Income*, to improve the transparency of reporting these reclassifications. Other comprehensive income includes gains and losses that are initially excluded from net income for an accounting period. Those gains and losses are later reclassified out of accumulated other comprehensive income into net income. The amendments in the ASU do not change the current requirements for reporting net income or other comprehensive income in financial statements. All of the information that this ASU requires already is required to be disclosed elsewhere in the financial statements under GAAP. The new amendments will require an organization to:

- Present (either on the face of the statement where net income is presented or in the notes) the effects on the line items of net income of significant amounts reclassified out of accumulated other comprehensive income - but only if the item reclassified is required under GAAP to be reclassified to net income in its entirety in the same reporting period; and

- Cross-reference to other disclosures currently required under GAAP for other reclassification items (that are not required under GAAP) to be reclassified directly to net income in their entirety in the same reporting period. This would be the case when a portion of the amount reclassified out of accumulated other comprehensive income is initially transferred to a balance sheet account (e.g., inventory for pension-related amounts) instead of directly to income or expense.

The amendments apply to all public and private companies that report items of other comprehensive income. Public companies are required to comply with these amendments for all reporting periods (interim and annual). The amendments are effective for reporting periods beginning after December 15, 2012, for public companies. Early adoption is permitted. The adoption of ASU No. 2013-02 is not expected to have a material impact on our financial position or results of operations.

In July 2013, the FASB issued Accounting Standards Update 2013-11 Income Taxes (Topic 740) Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carry-forward, a Similar Tax Loss, or a Tax Credit Carry-forward Exists. An unrecognized tax benefit, or a portion of an unrecognized tax benefit, should be presented in the financial statements as a reduction to a deferred tax asset for a net operating loss carry-forward, a similar tax loss or a tax credit carry-forward, except as follows. To the extent a net operating loss carry-forward, a similar tax loss or a tax credit carry-forward is not available at the reporting date under the tax law of the applicable jurisdiction to settle any additional income taxes that would result from the disallowance of a tax position or the tax law of the applicable jurisdiction does not require the entity to use, and the entity does not intend to use the deferred tax asset for such purpose, the unrecognized tax benefit should be presented in the financial statements as a liability and should not be combined with deferred tax assets. The assessment of whether a deferred tax asset is available is based on the unrecognized tax benefit and deferred tax asset that exist at the reporting date and should be made presuming disallowance of the tax position at the reporting date. This Update applies to all entities that have unrecognized tax benefits when a net operating loss carry-forward, a similar tax loss, or a tax credit carry-forward exists at the reporting date. The amendments in this Update are effective for fiscal years, and interim periods within those years, beginning after December 15, 2013.

The Company has implemented all new accounting pronouncements that are in effect. These pronouncements did not have any material impact on the financial statements unless otherwise disclosed, and the Company does not believe that there are any other new accounting pronouncements that have been issued that might have a material impact on its financial position or results of operations.

Revenue Recognition

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

Income Taxes

Deferred taxes are calculated using the liability method whereby deferred tax assets are recognized for deductible temporary differences and operating loss and tax credit carry forwards and deferred tax liabilities are recognized for taxable temporary differences. Temporary differences are the differences between the reported amounts of assets and liabilities and their tax bases. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. Deferred tax assets and liabilities are adjusted for the effects of changes in tax laws and rates on the date of enactment.

In June 2006, the FASB interpreted its standard for accounting for uncertainty in income taxes, an interpretation of accounting for income taxes. This interpretation clarifies the accounting for uncertainty in income taxes recognized in an entity's financial statements in accordance the minimum recognition threshold and measurement attributable to a tax position taken on a tax return is required to be met before being recognized in the financial statements.

Research and Development Costs

Expenditures for research and development are expensed as incurred. Such costs are required to be expensed until the point that technological feasibility is established.

Concentration of Credit Risk

The Company has no significant off-balance-sheet concentrations of credit risk such as foreign exchange contracts, options contracts or other foreign hedging arrangements. The Company maintains the majority of its cash balances with one financial institution in the form of demand deposits.

NOTE 4 – BUSINESS ACQUISITION

As of April 30, 2014, the Company had completed the purchase of Bio Blue Bird. Shares for both Austrianova Singapore and the Company originally held in escrow under the SG Austria APA have been released from escrow and returned to the respective original owners, with the 100,000,000 shares of common stock having been returned to the treasury of the Company. Bio Blue Bird is now a wholly owned subsidiary of the Company.

NOTE 5 – DEBT

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

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

NOTE 6 – COMMON STOCK TRANSACTIONS

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

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

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

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

During the year ended April 30, 2013 the company issued 39,622,400 shares of common stock for $1,136,000 proceeds sold through the Company's Private Placement Memorandum and $102,203 of related interest expense. All shares were issued without registration under the Securities Act of 1933, as amended (“Securities Act”), in reliance upon the exemption afforded by Section 4(2) of that Act. No underwriters were involved.

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

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

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

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

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

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

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

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

NOTE 7 – PREFERRED STOCK

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

- Series E Preferred Stock does not bear any dividends;
- Each share of Series E Preferred Stock is entitled to receive its share of assets distributable upon the liquidation, dissolution or winding up of the affairs of the Company. The holders of the Series E Preferred Stock are entitled to receive cash out of the assets of the Company before any amount is paid to the holders of any capital stock of the Company of any class junior in rank to the shares of Series E Preferred Stock;
- Each share of Series E Preferred Stock is convertible, at the holder's option, into shares of common stock, at the average closing bid price of the common stock for five trading days prior to the conversion date; and
- At every meeting of stockholders, every holder of shares of Series E Preferred Stock is entitled to 50,000 votes for each share of Series E Preferred Stock, with the same and identical voting rights as a holder of a share of common stock; therefore, the holder of shares of Series E Preferred Stock can effectively increase the Company issued common stock shares without a vote of the common stock shareholders, thus enabling any potential shortfall of authorized common stock outstanding from being converted should a holder of Series E Preferred Stock wish to convert.

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

Holders of Series E Preferred Stock have specific rights to be paid in cash out of the assets of the Company prior to any junior class of common stock. As a result of the obligations for Series E Preferred Stock, the Company has determined these redemption features have the potential to be outside the control of the Company and, therefore, the Company has classified the Series E Preferred Stock outside of shareholder's equity in accordance with ASC 480 regarding instruments with debt and equity features. Thus, the full value for the convertible Series E Preferred Stock was recorded outside of stockholders' equity in the accompanying unaudited consolidated balance sheet.

NOTE 8 – WARRANTS

A summary of the status of the Company's outstanding warrants for common stock as of April 30, 2014 and 2013 and changes during the periods is presented below:

	Warrants	Weighted Average Price	Weighted Average Fair Value
Outstanding, April 30, 2013	59,433,600	$ 0.125	$ 0.064
Exercised	(1,768,000)	–	–
Issued	–	–	–
Outstanding, April 30, 2014	57,665,600	0.18	0.065
Exercisable, April 30, 2014	57,665,600	$ 0.18	$ 0.065

Range of Exercise Prices	Number Outstanding at 4/30/14	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price
$0.075, $0.12, $0.18 and $0.25	57,665,600	3.6	$ 0.18

On January 21, 2014, the Company began the implementation of its "Warrant Conversion Program". The program consists of having every PPM investor convert his or her Class A warrants, with a conversion price of $0.075 per share, into shares of common stock and receive an equal number of new Class D warrants, with a conversion price of $0.25 per warrant share. As of April 30, 2014, 18,755,200 Class A warrants were converted for total cash proceeds of $1,380,720 and conversion of $25,920 of debt to an officer. The Company has also begun to convert its Class B warrants, with a conversion price of $0.12 per share, into shares of common stock. As of April 30, 2014, 1,768,000 Class B warrants were converted for total cash proceeds of $212,160.

NOTE 9 – LEGAL PROCEEDINGS

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

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

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

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

The Company's wholly owned subsidiary Freedom-2, Inc. and Brown University are parties to an Intellectual Property License Agreement dated May 16, 2009. Brown University asserted a claim against the Company and Freedom-2, Inc. for $400,000 under the Property License Agreement. Although the Company and Freedom-2, Inc. denied liability, they nevertheless wanted to resolve the dispute without becoming embroiled in time consuming and costly litigation. Effective December 9, 2013 a settlement agreement was entered into between Brown University, the Company and Freedom-2, Inc. pursuant to which the parties released each other for all claims relating to the Property License Agreement. In addition, the Company agreed to issue 2,000,000 shares of common stock to Brown University to consummate the settlement. The shares of common stock have been issued and the mutual general releases between the parties are in effect.

NOTE 10 – RELATED PARTY TRANSACTIONS

As of April 30, 2013 the Company owed a shareholder $393,158. During May 2013, the Company received additional loans of $77,853 from that shareholder. In May 2013, the Company issued 26,000,000 shares of common stock in exchange for debt of $471,010 and accrued interest of $31,095. The shares were valued using the closing price of the common stock on the day of issuance for a total of $4,475,000 resulting in a loss on settlement of debt of $3,973,795.

As of April 30, 2013, the Company owed $227,569 to two of its officers. The loans accrue interest at 8% and are due on demand. During the year ended April 30, 2014 the Company repaid $27,317 of principle and interest to one of the officers satisfying that debt in full. As of April 30, 2014 the Company owed $140,143 of principle and $33,960 of accrued interest to the other officer.

As of April 30, 2014, the Company owed its CEO $3,717 for reimbursement of travel expenses.

NOTE 11 – COMMITMENTS & CONTINGENCIES

Operating Lease

The Company currently leases office space at 12510 Prosperity Drive, Suite 310, Silver Spring, Maryland 20904. The current lease is due to expire on July 31, 2016. Rent expense for the years ended April 30, 2014 and 2013 was $49,085 and $56,763, respectively.

Year	Amount
FY 2015	$ 49,629
FY 2016	51,117
Thereafter	12,873
	$ 113,619

NOTE 12 - INCOME TAXES

Net deferred tax assets consist of the following components as of April 30:

	2014	2013
NOL	$ (36,638,304)	$ (35,372,287)
Net Loss	(27,254,020)	(1,598,102)
Shares issued for services	17,928,309	984,696
Shares issued for interest expense	–	102,203
Amortization of Debt Discount	–	(5,695)
Loss on conversion of debt	3,993,295	39,000
Loss on conversion of preferred stock	5,895,000	–
Gain on forgiveness of debt	(1,633,380)	(277,085)
NOL	$ (37,709,100)	$ (36,638,304)
Effective Rate	0.34	0.34
Deferred Tax Asset	(12,821,094)	(12,457,023)
Valuation Allowance	12,821,094	12,457,023
Deferred Tax Asset	$ –	$ –

The FASB's interpretation had no material impact on the Company's financial statements for the year ended April 30, 2014. As of April 30, 2014, the Company had a net operating loss carry forward for income tax reporting purposes of approximately $37,700,000 that may be offset against future taxable income through 2033. Furthermore, during the year ended April 30, 2014 there was an increase in the valuation allowance of $364,071. Current tax laws limit the amount of loss available to be offset against future taxable income when a substantial change in ownership occurs. Therefore, the amount available to offset future taxable income may be limited. No tax benefit has been reported in the financial statements, because the Company believes there is a 50% or greater chance the carry forwards will expire unused. Accordingly, the potential tax benefits of the loss carry forwards are offset by a valuation allowance of the same amount.

NOTE 13 – SUBSEQUENT EVENTS

The Company has performed an evaluation of subsequent events in accordance with ASC Topic 855, noting no additional subsequent events other than the following:

Subsequent to April 30, 2014, the Company issued 17,628,000 shares of common stock satisfying its stock payable in full.

On May 28, 2014 the Company and Lincoln Park executed a termination agreement releasing each other of certain obligation under its stock purchase agreement between Lincoln Park and the Company. The termination agreement provided: (i) the representations and warranties of Lincoln Park and the Company contained in the stock purchase agreement; (ii) the covenants regarding “Variable Rate Transactions” contained in the stock purchase agreement (“Variable Rate Covenants”); (iii) the indemnification provisions set forth in Section 9 of the stock purchase agreement; (iv) the agreements and covenants set forth in the stock purchase agreement regarding notice, governing law and certain other related administrative provisions; and (v) the obligations of the Company to register for resale all 14,125,000 shares of common stock currently owned by Lincoln Park each survive such termination and continue in full force and effect indefinitely, and provided further that the Variable Rate Covenants will terminate upon the earlier of the one year anniversary of the effectiveness of the registration statement referred to in the stock purchase agreement and the date on which Lincoln Park has sold all of its shares of common stock. Pursuant to the termination agreement, Lincoln Park consented to the Company entering into the Chardan Agreement, so long there are no provisions within the Chardan Agreement that in any manner, directly or indirectly, limit Lincoln Park’s ability to carry out or effect the sale of shares of common stock pursuant to a registration statement or otherwise, or in any manner, directly or indirectly, conflict with the surviving obligations under the termination agreement and the Company and Chardan execute the Chardan Agreement within three calendar days from the effective date of the Chardan Agreement and the Company files a Form 8-K to report this transaction within four business days of the Chardan Agreement’s execution date.

As consideration for terminating the stock purchase agreement, the Company issued Lincoln Park an additional 1,062,500 shares of common stock. These shares were valued at $0.28 per share (the closing price of the common stock on May 30, 2014) for non-cash expense of $297,500.

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

On May 29, 2014, an investor converted 550,000 shares of Class B warrants for $66,000.

As discussed above, the Company acquired 100% of the shares and assets of Bio Blue Bird, including its Intellectual property related to the "Cell-in-a-Box® live cell encapsulation technology. In that same transaction, the Company also received a 14.5% ownership in SG Austria. The Company also entered into a Licensing Agreement with Austrianova Singapore for the treatment of diabetes utilizing the Cell-in-a-Box® technology ("Diabetes Licensing Agreement"). Under the Diabetes Licensing Agreement, the Company was granted an exclusive worldwide license to use the Cell-in-a-Box® trademark and its associated technology specifically addressing insulin and other critical component production for the treatment of diabetes. The Company has retained Vantage Point Advisors, Inc. ("VPAI"), to perform a valuation analysis of its contingent payment liability associated with the future milestone and royalty payments stemming from the Diabetes Licensing Agreement. The Company has also retained VPAI to perform a valuation analysis of its 14.5% ownership interest in SG Austria. These two valuations are currently underway and will be completed in the near term. Based upon the results of these valuations, the Company will adjust the value of its assets as required.

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

There are not and have not been any disagreements between us and our accountants on any matter of accounting principles, practices or financial statement disclosure.

ITEM 9A. CONTROLS AND PROCEDURES

The Company's management, including the Chief Executive Officer, President and General Counsel of the Company, as its principal executive officer, and the Chief Financial Officer of the Company, as its principal financial officer (collectively, "Principal Executive Officers"), have evaluated the effectiveness of the Company's "disclosure controls and procedures," as such term is defined in Rule 13a-15(e) promulgated under the Exchange Act. Based upon this evaluation, the Principal Executive Officers have concluded that, as of April 30, 2014, the Company's disclosure controls and procedures were effective for the purpose of ensuring that the information required to be disclosed in the reports that the Company files or submits to the SEC pursuant to the Exchange Act is recorded, processed, summarized and reported within the time period specified by the SEC's rules and forms and is accumulated and communicated to the Company's management, including its Principal Executive Officer, as appropriate to allow timely decisions regarding required disclosures.

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

Management's Report on Internal Control over Financial Reporting

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

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

Under the supervision and with the participation of the Principal Executive Officers, management conducted an evaluation of the effectiveness of its internal control over financial reporting as of April 30, 2014 and identified the following material weaknesses in internal control over financial reporting:

- Ineffective corporate governance;
- Ineffective communication of internal information;
- Insufficient procedures and control documentation;
- Insufficient segregation of duties; and
- Insufficient information technology controls and documentation.

Because of these material weaknesses, the Principal Executive Officers concluded that, as of April 30, 2014, our internal control over financial reporting was not effective based on the criteria outlined in *Internal Control-Integrated Framework (1992)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. We have undertaken the process of implementing new procedures and controls in fiscal year 2015 and to review further our procedures and controls in 2015. In addition, we expect to make additional changes to our infrastructure and related processes that we believe are also reasonably likely to strengthen and materially affect our internal control over financial reporting.

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

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

Changes in Internal Control over Financial Reporting There were no additional changes, other than those detailed above under Management Report on Internal Control over Financial Reporting, in our internal control over financial reporting during the most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

This Report does not include an attestation report of the Company’s independent registered public accounting firm regarding internal control over financial reporting. Management’s report was not subject to attestation by our registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit us to provide only management’s report in this Report.

ITEM 9B. OTHER INFORMATION

None/Not applicable.

PART III – FINANCIAL INFORMATION

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The directors and executive officers of the Company and their ages as of August 1, 2014, are as follows:

	Age	Position
Kenneth L. Waggoner, JD	65	Chief Executive Officer, President and General Counsel of the Company and Chief Executive Officer and General Counsel of MMS
Patricia Gruden	73	Chief Financial Officer, Secretary and Chairman of the Board
Gerald W. Crabtree, PhD	73	Chief Operating Officer and Director
Robert F. Ryan, PhD	54	Chief Scientific Officer and Director
Robert Bowker	65	Director
Richard Goldfarb, MD, FACS	60	Director
Timothy Matula	53	President of MMS and Director

Biographical Information for Kenneth L. Waggoner, JD

Kenneth L. Waggoner became the Chief Executive Officer and President of the Company on November 25, 2013. Shortly thereafter Mr. Waggoner assumed the additional position of General Counsel for the Company. He also serves as the Chief Executive Officer and General Counsel of MMS. Mr. Waggoner has almost four decades of experience in management, business, operations and the practice of law. He started his career as an attorney in private practice. Notably, he was a senior partner with Brobeck, Phleger and Harrison, named one of the top two law firms worldwide that provide services to biotechnology clients, including Chiron, Amgen, Biogen, Idec, Sangamo, Ligand, DepoTech and many others. He was the Managing Partner of Brobeck's Los Angeles office. Mr. Waggoner was also a member of the Executive Committee for almost ten years and on the Policy Committee for numerous years managing Brobeck's worldwide operations with annual revenues in excess of $750,000. While at Brobeck, Mr. Waggoner was the co-Chairman of Brobeck's worldwide Environmental Law Group.

Further highlights of Mr. Waggoner's career include leadership and legal positions with several start-up companies during the last several years as well as working with Fortune 500 companies most of his professional career. During his tenure with Chevron, Mr. Waggoner served as the Vice President and General Counsel of its global downstream operations where he was responsible for the overall management of legal services to the North American, Latin American, Europe and Asian Products Companies. While at Chevron Mr. Waggoner led the successful restructuring of Chevron's global Legal Department following Chevron's acquisition of Texaco.

Mr. Waggoner commenced employment with the Company on September 1, 2014. Between January 2009 and August 2014, Mr. Waggoner provided legal and other services to VelaTel Global Communications, Inc., formerly known as China Tel Group, Inc.

Mr. Waggoner received his Juris Doctorate with honors from Loyola University School of Law in Los Angeles in 1973 and his Bachelor of Arts degree in Political Science with honors in 1970 from California State University at Long Beach.

Biographical Information for Patricia Gruden

Mrs. Gruden has worked for the Company in numerous executive capacities over the years. She served as President, Chief Executive Officer and Chief Financial Officer of EFoodSafety, Inc. from August 2005 through March 2009 and a member of the Board from October 2000 to March 2009. She returned to stabilize and aid the Company back into working order in June 2010, first returning as the Chief Financial Officer and then later as the Chairman of the Board. Between January 2012 and May 2013, Mrs. Gruden was unable to fulfill her assigned duties as a result of health reasons. She returned to the Company in May 2013, to once again become the Chief Financial Officer and the Chairman of the Board – her current positions with the Company. Mrs. Gruden has extensive business experience in operations, training, finance, management, expansion of start-up and growth companies and political lobbying.

Mrs. Gruden has been selected as one of the ten most influential women in the transportation and travel industry in Arizona and has been honored by Athena as one of the 100 most influential women in Arizona. Mrs. Gruden was also elected the first woman President of a Chamber of Commerce in Arizona and had been selected to represent Arizona at the White House Conference for Small Business.

Biographical information for Gerald W. Crabtree, PhD

Dr. Gerald W. Crabtree has served as the Chief Operating Officer for Nuvilex since February of 2011 and is a member of the Board. His background in the biomedical sciences has been substantial, having been involved with various biopharmaceutical companies where he has alternatively supervised and coordinated the development of multiple drug candidates, prepared clinical protocols, investigator brochures, monographs, and research and review articles.

As Director of Project Planning and Management, at Bristol-Myers Squibb, ,Dr. Crabtree established and directed, from inception, a department that monitored and coordinated the development of oncologic and immunologic drugs from initial discovery through regulatory approval and personally served as project manager for the development of the anticancer agent, Taxol®.

Dr. Crabtree was previously Department Chairman of Molecular Pharmacology at ICN Pharmaceutical's Nucleic Acid Research Institute and prior to that Associate Professor of Medicine with the Roger Williams Cancer Center at Brown University. Most recently, Dr. Crabtree served as Interim CEO of PhytoCeutica, Inc., where he assisted in the preparation and review of FDA documents, clinical study protocols, investment acquisitions, and contracts and business plans.

Prior to joining the Company in February of 2011, Dr. Crabtree worked for PhytoCeutica, Inc. in its headquarters at the Yale Science Park in New Haven, Connecticut. Dr. Crabtree commenced work with PhytoCeutica in 2006 and worked as a consultant and later assumed the position of "Interim CEO" until 2010. Dr. Crabtree resumed his consulting business after leaving PhytoCeutica until he joined the Company.

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

Biographical information for Robert F. Ryan, PhD

Dr. Robert F. Ryan has become a specialist in the field of emerging biotechnology, specializing in assisting small companies with insight and bringing products to market through the rigorous FDA approval process. Dr. Ryan has broad scientific experience in biochemistry, cell and molecular biology, human genetics, novel therapies, and basic and clinical cancer research, having received his Masters in biochemistry, cell and molecular biology at the Medical College of Georgia, studying sickle cell anemia, and his PhD in molecular genetics at Thomas Jefferson University characterizing DNA and RNA binding properties of zinc finger proteins.

Additional training during his post-doctoral fellowships included studying mechanisms of transcriptional repression and protein-protein interaction at The Wistar Institute in Philadelphia, assessing transcriptional repression and histone deactylase functionality in *Xenopus laevis* at the National Institute of Child Health and Diseases at NIH and glucocorticoid receptor function and binding properties at the National Cancer Institute. Through his training, his experiences extend across the fields of aging, hemoglobinopathies, gene expression, human diseases, DNA, RNA, proteins and their interactions, stem cell research and applications, oncology, clinical protocols and therapies.

Since 2002, Dr. Ryan has served as the Chief Executive Officer of RFR Consulting where he focused on helping businesses in the biotech industry through grant writing, business management, scientific guidance, FDA regulatory advice and advising investors on potential investment opportunities. In January of 2011, Dr. Ryan joined the Company as the President and Chief Executive Officer. He became a member of the Board in February 2012. Dr. Ryan resigned as the President and Chief Executive Officer and became the Chief Scientific Officer of the Company on November 25, 2013.

Biographical Information for Robert Bowker

Robert Bowker has served as President of Knock-Out Technologies, Ltd. and as a member of the Board since May 2004. Mr. Bowker has extensive knowledge of and experience with herbs, natural supplements and natural healing. Mr. Bowker is the inventor of Citroxin™ , Oraphyte™ , and Cinnechol™ .. For the past 30 years, Mr. Bowker has been conducting research in the areas of microbiology, zoology and environmental sciences. For over the past 5 years and continuing to date, Mr. Bowker has provided consulting services to Nuvilex in microbiology and environmental sciences and has been involved in the Company's nutraceutical formulations.

Biographical Information for Richard Goldfarb, MD, FACS

Dr. Richard Goldfarb has served as President of MedElite, Inc. and as a member of the Board since September 2005. Dr. Goldfarb graduated from University of Health Sciences / Finch University the Chicago Medical School with top honors in Surgery. He completed his surgical training at Northeastern Ohio College of Medicine. He obtained additional training in cosmetic surgery at the University of Pennsylvania, Department of Plastic Surgery. Dr. Goldfarb also trained at Yale University and is a Member of the American Academy of Cosmetic Surgeons.

Dr. Goldfarb has 20 years of surgical experience, including liposuction, and has been performing SmartLipo since its inception. He was the first in Pennsylvania to receive the SmartLipo technology and has performed the most procedures in this area. Dr. Goldfarb is Board Certified and a Fellow of the American College of Surgeons. He is a member of the American Academy of Cosmetic Physicians. In view of his skill in performing this SmartLipo procedure, Cynosure has commissioned Dr. Goldfarb to travel throughout the country teaching and training other physicians the SmartLipo surgical procedure.

Dr. Goldfarb is the owner, and serves as the CEO, of the Center for SmartLipo & Plastic Surgery. He has been so for over five years.

Biographical Information for Timothy Matula

Timothy Matula is the President of Medical Marijuana Sciences, Inc. and has been since it was formed in February of 2013. He has served as a member of the Board since September 2004. From August of 2005 to March of 2009, Mr. Matula served as the Secretary for the Company.

Mr. Matula has a broad background in the financial sector. Mr. Matula joined Shearson Lehman Brothers as a financial consultant in 1992. In 1994, he joined Prudential Securities, which he left in 1997 while serving as an Associate Vice President, Investments and Quantum Portfolio Manager. From the time Mr. Matula left Prudential Securities until June of 2008, he provided consulting services to a broad range of companies in the United States and abroad. In June of 2008 and until January of 2012, Mr. Matula worked for VelaTel Global Communications, Inc. as the Director of Corporate Communications. In January of 2012, Mr. Matula became the Senior Vice President, Global Strategy, for Live Deal, Inc. where he is currently employed in addition to his employment with the Company.

Compliance with Section 16(a) of the Exchange Act

The Company does not have a class of securities registered pursuant to Section 12 of the Exchange Act. Accordingly, the Company's executive officers and directors and persons who own more than 10% of its equity securities are not subject to the beneficial ownership reporting requirements of Section 16(a) of the Exchange Act.

There are no family relationships among the Company’s executive officers, directors and significant employees. As of April 30, 2014, the Company personnel do not have any involvement in legal proceedings requiring disclosure pursuant to the Rules and Regulations of the SEC.

The corporate governance as of April 30, 2014 includes Board meetings which are run by the Board, with Patricia Gruden as Chairman of the Board and Secretary leading the meetings. Directors include Mrs. Gruden, Mr. Bowker, Dr. Crabtree, Dr. Goldfarb Mr. Matula and Dr. Ryan.

Code of Ethics and Corporate Policy

The Company has adopted a Code of Ethics and Corporate Policy. The Policy is presented below and can be found in Exhibit 14.1:

> In all societies, the opportunity to be a successful member of the community is an important role we must all be a part of. Any company must, therefore, understand its critical role and how to be a good member of that community. Like a three-legged stool, of which all three legs must exist in order for it to stand, we at Nuvilex see three critical components for our success and ability to be a good member of our community at large, both here and abroad: The Company, Investors & Shareholders, and our Customers & Patients. In no particular order do these responsibilities preside, since all are critical, required for success, and important to the Company and our communities in which we reside, work and play.
>
> Therefore, one of those legs stands for our responsibility to the Company, including employees, near and far, in house and out, research, development, sales, and marketing members through to our vendors. We recognize their merit and aim for all to engender a sense of well-being and security in their jobs through good working conditions, relationships, and compensation for a job well done and helping them address and fulfill their family responsibilities. Furthermore, there is equal opportunity for employment, development, advancement, and allowance for suggestions to advance the Company. Lastly, we provide management and guidance, through being good leaders and enabling opportunities for redressing issues.

Another leg of the stool stands for the responsibility to our investors and stockholders. Although the Company must experiment with new ideas and plans, it is tantamount to being successful, for through our success, we are able to return this to our investors and shareholders, without whom we would not exist as a Company. We will therefore, utilize research as a means to an end, developing innovative programs and advancing the state of the Company as a result, with the clear intention to ensure success and appreciation of those who believe in us and in our dreams, research, plans and our provision of ultimately useful products for the community.

The final leg of the stool represents how we must always be cognizant of those who use our products and services. In meeting their needs, everything we do should be designed with the highest quality in mind so as to ensure a valuable end product for those for whom we ultimately work, our customers and patients.

ITEM 11. EXECUTIVE COMPENSATION

The following table sets forth information about all cash and non-cash compensation awarded to, earned by, or paid to: (i) all persons serving as the Company's principle executive officer during the last two fiscal years; (ii) all persons serving as the Company's principle financial officer during the last two fiscal years; (iii) the Company's three most highly compensated executive officers (other than principle executive officers and principle financial officers) serving as such at the end of the last two fiscal years; and (iv) up to two additional persons for whom disclosure would have been provided pursuant to clause (iii) above but for the fact that the person was not serving as an executive officer of the Company at the end of the last fiscal year, and each current director of the Company during fiscal years ended April 30, 2014, 2013 and 2012. There were no other forms of compensation provided to the Company’s directors or officers in the form of health or life insurance benefits, options plans, car or other allowances or key-man life insurance that are not shown in the Summary Compensation Table below.

Summary Compensation Table

Name	Principal Position	Date	Salary	Shares of Stock Awarded	Stock Value	Total Compensation
Kenneth L. Waggoner, JD	Chief Executive Officer, President and General Counsel	5/1/2013 - 4/30/2014	$ 50,000	10,000,000	$ 3,230,000	$ 3,280,000
		5/1/2012 - 4/30/2013	$ –	–	$ –	–
Patricia Gruden	Chief Financial Officer and Chairman of the Board	5/1/2013 - 4/30/2014	$ 34,000	11,500,000	$ 3,324,000	$ 3,358,000
		5/1/2012 - 4/30/2013	$ –	–	$ –	$ –
Gerald W. Crabtree, PhD	Chief Operating Officer	5/1/2013 - 4/30/2014	$ 59,830	12,540,000	$ 3,555,795	$ 3,615,625
		5/1/2012 - 4/30/2013	$ 17,500	3,986,668	$ 201,769	$ 219,269
Robert Bowker	President of Knock-Out Technologies, Ltd. and Director	5/1/2013 - 4/30/2014	$ 90,000	1,000,000	$ 96,000	$ 186,000
		5/1/2012 - 4/30/2013	$ –	3,500,000	$ 98,000	$ 98,000
Richard Goldfarb, MD, FACS	President of MedElite, Inc and Director	5/1/2013 - 4/30/2014	$ –	500,000	$ 48,000	$ 48,000
		5/1/2012 - 4/30/2013	$ –	–	$ –	$ –
Timothy Matula	Director	5/1/2013 - 4/30/2014	$ 20,000	14,500,000	$ 3,612,000	$ 3,632,000
Robert F. Ryan, PhD	Chief Scientific Officer	5/1/2013 - 4/30/2014	$ 35,000	2,830,000	$ 333,993	$ 368,993
		5/1/2012 - 4/30/2013	$ –	8,130,000	$ 384,659	$ 384,659

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

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

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

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

The Company did not pay or accrue any other compensation, in the form of bonus, stock awards, option awards, incentive plan compensation or nonqualified deferred compensation earnings to any executive officer for services as an executive officer during the fiscal years ended April 30, 2014, 2013 and 2012; neither were there any prerequisites or other personal benefits. The Company does not have any option plan, equity incentive plan or retirement plan at the present time.

Members of the Board are compensated for their participation on the Board for performance of their duties as directed by the Chairman of the Board. The Board has not set a fixed compensation fee plan for directors, but chooses to review Board and individual Director performance on an annual basis and compensation is earned on a merit-system.

Employment Arrangements

Dr. Robert F. Ryan

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

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

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

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

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

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

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

During May of 2014, a dispute arose between the Company and Dr. Ryan relating to: (i) the validity, authenticity and approval of the MOU and the Employment Agreement; (ii) the circumstances surrounding the Company's issuance of stock and compensation to Dr. Ryan; and (iii) Dr. Ryan's entitlement to the compensation previously paid and described in the various purported agreements. The Company is currently investigating the facts relating to these issues and cannot provide assurance that the description of Dr. Ryan's compensation in prior filings or in this Report are accurate. On May 14, 2014, the Board adopted a resolution to eliminate any further accrual of Dr. Ryan's shares pursuant to a Board resolution and continued his leave of absence with pay pending the completion of the Company's review into Dr. Ryan's activities. The Company is in the process of determining whether a global settlement can be reached with Dr. Ryan with respect to all claims arising from Dr. Ryan's employment with the Company, although no assurances can be given that such a settlement will ultimately be entered into between Dr. Ryan and the Company.

Kenneth L. Waggoner, JD

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

Dr. Gerald W. Crabtree

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

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

Patricia Gruden

In her capacity as the Chief Financial Officer of the Company, Mrs. Gruden does not work for the Company in accordance with an agreement, whether written or oral, that specified the terms of her employment. She was, however, compensated as the Chairman and member of the Board. Her compensation was set in accordance with the policy of the Company in compensating all of its directors. As described above, the Board does not set a fixed compensation fee for directors; instead, it reviews individual director performance on an annual basis. Compensation is earned on a merit-system based upon a review of the preceding year's performance.

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

The following table sets forth at August 1, 2014, certain information with respect to the beneficial ownership of the Company's common stock by each person known by us to be the beneficial owner of more than five percent (5%) of the Company's common stock; by each of the Company's directors and named executive officers and by all executive officers and directors as a group.

The address of all beneficial owners is 12510 Prosperity Drive, Suite 310, Silver Spring, Maryland 20904. Each person has sole voting and investment power with respect to the shares of common stock.

Name and Address	Number of Shares Beneficially Owned (1)	Percentage of Common Stock (1)
Kenneth L. Waggoner, JD, Chief Executive Officer, President and General Counsel	10,000,000	1.41%
Patricia Gruden, Chief Financial Officer and Chairman of the Board	26,145,300	3.69%
Gerald W. Crabtree, PhD, Chief Operating Officer and Board Member	18,046,667	2.54%
Robert Bowker, Board Member	10,007,000	1.41%
Richard Goldfarb, MD, FACS, Board Member	15,920,000	2.24%
Timothy Matula, President of MMS and Board Member	17,100,500	2.41%
Robert F. Ryan, PhD, Chief Scientific Officer and Board Member	28,346,800	4.00%
All directors and executive officers as a group (7 persons)	125,566,267	17.70%

(1) Percentages based on 709,256,214 shares of common stock issued and outstanding as of July 30, 2014.

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

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 a shareholder $0 and $393,158; respectively, for operating expenses. All loans bear interest at 6% and were due within one to three years.

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.

As of April 30, 2014 and 2013, the Company owed Dr. Robert Ryan $140,143 and $201,143; respectively, at 8% interest.

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

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following is a summary of the fees billed by the Company's independent auditor, Robison, Hill & Co., for professional services rendered for each of the last two fiscal years ended April 30, 2014 and 2013:

Service	2014	2013
Audit Fees	$ 38,000	$ 42,500
Audit-Related Fees	$ —	$ —

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

PART IV

ITEM 15. EXHIBITS

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

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

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.
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.	Filed herewith.**
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.	Filed herewith.**
10.3	Manufacturing Framework Agreement between Austrianova Singapore Pte. Ltd. and Registrant dated March 20, 2014.	Filed herewith.
10.4	Master Services Agreement between ViruSure GmbH and Registrant dated April 7, 2014.	Filed herewith.

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.	Filed herewith.**
10.7	Master Consultancy Agreement between BB Biotech Consulting GmbH and Registrant dated as of April 15, 2014.	Filed herewith.**
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.	Filed herewith.
10.10	Employment Agreement made the 31st day of January 2012 between the Company and Robert F. Ryan, M.S., Ph.D.	Filed herewith.
14.1	Code of Ethics.	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the SEC on July 29, 2013.
21.1	List of Subsidiaries.	Filed herewith.
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under Sarbanes-Oxley Act of 1934, as amended.	Filed herewith.
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under Sarbanes-Oxley Act of 1934, as amended.	Filed herewith.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002*.	Filed herewith.
32.2	Certification of Chief 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, 2013	Filed herewith.

*Exhibits 32.1 and 32.2 are 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 exhibits 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

August 1, 2014 By: /s/ Kenneth L. Waggoner
Kenneth L. Waggoner, JD
Chief Executive Officer and President
(Principal Executive 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.

August 1, 2014 By: /s/ Patricia Gruden
Patricia Gruden, Chairman of the Board and Chief Financial Officer (Principal Financial and Accounting Officer On behalf of the Registrant)

August 1, 2014 By: /s/ Robert Bowker
Robert Bowker, Director

August 1, 2014 By: /s/ Richard Goldfarb
Richard Goldfarb, MD, FACS, Director

August 1, 2014 By: /s/ Gerald W. Crabtree
Gerald W. Crabtree, PhD, Director

Exhibit 10.1

LICENSE AGREEMENT

Relating to

Encapsulated Cells Producing Viral Particles

and

Encapsulated Cells Expressing Biomolecules

LICENSORS

BAVARIAN NORDIC A/S, reg. no. 16271187,

a company incorporated in Denmark, whose registered office is at Bøgeskovvej 9, DK-3490 Kvistgård, Denmark

and

GSF • Forschungszentrum für Umwelt u. Gesundhelt GmbH,

Ingolstädter Landstr. 1, D-85764 Neuherberg, Deutschland

and

LICENSEE

Bio Blue Bird AG,

Pflugstr. 7, FL-9490 Vaduz, Liechtenstein

*** 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.

*** 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.

This Contract is made the [ ] day of June 2005 between:

(1) **BAVARIAN NORDIC A/S,** reg. no. 16271187, a company incorporated in Denmark, whose registered office is at Bøgeskovvej 9, DK-3490 Kvistgård, Denmark **("BAVARIAN NORDIC")** and

(2) **GSF • Forschungszentrum für Umwelt u. Gesundheit GmbH,** Ingolstädter Landstr. 1, D-85764 Neuherberg, Deutschland **("GSF")**

(BAVARIAN NORDIC and GSF jointly referred to as "LICENSORS) and

(3) Bio Blue Bird AG, Pflugstr. 7, FL-9490 Vaduz, Liechtenstein **("LICENSEE")**.

Whereas:

(A) LICENSORS are co-owners of protective rights related to the encapsulation of cells. The protective rights all relate back to the two Danish applications DK 0740/95 filed on June 27, 1995, and DK 0352/96 filed on March 27, 1996.

(B) LICENSORS have extensive experience and expertise within research, development, and clinical trials of Technology directed to encapsulated cells producing viral particles and encapsulated cells expressing biomolecules;

(C) LICENSORS have Licensed Patent Rights and Clinical Data pertaining to technology directed to encapsulated cells producing viral particles and encapsulated cells expressing biomolecules;

(D) LICENSEE has extensive experience and expertise within research, development, and clinical trials within technology directed to encapsulated cells producing viral particles and encapsulated cells expressing biomolecules;

(E) LICENSEE and LICENSORS now desire to enter into this Agreement whereby LICENSEE is granted a license to make, have made, obtain market approval, market and sell the Licensed Product in the fields of encapsulated cells producing viral particles and encapsulated cells expressing biomolecules;

It is agreed:

1 Definitions

1.1 The following definitions shall be used for the purposes of interpreting the Agreement and all documents relating thereto except where the context requires otherwise:

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

1.1.2 "Agreement" shall mean this agreement including the Annexes.

*** 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.

1.1.3 **"Buyer"** shall mean a person other than LICENSEE, sub-licensees or its Affiliates who is the first third party to purchase the particular Licensed Product from LICENSEE, sub-licensees or its Affiliates, such as, for instance, the distributor of the Licensed Products. For the avoidance of doubts, Buyer will not necessarily be the end consumer of the Licensed Products.

1.1.4 **"Clause"** shall mean a Clause within the Agreement.

1.1.5 **"Clinical Data"** shall mean Bavarian Nordic's proprietary data with respect to Technology directed to encapsulated cells producing viral particles and encapsulated cells expressing biomolecules as listed in Annex 1 attached hereto.

1.1.6 **"Commencement Date"** shall be the date when the Condition Precedent as stipulated in Clause 2.1 has been fulfilled and this Agreement is signed by all Parties and the inventors mentioned in Clause 2.2.

1.1.7 **"Competent Authority"** shall mean any national or local agency, authority, department, inspectorate, minister, ministry official, parliament or public or statutory person (whether autonomous or not) of any government of any country having jurisdiction over either any of the activities contemplated by this Agreement or the Parties including the U.S. Food and Drug Administration, the European Commission, The Court of First Instance and the European Court of Justice;

1.1.8 **"Confidential Information"** shall mean any and all technical or commercial information which is now or at any time hereafter during the term of this Agreement in the possession of either Party or Its Affiliates and is derived from the other Party or its Affiliates which is of a confidential nature or is received in circumstances in which that Party knows or should know that the information is confidential including without limitation, data, know-how, formulae, processes, designs, photographs, drawings, specifications, software programs and samples and any other material bearing or incorporating any such information together with financial and commercial information relating to the business of either Party;

1.1.9 **"Field of this Agreement"** shall mean the development, manufacture, sale and/or distribution of Licensed Products or other use based on the Licensed Patent Rights and Clinical Data directed to encapsulated cells producing viral particles and encapsulated cells expressing biomolecules.

1.1.10 **"First Commercial Sale"** shall mean on a country-by-country basis the date of first commercial sale of a Licensed Product by LICENSEE. its Affiliate or sub-licensee in such country after Market Approval, or the successful completion of Phase Ill pivotal trials, to a Buyer.

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1.1.11 "Force Majeure" shall mean conditions beyond the control of the Parties, including without limitation, voluntary or involuntary compliance with any regulation, law or order of any government, war, civil commotion, labour strike or lock-out. epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe; provided, however, the payment of invoices due and owing hereunder shall not be delayed by the payer because of a force majeure affecting the payer.

1.1.12 "Licensed Patent Rights" shall mean the patents and the patent applications listed in Annex 2 attached hereto, together with any extensions, registrations, confirmations, reissues, continuations, continuations in part, divisions, reexamination certificates, revalidations, additions, substitutions, or renewals thereof and any patents or Supplementary Protection Certificates (SPCs) issuing therefrom.

1.1.13 "Licensed Products" shall mean any product which cannot be developed, manufactured, used or sold without infringing one or more Valid Claims under the Licensed Patent Rights in the respective country.

1.1.14 "Net Sales Value" shall mean the invoiced sales of Licensed Product by LICENSEE and its Affiliates and sub-licensees to a Buyer excluding:

(i) the cost of transportation and insurance;

(ii) commissions, cash discounts, trade discounts and quantity discounts actually granted to the buyer;

(iii) allowances or credits actually granted to the buyer on account of settlement of complaints, returns and replacements; and

(iv) sales taxes (including VAT) and/or taxes, and/or tariff duties directly imposed on sales of the Licensed Product;

(v) upfront payments by third parties to secure distribution or sales rights.

1.1.15 "Parties" shall mean LICENSEE and LICENSORS.

1.1.16 "Royalty Term" shall mean the period during which royalties are payable b y LICENSEE to LICENSORS in accordance with Clause 5.2 below.

1.1.17 "Territory" shall mean all countries in which Licensed Patent Rights exist.

1.1.18 "Valid Claim" shall mean a claim of a published patent application and/or an issued and unexpired patent in a particular country which has not been held permanently revoked, unenforceable or invalid by a decision of a court or other governmental or international agency of competent jurisdiction, and which is unappealable or unappealed within the time allowed for appeal, and which has not been admitted invalid, disclaimed or otherwise abandoned and which would be infringed by LICENSEE (in the absence of the licence granted in this Agreement) in the event of sale of the Licensed Product by LICENSEE in that country.

1.2 The interpretation and construction of the Contract shall be subject to the following provisions:

1.2.1 a reference to any statute, enactment, order, regulation or other similar instrument shall be construed as a reference to the statute, enactment, order, regulation or other similar instrument as subsequently amended or re-enacted;

1.2.2 the headings to Clauses are for ease of reference only and shall not affect the interpretation or construction of the Clauses; and

1.2.3 where the context allows, the masculine includes the feminine and the neuter, and the singular includes the plural and vice versa.

1.2.4 where any provision is expressed to be subject to the knowledge of any Party or that Party's Affiliates it will be implied that that knowledge (or absence of knowledge) follows diligent enquiry.

1.2.5 References herein to a Party shall include a reference to that Party's Affiliates unless the context otherwise requires.

2 Condition Precedent

2.1 **Withdrawal of Law Suit**. Professor Dr. Walter H. Günzburg will withdraw the court action 21 0 14970/04 of Regional Court Munich I in the matter of Prof. Dr. Walter H. Günzburg v. Bavarian Nordic Research Institute A/S and GSF-Forschungszentrum für Umwelt und Gesundheit GmbH immediately after the present agreement has been signed. The LICENSORS will agree to the withdrawal of the court action. Each Party will bear the costs generated on its respective side by and in the course of the law suit; no refund will be made to any of the other Parties. An application with regards to costs will not be filed with the Regional Court Munich I.

2.2 **Acknowledgement of Patent Proprietorship.** The inventors of the Licensed Patent Rights (Walter H. Günzburg, Brian Salmons, Robert Saller, and Peter Karle) hereby acknowledge that the proprietorship of the inventions covered by the protective rights mentioned in Article (A) above and any patent rights worldwide pertaining thereto belongs to Bavarian Nordic A/S and GSF, also having considered the German Act on Employee's Inventions, and that each assignment executed and signed with respect to said inventions are valid, enforceable, and applicable worldwide.

3 Licence

3.1 **License to LICENSEE**. Subject to the terms of this Agreement, LICENSORS hereby grant to LICENSEE the non-exclusive irrevocable (except as provided for in clause 9.2) royalty-bearing, licence, with the right to sublicense in accordance with Clause 3.2, under the Licensed Patent Rights to further develop, make, have made (including services under contract for Licensee or sub-licensee, by Contract Manufacturing Organizations, Contract Research Organisations, Consultants, Logistics Companies or others), obtain marketing approval, sell and offer for sale the Licensed Product or otherwise use the Licensed Patent Rights in the Territory within the Field 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.

3.2 **Sublicense**. In the event that LICENSEE grants a sublicense of the rights granted under Clauses 3.1 above:

3.2.1 Within thirty (30) days after entering into the sublicense, LICENSEE shall deliver a copy of such sublicense agreement to BAVARIAN NORDIC on behalf of LICENSORS.

3.2.2 Any sublicense agreement shall (i) be consistent with, and not extend beyond the scope of the terms and conditions of this Agreement, and (ii) require the sub-licensee to agree to comply with all relevant terms and conditions of this Agreement including, without limitation, the obligation to maintain the confidentiality of Confidential Information in accordance with the terms and conditions of Clause 13.1 hereof and the obligations to pay royalties pursuant to Clause 5.1 hereof. This does, however, not exclude LICENSEE from charging a higher royalty rate to sub-licensees than agreed upon in Clause 5.1.

3.2.3 The LICENSEE shall be responsible to the LICENSORS for the amount of the royalty fee agreed upon between the LICENSEE and LICENSORS for royalties due with respect to Net Sales Value of Licensed Products sold by any sub-licensee having a sublicense granted under this agreement as if they were sales by the LICENSEE.

4 Clinical Data

4.1 BAVARIAN NORDIC hereby grants LICENSEE and any sub-licensee, the non-exclusive right to use the Clinical Data (Annex 1) that may be deemed necessary or appropriate in order for LICENSEE or any sub-licensee to develop, make, have made (including services under contract for LICENSEE or sub-licensee, by Contract Manufacturing Organizations, Contract Research Organisations, Consultants, Logistics Companies or others), obtain marketing approval, sell and offer for sale the Licensed Products or otherwise use the Clinical Data pursuant to Clause 3.

5 Royalty Payments

5.1 **Royalty.** Subject to the terms of this Agreement, LICENSEE shall pay to BAVARIAN NORDIC for the use of a Valid Claim during the Royalty Term on a country-by-country basis, royalties equal to [**********] of Net Sales Value of each Licensed Product sold by LICENSEE and/or its Affiliates and/or its sub-licensees to a buyer. Insofar as more than one Valid Claim is pending in a country this does not affect the amount of royalties (even if three or more Valid Claims are pending the royalties amount to [**] Sales Value of each Licensed Product).

5.2 **Royalty Term.** LICENSEE's obligation to pay royalties under Clause 5.1 above shall commence on the First Commercial Sale of the Licensed Product in a particular country, and shall continue on a country by country basis until the expiration of the last Valid Claim within the Licensed Patent Rights in such country.

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5.3 **Quarterly Payments.** All royalties under Clause 5.1 arising from sales by LICENSEE and/or its Affiliates shall be payable on a country-by-country basis and shall be paid quarterly as soon as possible but in any event within thirty (30) days of the end of the relevant calendar quarter. All royalties under Clause 5.1 arising from sales by sub-licensees of LICENSEE shall be payable on a country-by-country basis and shall be paid quarterly as soon as possible but in any event within sixty (60) days of the end of the relevant calendar quarter.

5.4 **LICENSEE Royalty Reports.** Each royalty payment shall be accompanied by a statement stating the number and type of sold Licensed Products and aggregate gross invoiced price and the calculation of Net Sales Value, by country, of each sale invoiced during the relevant calendar quarter.

5.5 **Payment Method.** All payments due under this Agreement to LICENSORS shall be made by bank wire transfer in immediately available funds to an account designated by BAVARIAN NORDIC.

5.6 **Currency**. Royalties under this Agreement shall be calculated in the local currency of each country and converted into EUR and paid in EUR on the basis of the average currency exchange rate for the applicable calendar quarter quoted by the ECB.

5.7 **Taxes**. LICENSORS shall pay any and all taxes levied on account of payments it receives under this Agreement. All royalty payments under this Agreement shall be excluding VAT, if applicable.

5.8 **Records and Inspection.** LICENSEE and its Affiliates and sub-licensees shall keep complete, true and accurate books of account and records for the purpose of determining the payments to be made under this Agreement. Such books and records shall be kept for at least five years following the end of the calendar quarter to which they pertain. Such records will open for inspection during such five year period by independent accountants, solely for the purpose of verifying payment statements hereunder. Such inspections shall be made no more than once in each period of twelve months, at reasonable time and on reasonable notice. Any amounts showed to be owed but unpaid shall be paid within thirty (30) days from the accountant's report, plus interest from the original date due. Inspections conducted under this Clause 5.8 shall be at the expense of LICENSORS, unless a variation or error producing an increase exceeding 10% of the royalty amount stated for any period covered by the inspection is established in the course of such inspection, whereupon all costs relating to the inspection for such period will be paid promptly by LICENSEE. In case the inspection reveals an overpayment by LICENSEE, the overpayment (plus interest, but minus the costs of the inspection) shall be paid back within thirty (30) days from the accountant's report.

5.9 **Interest.** Interest shall accrue on sums outstanding after the due date for payment at the rate of 5% (five percent) per annum over ECB base rate from time to time.

6 **Intellectual Property**

6.1 **Ownership.** Subject to the licenses granted. under this Agreement, each Party shall continue to own (and/or control) the entire right, title and interest in and to any and all of the inventions, Confidential Information and intellectual property rights owned (and/or controlled) solely by such Party and its employees or agents as of the Commencement Date.

*** 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.

6.2 Subject to the licenses granted under this Agreement, LICENSORS shall own the entire right, title and interest in and to any and all of the Licensed Patent Rights and BAVARIAN NORDIC shall own the entire right, title and interest in and to the Clinical Data.

6.3 **Patent Prosecution.** LICENSORS shall have the sole and exclusive right, except as otherwise provided below, to file, prosecute and maintain any patents with claims covering inventions in the Licensed Patent Rights. LICENSORS shall use good faith, diligent efforts to file, prosecute, and maintain such patents, including Supplementary Protection Certificates ("SPC"), and shall consider the best interest of both LICENSEE and LICENSORS in so doing. If LICENSORS decline to file or prosecute a patent or SPC application or maintain a patent within the Licensed Patent Rights, LICENSORS shall timely, at least three months before any relevant deadline, notify LICENSEE and LICENSEE may thereafter file and prosecute at its expense a patent or SPC application or maintain a patent claiming such invention. LICENSORS shall in such case provide to LICENSEE all necessary assistance, in particular assignment declarations and copies of all relevant patent office correspondence and copies of the relevant patent application and all patent documents. As a result of its maintenance of such patents or filing and or prosecution of such patent or SPC applications (or paying any fees according to this Clause), LICENSEE shall acquire all rights in these patents (including SPCs) and patent applications for that jurisdiction and cease to be obliged to further pay royalties here based on said patents (including SPCs) or patent applications prosecuted or maintained at Its own expense.

6.4 **Notification of prosecution.** LICENSORS agree to inform LICENSEE Immediately about any essential developments regarding the application proceedings and the status of the Licensed Patent Rights, such as official objections, oppositions and/or issue of patent. In addition, LICENSEE may request information from LICENSORS on these issues twice a year.

6.5 **Notification of Infringement.** If either Party learns of any infringement or threatened infringement by a third party of the Licensed Patent Rights, such Party shall promptly notify the other Party and shall provide such other Party with all evidence of such infringement in its possession or otherwise available to such Party.

6.6 **Enforcement of Licensed Patent Rights.** LICENSORS shall have the initial right, but not the obligation, to institute, prosecute and control at its own expense and by counsel of its own choice, any action or proceeding with respect to infringement of any Licensed Patent Rights. If LICENSORS do not want to institute, prosecute and control at its own expense and by counsel of its own choice, any action or proceeding with respect to infringement of any Licensed Patent Rights in the Territory, then LICENSEE shall have the right, but not the obligation, to institute, prosecute and control at its own expense and by counsel of its own choice, any action or proceeding with respect to infringement of any Licensed Patent Rights. LICENSORS will have the right to be represented in any action or proceeding brought by LICENSEE by counsel of its own choice and at its own expense. Apart from that, the Party controlling any suit under this Clause 6.6 shall bear all costs and expenses of such suit. All damages or other monies awarded or received in settlement of such suit shall be used to reimburse each Party for all costs and expenses incurred in such infringement action, however, starting with the costs and expenses of the Party controlling the suit. Any additional amounts will be divided between LICENSEE and LICENSORS at a ratio of 66.6% to 33.3%. in case LICENSEE controlled the suit under this Clause 6.6. No settlement, consent, judgment or other voluntary final disposition of such suit may be entered into without the consent of LICENSORS, whose consent shall not be unreasonably withheld.

*** 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 Representations And Warranties

7.1 Each Party warrants to the other that:

7.1.1 it is a corporation duly organised, validly existing and in good standing under the laws of the jurisdiction in which it is incorporated;

7.1.2 it has the corporate power and authority and the legal right to enter into this Agreement free from any conflicting right owed to a third party and to perform its obligations hereunder;

7.1.3 it has taken all necessary corporate action on its part to authorise the execution and delivery of this Agreement and the performance of its obligations hereunder;

7.1.4 this Agreement has been duly executed and delivered on behalf of each Party, and constitutes a legal, valid, binding obligation, enforceable against such Party in accordance with its terms. All necessary consents, approvals and authorisations of all governmental authorities and other persons required to be obtained by such Party in connection with the execution of this Agreement have been obtained.

7.1.5 the execution and delivery of this Agreement and the performance of such Party's obligations hereunder do not constitute a default or require any consent under any contractual obligation of such Party.

7.2 LICENSORS declare that they are free to make arrangements regarding the Licensed Patent Rights and that - apart from the Munich Proceedings mentioned in Clause 2.1 - they have no knowledge either that third parties have launched attacks against the Licensed Patent Rights or that the Licensed Patents Rights are affected by rights of third parties, in particular in the form of prior use rights or a dependency on intellectual property rights of third parties.

8 Indemnification and Liability

8.1 **Indemnification by LICENSEE.** LICENSEE hereby agrees to indemnify, hold harmless and defend LICENSORS and its officers, directors and employees against any and all liability, damages, judgments, awards or costs of defence (including without limitation reasonable attorneys' fees, expenses to defend and amounts paid in settlement of any action) resulting from any claim or claims by third parties solely to the extent that such claim or claims: (a) are based on the material breach of any obligation or representation or warranty by LICENSEE set forth in this Agreement; (b) are based on the gross negligence or willful misconduct of LICENSEE, or any of its employees or agents; or (c) arise out of the possession, storage, transport, manufacture, use, administration, sale, distribution or other disposition of Licensed Product(s) by or on behalf of LICENSEE (other than LICENSORS), provided that such indemnification shall not apply to the extent that any such claim would require indemnification by LICENSORS under Clause 8.2 below.

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8.2 **Indemnification by LICENSORS.** LICENSORS hereby agree to indemnify, hold harmless and defend LICENSEE and its officers, directors and employees against any and all liability, damages, judgments, awards or costs of defence (including without limitation reasonable attorneys' fees, expenses to defend and amounts paid in settlement of any action) resulting from any claim or claims by third parties solely to the extent that such claim or claims: (a) are based on the material breach of any obligation or representation or warranty by LICENSORS set forth in this Agreement; (b) are based on the gross negligence or willful misconduct of LICENSORS, or any of its employees or agents; or (c) arise out of the possession, storage, transport, manufacture, use, administration, sale, distribution or other disposition of Licensed Product(s) by or on behalf of LICENSORS, provided that such indemnification shall not apply to the extent that any such claim would require indemnification by LICENSEE under Clause 8.1 above.

8.3 **Indemnification Procedure.** A Party seeking indemnification under this Clause (the "Indemnified Party") shall give prompt notice of the claim to the other Party (the "Indemnifying Party") and, provided that the Indemnifying Party is not contesting the indemnity obligation, shall permit the Indemnifying Party to control any litigation relating to such claim and disposition of any such claim, provided that the Indemnifying Party shall act reasonably and in good faith with respect to all matters relating to the settlement or disposition of any claim as the settlement or disposition relates to the parties being indemnified under this section, and the Indemnifying Party shall not settle or otherwise resolve any claim without prior notice to the Indemnified Party and the consent of the Indemnified Party, if such settlement involves any remedy other than the payment of money by the Indemnifying Party. The Indemnified Party shall cooperate with the Indemnifying Party in its defence of any claim for which indemnification is sought under this section.

8.4 Commencing not later than the date of First Commercial Sale of the first Licensed Product, LICENSEE or any sub-licensee shall obtain and carry in full force and effect product liability insurance in amounts, which are reasonable and customary in the pharmaceutical industry for similar products.

9 Term And Termination

9.1 **Term and Termination.** The Agreement shall commence on the Commencement Date and, save as otherwise provided, continue on a country by country basis until the expiration of the last valid claim of the Licensed Patent Rights. Except for clause 9.2, the parties shall have no right for termination of the Agreement.

9.2 **Termination for Cause.** In addition to any other rights a Party may have at law, upon a material breach of this Agreement by a Party, the non-breaching Party shall have the right to provide written notice describing such breach and stating its intention to terminate this Agreement if such breach is not cured. If the breaching Party does not cure the breach within forty five (45) days of receipt of such notice, then the non-breaching Party will have the right, by written notice provided within forty five (45) days thereafter, to terminate this Agreement and all licenses or sublicenses granted by the non-breaching Party to the breaching Party.

9.3 **Effect of Termination.**

*** 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.

9.3.1 In the event of termination or expiry of this Agreement, the following provisions (Clauses) of this Agreement shall survive (2.2, 8, 9.3, 13.1, 14.1).

9.3.2 In the event of termination of this Agreement, LICENSEE or its respective Affiliates or sub-licensees, as the case may be, shall cease immediately to use, make, have made, and sell Licensed Products after a 3-month phase-out period, if not agreed otherwise between the Parties, in which LICENSEE, its respective Affiliates or its sub-licensees are permitted to sell the Licensed Products on stock; and both parties shall to the extent possible return to the other party all Licensed Patent Rights, Clinical Data and destroy or return all Confidential Information, without delay at their own cost and expense.

10 Development Efforts and Obligations

10.1 **Development Efforts.** LICENSEE, or its respective Affiliates or sub-licensees, as the case may be, shall devote all reasonable efforts to develop the Licensed Product as promptly as possible. LICENSEE shall, on a current basis, provide BAVARIAN NORDIC on behalf of LICENSORS with information on the following activities regarding its development and sale of the Licensed Product in the Territory:

-filing an investigational new drug application (IND).

- start of a Phase Ill clinical study.

-first Product Approval in US.

- first Product Approval in Europe.

- first Product Approval in Japan.

- Market Authorization in the US, Europe and/or Japan.

10.2 LICENSEE or its respective Affiliates or sub-licensees, as the case may be, shall conduct all human clinical trials with Licensed Products in accordance with applicable international standards (ICH/GCP) and local regulations. LICENSEE agrees, subject to regulatory guidelines and restrictions, to provide LICENSORS with a summary of the results of clinical study protocols regarding human clinical trials involving Licensed Products, at the end of the Phase III clinical trials.

11 Marketing Efforts and Obligations

11.1 **Marketing Efforts.** LICENSEE, or its respective Affiliates or sub-licensees, as the case may be, shall devote all reasonable efforts to commence manufacturing and commercialising the Licensed Product as promptly as possible.

12 Adverse drug events and product recalls

12.1 LICENSEE or its respective Affiliates or sub-licensees, as the case may be, shall be responsible for conducting any recall of defective Licensed Products marketed by them within the Territory. LICENSORS shall co-operate with and give all reasonable assistance to LICENSEE in conducting any such recall, at LICENSEE's expense.

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13 Confidentiality

13.1 **Confidentiality Obligation.** During the term of this Agreement, and for two (2) years thereafter, each Party shall maintain in confidence any and all Confidential Information disclosed to it by the other Party pursuant to the activities under this Agreement. The Clinical Data shall, however, be maintained by LICENSEE in confidence for as long as the pertinent legal provisions allow. Each Party further agrees that it shall not use for any purpose other than the purposes expressly contemplated under this Agreement and shall not disclose to any third party the Confidential Information of the other Party, except that either Party may disclose Confidential Information under a similar obligation of confidentiality and non-use and on a need-to-know basis to its directors, officers, employees, consultants, or agents.

13.2 **Exceptions.** The obligations of confidentiality and non-use contained in Clause 13.1 above shall not apply to any Information to the extent that it can be established by the Party receiving the Confidential Information (the "Receiving Party") that such Confidential Information:

13.2.1 was already known to the Receiving Party, other than under an obligation of confidentiality, at the time of disclosure by the other Party;

13.2.2 was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party;

13.2.3 became generally available to the public or otherwise part of the public domain after its disclosure to the Receiving Party through no fault attributable to the Receiving Party;

13.2.4 was disclosed to the Receiving Party, other than under an obligation of confidentiality to a third party, by a third party who had no obligation to the disclosing Party not to disclose such information to others; or

13.2.6 was independently discovered or developed by the Receiving Party without the use of Confidential Information belonging to the disclosing Party.

13.3 **Authorized Disclosure.** Notwithstanding the limitations in Clause 13.1, each Party may disclose Confidential Information belonging to the other Party (or otherwise subject to this Clause 13.3), to the extent such disclosure is reasonably necessary in the following instances, but solely for the limited purpose of such necessity:

13.3.1 regulatory and tax filings;

13.3.2 prosecuting or defending litigation;

13.3.3 complying with applicable governmental laws or regulations or valid court orders;

13.3.4 disclosure to Affiliates, sub-licensees, agents or other contractors (including Contract Manufacturing Organizations, Contract Research Organisations, Consultants, Logistics Companies or others) as needed in furtherance of a Party's obligations or rights under this Agreement; *provided, however,* that prior to any disclosure, the disclosee must have agreed to be bound by similar terms of confidentiality and non-use at least equivalent in scope to those set forth in this Clause 13.

*** 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.

13.4 **Press Releases and Other Disclosures.** Except as required by law or in accordance with this Clause 13.4, neither Party shall have the right to make any public announcements or other disclosures concerning the terms or performance of the Agreement without the prior written consent of the other, which shall not be unreasonably withheld. Notwithstanding the foregoing, the Parties agree that (a) each Party may disclose this Agreement in confidence to its attorneys, accountants and other professional advisors and to existing or potential investors, licensees, acquirers or merger partners, provided that, with respect to the latter group, such Party obtains agreement of such recipient to maintain such disclosed information in confidence; (b) each Party may disclose the existence of this Agreement to third parties, and (c) each Party may desire or be required to issue press releases relating to activities under this Agreement, and the Parties agree to consult with each other reasonably and in good faith with respect to the text of such press releases (under this subsection (c)) prior to the issuance thereof, provided that a Party may not unreasonably withhold consent to such releases. All such public disclosures with respect to this Agreement must be accurate and comply with applicable law and regulations. In the event of a required or desired public announcement, such Party shall provide the other Party with a reasonable opportunity to review and comment on the content of such announcement prior to its being made. In the event that either Party files a copy of this Agreement according to existing stock exchange rules, such Party shall use reasonable efforts to obtain confidential treatment of economic and trade secret information to the maximum extent permitted.

14 **Miscellaneous**

14.1 **Governing Law and Jurisdiction.** This Agreement shall be governed by and interpreted in accordance with German Law (however, the conflicts of law provisions being excluded) at the exclusive jurisdiction of the Courts in Munich, Germany.

14.2 **Entire Agreement.** This Agreement and the Annexes constitute the entire, final and complete agreement and understanding between the Parties, and replace and supersede all prior discussions and agreements between them, with respect to the Licensed Product. No amendment, modification or waiver of any terms or conditions hereof shall be effective unless made in writing and signed by a duly authorized officer of each Party.

14.3 **Most favoured status.** LICENSORS undertake to allow LICENSEE the same conditions as those in license agreements with other licensees of the Licensed Patent Rights with respect to lower royalty obligations than three (3) percent in combination with zero milestone payments. For the avoidance of doubts, this favoured status clause does not apply if LICENSORS provide such other licensees with lower royalty obligations in combination with reasonable milestone payments.

14.4 **Successors and Assigns.** This Agreement shall be binding upon each of the Parties, their successors and assigns. LICENSORS undertake to impose the obligations under this Agreement upon any legal successors to which the Licensed Patent Rights may be assigned. Except as otherwise expressly provided for in this Agreement, either Party shall not be entitled to assign any rights hereunder to any party without the prior written consent of the other Party, except that, a Party may assign this Agreement to its successor in interest pursuant to a merger, acquisition or sale of all or substantially all of its assets.

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14.5 Force Majeure. Both Parties shall be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by Force Majeure and the non-performing Party promptly provides notice of the prevention to the other Party. If the Force Majeure in question prevails for a continuous period in excess of 3 [three] months, the parties shall enter into *bona fide* discussions with a view to agreeing upon such alternative arrangements as may be fair and reasonable. If the Parties cannot agree such alternative arrangements then either Party shall be entitled to terminate this Agreement immediately by written notice.

14.6 Notices. Except as otherwise expressly provided within the Agreement, no notice or other communication from one Party to the other shall have any validity under the Agreement unless made in writing by or on behalf of the Party concerned. This written form requirement also applies to its surrender.

14.7 Any notice or other communication which is to be given by either Party to the other shall be given by letter, or by facsimile transmission or electronic mail confirmed by letter. Such letters shall be delivered by hand or sent prepaid by first class post, addressed to the other Party, with receipted recorded delivery. If the other Party does not acknowledge receipt of any such letter, facsimile transmission or item of electronic mail, and the relevant letter is not returned as undelivered, the notice or communication shall be deemed to have been given at the day of signature of the receipt of recorded delivery.

Notices to:

To LICENSORS: Bavarian Nordic A/S
Bøgeskovvej 9
DK-3490 Kvistgård
Denmark
Attn: Director of Intellectual Property Rights

With copies to: Bavarian Nordic GmbH
Patent Department
Fraunhoferstraβe 13
D-82 152 Martinsried
Germany

and GSF- Forschungszentrum für
Umwelt und Gesundheit,
GmbH Legal Department
Ingolstädter Landstrasse 1
86764 Neuherberg
Germany

To LICENSEE: Bio Blue Bird AG
Pflugstr. 7
FL-9490 Vaduz
Liechtenstein
Attn: Dr. Gerold Hoop

*** 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.

With copies to: Prof. Dr. Walter Günzburger
Weyprechtgasse 10,
A-2340 Mödiing
Austria

14.8 **No Strict Construction.** This Agreement has been prepared jointly and shall not be strictly construed against either Party. Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision.

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

14.10 **No Waiver.** Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, excepting only as to an express written and signed waiver as to a particular matter for a particular period of time.

14.11 **Independent Contractors**. Each Party shall act solely as an independent contractor, and nothing in this Agreement shall be construed to give either Party the power or authority to act for, bind or commit the other Party in any way. Nothing herein shall be construed to create the relationship of partnership, principal and agent or joint venture between the Parties.

14.12 **Counterparts.** This Agreement may be executed in one or more counterparts, each of which shall be an original and all of which shall constitute together the same document.

Date: 4 July 2005
Signed:
Print Name: Li Westerlund, Director of Intellectual Property Rights
for and on behalf of BAVARIAN NORDIC A/S

Date: 4 July 2005
Signed: i.A.
Print Name: Martin Reichel, Head of Legal Dept. Dr. Martin Dietz, Patents and Technology Transfer
for and on behalf of GSF - Forschungszentrum für Umwelt u. Gesundheit GmbH

*** 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

Date: 28.7.05

Signed:

Print Name: Prof. Dr. Walter H. Günzburg

for and on behalf of Bio Blue Bird AG

Date: 28.7.05

Signed and Confirmed by the Inventors:

We have read, understood, and consented to the status of ownership, *i.e.,* BAVARIAN NORDIC and GSF, and hereby formally confirm that we do not have ownership to the Licensed Patent Rights referred to in Annex 2 of this Agreement. We therefore also acknowledge the statement specifically made in Clause 2.2 and confirm that, after having thoroughly read this statement, we understand that we are hereby estopped from making further claims to ownership of the referenced inventions.

Date: 28.7.05

Signed:

Walter H. Günzburg:

Date: 26/7/05

Signed:

Brian Salmons:

Date: 21.07.05

Signed:

Robert Saller:

Date: 25-7-2005

Signed:

Peter Karle:

*** 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

Annex 2

Internal Ref. No. / Owner(s)	Title	Priority No. / Application No. and Appl. Dates	Publication No.	Applications	Patents
BN 6 BN/GSF	Encapsulated cells producing retroviral particles	DK 19950000740 WO1996EP02748 24.06.1996	WO9701357	CA 2,222,559 HK 98110992.0 JP 504165/97 NO 975813	AU 708273 BY 6376 **CN 96195050** CZ 286979 EP 0 835 137 AT-BE-CH-DE-DK-ES-FI-FR-GB-GR-IE-IT-LI-LU-MC-NL-PT-SE AL-LT-LV-SI EP-Validation suspended IL 122119 **KR 484883** NZ 312671 PL185338 RU 2187301 UA 65525 US 6,776,985
BN 10 BN/GSF	Cytochrome P450 transducing retroviral vectors	DK19960000352 WO1997EP01585 27.03.1997	WO9735994	CA 2,250,173	AU 713382 CZ 228074 EP 0 892 852 AT-BE-CH-DE-DK-ES-FI-FR-GB-GR-IE-IT-LI-LU-MC-NL-PT-SE AL-LT-LV-RO-SI EP-Validation suspended

*** 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

					HU 221349
				IL 125795 JP 534051/97 NO 984540	NZ 331765
				PL 329071 Notice of Allowance received	RU 2185821 RU 2223788 SK 282744
					US 6,540,995 US 6,893,634

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Exhibit 10.2

AMENDMENT TO LICENSE AGREEMENT

Relating to

Encapsulated Cells Producing Viral Particles

and

Encapsulated Cells Expressing Biomolecules

LICENSORS

BAVARIAN NORDIC A/S, reg. no. 16271187,

a company incorporated in Denmark, whose registered office is at Bøgeskovvej 9, DK-3490 Kvistgård, Denmark

and

GSF • Forschungszentrum für Umwelt u. Gesundhelt GmbH,

Ingolstädter Landstr. 1, D-85764 Neuherberg, Deutschland

and

LICENSEE

Bio Blue Bird AG,

Pflugstr. 7, FL-9490 Vaduz, Liechtenstein

*** 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.

This Amendment is made effective the twentieth day of December 2006 between:

(1) **BAVARIAN NORDIC A/S,** reg. no. 16271187, a company incorporated in Denmark, whose registered office is at Bøgeskovvej 9, DK-3490 Kvistgård, Denmark **("BAVARIAN NORDIC")** and

(2) **GSF • Forschungszentrum für Umwelt u. Gesundhelt GmbH,** Ingolstädter Landstr. 1, D-85764 Neuherberg, Deutschland **("GSF")**
(BAVARIAN NORDIC and GSF jointly referred to as "LICENSORS) and

(3) Bio Blue Bird AG, Pflugstr. 7, FL-9490 Vaduz, Liechtenstein **("LICENSEE")**.

Whereas:

(A) LICENSEE and LICENSORS entered into a License Agreement on 6 July 2005 (the "License Agreement") whereby LICENSEE was granted a non-exclusive license to, in particular, further develop, make, have made (including services under contract for Licensee or sub-licensee, by Contract Manufacturing Organizations, Contract Research Organisations, Consultants, Logistics Companies or others), obtain marketing approval, sell and offer for sale the Licensed Product or otherwise use the Licensed Patent Rights in the Territory within the Field of this Agreement.

(B) LICENSEE and LICENSORS now want to amend said License Agreement in order to reflect that the license granted shall be exclusive and the royalty rate increased and LICENSEE taking over expenses;

(C) LICENSEE and LICENSOR now also want to amend said License Agreement to make clear that the license will survive as a license granted by one of the LICENSORS if the other LICENSOR rejects performance under this Agreement due to any actions or declarations of insolvency;

(D) LICENSEE and LICENSORS agree that except as amended hereby, the provisions of the License Agreement remain unchanged and in full force and effect.

It is agreed:

1 Licence

1.1 The license granted in Clause 3.1 and 4 of the License Agreement shall be changed from a non-exclusive into an exclusive license.

2 Royalty Payments

2.1 The royalty rate according to Clause 5.1 of the License Agreement shall be increased from [**********] of Net Sales Value of each Licensed Product sold by LICENSEE and/or its Affiliates and/or its sub-licensees to a buyer.

3 Intellectual Property- Patent Prosecution

3.1 Clauses 6.1, 6.2, 6.4 and 6.5 of the License Agreement shall remain unchanged but Clauses 6.3 and 6.6 shall be changed to reflect changes to the responsibilities of the parties concerning filing, prosecution, maintenance etc. of the Licensed Patent Rights. Therefore, Clauses 6.3 and 6.6 shall be deleted and replaced by the following wording:

*** 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.

Clause 6.3

Patent Prosecution. LICENSORS shall have the sole and exclusive right, except as otherwise provided below, to file, prosecute and maintain any patents with claims covering inventions in the Licensed Patent Rights. LICENSORS shall use good faith, diligent efforts to file, prosecute, and maintain such patents, including Supplementary Protection Certificates ("SPC"), and shall consider the best interest of both LICENSEE and LICENSORS in so doing. As of the first day of January 2007 LICENSEE will bear LICENSORS' external attorneys' costs and official fees necessary for filing, prosecuting and maintaining any patent claims covering inventions in the Licensed Patent Rights. LICENSORS' internal costs will be borne by themselves. At the end of each calendar quarter LICENSORS shall send LICENSEE a detailed specification of external costs and fees incurred in that quarter, if any. Upon receipt of such specification LICENSEE shall pay the external costs and fees within one month to the invoicing LICENSOR. Upon request from the LICENSEE, the invoicing LICENSOR shall provide invoices or other documents evidencing the external costs and fees.

If LICENSORS decline to file or prosecute a patent or SPC application or maintain a patent within the Licensed Patent Rights, LICENSORS shall timely, at least three months before any relevant deadline, notify LICENSEE and LICENSEE may thereafter file and prosecute at its expense a patent or SPC application or maintain a patent claiming such invention. LICENSORS shall in such case provide to LICENSEE all necessary assistance, in particular assignment declarations and copies of all relevant patent office correspondence and copies of the relevant patent application and all patent documents. As a result of its maintenance of such patents or filing and or prosecution of such patent or SPC applications (or paying any fees according to this Clause), LICENSEE shall obtain all rights in these patents (including SPCs) and patent applications for that jurisdiction and cease to be obliged to further pay royalties here based on said patents (including SPCs) or patent applications prosecuted or maintained at its own expense.

Clause 6.6

Enforcement of Licensed Patent Rights. LICENSEE shall have the initial right, but not the obligation, to institute, prosecute and control at its own expense and by counsel of its own choice, any action or proceeding with respect to infringement of any Licensed Patent Rights. If LICENSEE does not want to institute, prosecute and control at its own expense and by counsel of its own choice, any action or proceeding with respect to infringement of any Licensed Patent Rights in the Territory, then LICENSORS shall have the right, but not the obligation, to institute, prosecute and control at its own expense and by counsel of its own choice, any action or proceeding with respect to infringement of any Licensed Patent Rights. LICENSORS will have the right to be represented in any action or proceeding brought by LICENSEE by counsel of its own choice and at its own expense. Apart from that, the Party controlling any suit under this Clause 6.4 shall bear all costs and expenses of such suit. All damages or other monies awarded or received in settlement of such suit shall be used to reimburse each Party for all costs and expenses incurred in such infringement action, however, starting with the costs and expenses of the Party controlling the suit. Any additional amounts shall belong to the Party controlling the suit. No settlement, consent, judgment or other voluntary final disposition of such suit may be entered into without the consent of LICENSEE, whose consent shall not be unreasonably withheld.

*** 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.

4 Miscellaneous

4.1 The terms of this license will survive as a license granted by one of the LICENSORS if the other LICENSOR rejects performance under this Agreement due to any actions or declarations of insolvency based on applicable laws of liquidation.

4.2 This Amendment may be executed in one or more counterparts, each of which shall be an original and all of which shall constitute together the same document.

Date: 13 Dec 2006
Signed:
Print Name: Li Westerlund
for and on behalf of **BAVARIAN NORDIC A/S**

Date: 15 Jan 2007
Signed:
Print Name: M. Reichel Dr. W. Nagel
for and on behalf of **GSF - Forschungszentrum für Umwelt u. Gesundheit GmbH**

Date: 11 Dec 2006
Signed:
Print Name: W. H. GÜNZBURG
for and on behalf of **Bio Blue Bird AG**

*** 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.

Exhibit 10.3

MANUFACTURING FRAMEWORK AGREEMENT

This Manufacturing Framework Agreement ("MFA") is entered into as of this 20th day of March, 2014 ("Effective Date") between:

(1) **Austrianova Singapore Pte. Ltd.**, a Singapore corporation having its registered office and principal place of business at 20 Biopolis Way, #05-518 Centros, Singapore 138668. Reg. No. 200705334K ("Manufacturer"), and

(2) **Nuvilex, Inc.**, a Nevada corporation, having its principal office at 12510 Prosperity Drive, Suite 310, Silver Spring, Maryland 20904, Nevada Reg. No. C22368-1996 ("Client").

Manufacturer and Client are individually hereinafter referred to as "Party" and collectively hereinafter referred to as "Parties".

BACKGROUND

Whereas, Manufacturer and Client are parties to that certain Asset Purchase Agreement as more particularly defined and described in Definition "A" below, which provides Client with ownership of certain exclusive licenses that Client will use for the testing of certain cancer products;

Whereas, in furtherance of the Asset Purchase Agreement the Parties wish to enter into this MFA to set forth the terms and conditions under which Manufacturer shall manufacture and supply Client with encapsulated 22P1G and/or recloned 22P1G cells (collectively "22P1G cells"), the latter of which is presently ongoing, to enable Client to have the 22P1G cells necessary for certain clinical indications involving clinical testing in pre-clinical and clinical phases through Phase 2;

Whereas, this MFA supersedes with respect to clinical production and supply of the 22P1G cells, any prior verbally agreed terms or previous terms set forth in section 8 and SG Austria's obligations, points (b) and (c) on pages 9 and 10 of the Asset Purchase Agreement as applied to the encapsulated 22P1G cells and such resulting product for clinical testing in pre-clinical and clinical phases through Phase 2;

Whereas, this MFA is designed for Phase 2 trial material utilizing the encapsulated 22P1G cells, and

Whereas, should it become necessary to make material through a Phase 2/3 trial or a straight Phase 3 trial, then within one year of this Agreement being executed and the first two batches delivered and received by Client, both parties will negotiate in good faith for a new Manufacturing Agreement to be made for Pivotal Trial Supply and bridging commercial supply and eventual commercial manufacturing.

Now, therefore, in consideration of the foregoing promises and the covenants and obligations set forth in this MFA, the Parties agree as follows:

DEFINITIONS

Capitalized terms used, but not defined in this MFA, will have the same meaning assigned to them in the Asset Purchase Agreement. "Sections" refer to the sections of this MFA, unless explicitly provided to refer to a section or article of the Asset Purchase Agreement. As used in this MFA, the following capitalized terms will have the following meanings:

A. "Asset Purchase Agreement" will mean the "Third Addendum to the Asset Purchase Agreement" dated June 25, 2013 by and between Manufacturer and the Client.

B. "AI" will mean the "Active Ingredient," consisting of 22P1G and any of its derivative cells ("Cells"), which will be supplied by Client as at least ten vials of fully tested and validated Working Cell Bank cells, each vial containing at least 2 x 10^6 viable frozen cells. Client shall provide to Manufacturer all detailed protocols for the maintenance and cultivation of the Cells for manufacturing.

C. "Confirmation Date" will mean the date on which written confirmation of the delivery date is given by Manufacturer to Client relating to a Purchase Order.

D. "Goods" will mean the encapsulated 22P1G cells made by encapsulating the AI as described in the Specifications set forth in Appendix A attached hereto.

E. "Lot" will mean a single production run of the Goods.

F. "MFA Effective Date" will mean the date on which this MFA is executed.

G. "Purchase Order" will mean Client's written order for the Goods. The requirements for the contents of the Purchase Order are as provided in Section 1.11.

H. "GMP" and "cGMP" will mean Good Manufacturing Practice(s) and current Good Manufacturing Practice(s), respectively.

I. "Setup" will mean the initial process and work to create the capability(ies) to create the environment and to establish and design the correct parameters for the manufacturing process and all other aspects of the GMP facility such that manufacturing of the final cGMP product can be undertaken by Manufacturer.

"Clinical Forecast" shall mean an overview consisting of Study Information (including Study Name, Registration Number, Test Article, Study Type and Status), Accrual Metrics (including Number of Sites, Number of Subjects and Accrual Rate – both Planned and Actual), and the Study Milestones Timeline (including Study Start, Enrollment Complete, Data Lock, Reports Planned and Study Completion – both Planned and Actual).

J. "Ex-works" shall mean delivery from Manufacturer's facility to shipper or another party designated by Client.

K. "MCB" shall refer to the AI produced in the first amplification after cloning of the 22P1G cells, also known as the Master Cell Bank.

L. "WCB" shall refer to the cells produced by the amplification of the AI from the MCB, also known as the Working Cell Bank.

M. "US FED" shall mean the Federal Reserve (Central Bank) of the United States.

N. "Capsule" shall mean the product of the manufacturing process using of the "Cell-in-a-Box®" technology in which eukaryotic cells are encapsulated in a polymer where one constituent of the encapsulation material is cellulose sulphate and the other polydiallyldimethylammonium chloride.

OPERATIVE PROVISIONS

1. Manufacturing and Supply of the Goods

1.1 Manufacturer shall manufacture and supply the Goods to Client on the terms set forth in this MFA and any applicable Purchase Order.

1.2 Manufacturer may supply Client either directly by Manufacturer itself manufacturing the Goods, and/or indirectly, by providing Goods from one or more of Manufacturer‘s Affiliates, a Third Party and/or Third Parties.

1.3 The Goods to be manufactured and supplied to Client by Manufacturer under this MFA consist of two components: (i) the AI and (ii) the Capsule. The components of the Capsule will be supplied by Manufacturer.

1.4 A Setup will be undertaken by Manufacturer to establish and design the correct parameters for the manufacturing process. Subsequent use of the same AI will not necessitate any additional modification of the original Setup. The Setup costs (“Setup Fee”) will be borne by Client and are described in this MFA.

1.5 Following completion of the Setup, Manufacturer and Client will agree on the final specifications for the encapsulation of the AI as described in Appendix A and make any necessary changes to generate Appendix B. Any subsequent changes to the specifications for the AI will be recorded in a similar way. All changes will be appended to, and become part of, this MFA in an amended form as a new Appendix to this MFA. Any changes to the specifications may entail an additional Setup Fee(s).

1.6 The Goods will be manufactured according to GMP/cGMP standards and to the Specifications agreed between Manufacturer and Client. Client will supply the AI, including relevant external documentation from an accredited external provider to evidence that the AI is free of adventitious agents. Client can arrange this external documentation directly or, in the event that Client wishes Manufacturer to conduct the external testing to determine that the AI is adventitious agent free, Manufacturer will arrange all necessary testing and charge Client at the actual cost plus an administration fee of 7.5% of the cost of the tests listed below in addition to the agreed set-up fee and manufacturing costs/vial. Necessary tests for such adventitious agent free testing may include, but are not be limited to:

Identity:
Isoenzymes
DNA Fingerprinting
Others required by regulatory authorities and/or regulatory consultants

Microbial Contaminants:
Sterility according to European Pharmacopeia/United States Pharmacopeia/Japanese Pharmacopeia
Mycoplasma according to European Pharmacopeia/United States Pharmacopeia/Japanese Pharmacopeia

General Adventitious Viruses:

28-day in vitro assay for the presence of viral contamination using 3 cell lines (Vero, MRC-5 and, in addition, cells of the same species as the test sample).

In vivo assay for the presence of adventitious agents in suckling and adult mice, embryonated eggs and/or guinea pigs.

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)

Other Viruses:

Mouse antibody production test ("MAP")

Hamster antibody production test ("HAP")

Bovine viruses

Porcine viruses

Human viruses:

Standard PCR package: (includes HBV, HCV, EBV, CMV, HIV 1 & 2, HTLV I & II, HHV 6 to HHV8, SV40 and PB19)

Co-cultivation test using rhabdomyosarcoma (RD) cells for endogenous viruses

The exact choice of tests to be completed in the external testing shall be mutually discussed and agreed to between Client and Manufacturer dependent on the origin, history, results of previous testing (if any) and materials with which the AI has come into contact. For clarity, Client will be entitled to specify the exact nature of the tests required after such discussion in the event of a disagreement between the Parties. Client shall be responsible for the cost of tests it requires as set forth above in addition to the agreed set-up fee and manufacturing costs/vial, unless Manufacturer performs any tests not requested by Client in which case the cost of all such tests shall be borne by Manufacturer.

1.7 Manufacturer will admit the AI into the cGMP manufacturing facility upon Manufacturer's sole and complete satisfaction with all previous documentation of any and all prior handling of the AI (including materials and substances that the AI has been in contact with in its complete history) and the evidence showing the AI to be adventitious agent free.

1.8 Client will specify, and Manufacturer will have tested during the Setup, any non-standard substances required for the culture and expansion of the AI. Such substances will be detailed in the specific AI specifications and shall be purchased directly by Manufacturer at cGMP grade, with proper documentation and after audit by Manufacturer. The costs of the audit and the purchase of the non-standard substances will be borne by Client in addition to the agreed Setup Fee and manufacturing costs/vial. Non-standard growth substances are any media or component(s) required for the attachment, growth, release or activity of the AI apart from standard cell culture media specifically Dulbecco's Modified Eagles Medium (DMEM), Roswell Park Memorial Institute Medium (RPMI), trypsin substitutes, phosphate buffered saline, Dimethyl Sulfoxide (DMSO), high-grade cGMP quality water, fetal bovine serum, calf serum and horse serum, all of which must be porcine-component free and must be of US origin. Examples of such non-standard substances would be growth factors, adhesion matrices, such as collagen or laminin, and cell culture media apart from DMEM or RPMI.

1.9 Client will specify and Manufacturer will have tested during the Setup, any non-standard assays required as In Process Controls ("IPC") or as release assays. Such assays will have to be set up and validated by Manufacturer prior to acceptance of the first manufacturing Purchase Order. Such assays or IPCs will be detailed in the specific AI specifications. The cost of set-up, reagents, equipment and assay validation for such non-standard assays will be borne by Client in addition to the agreed Setup-Fee and manufacturing costs/vial. For the avoidance of doubt, non-standard assays are assays in addition to the following standard assays for use in assessing various aspects of the cell production and encapsulation:

Standard Items to Assess During and/or After Production	
Cell Morphology	Turbity
Cell Homogenicity	Osmolarity
Cell Vitality before Encapsulation	Cell Number and Concentration Measurements
Glucose Concentration	Sterility
pH	Endotoxin
Bioburden in Supernatant	Cells per capsule
Mycoplasma	Capsules per Vial
Cell Viability	Cell Viability in Capsules

1.10 The first Clinical Forecast is attached to this MFA as "Exhibit A." Each Calendar Quarter (every three months) after the Effective Date and for the duration of the term of this MFA, Client and Manufacturer will mutually agree upon a new Clinical Forecast by the thirtieth (30th) day into such Calendar Quarter, rolling forward one (1) Calendar Quarter in each forecast. Such Clinical Forecast will cover the immediately succeeding twelve (12) months after the Calendar Quarter in which it is agreed. Each Clinical Forecast will state the requested delivery date for each shipment. The amounts and dates set forth for the first Calendar Quarter in each Clinical Forecast will constitute a firm Purchase Order and will be binding upon Client. The Purchase Order portion of the Clinical Forecast must comply with Section 1.11 of this MFA to the extent applicable. The remainder of such Clinical Forecast will be for information purposes only. Manufacturer will reasonably cooperate with Client to seek to accommodate Client's timing requests for clinical supply. However, Manufacturer will not be required to supply on less than six (6) months notice for the first 3 purchase orders and thereafter at three (3) month's notice provided that this is considered feasible at the discretion of Manufacturer based on the current experience gained in the first 3 purchase orders and Manufacturer's supply is subject to the scheduling and availability of its suppliers and subcontractors for the Goods. Manufacturer's supply obligations are contingent on Client's timely and full payment of invoices in accordance with Section 2 of this MFA. As an example and not by way of limiting the foregoing, in the event the Parties timely agree on a Clinical Forecast, the Clinical Forecast shall constitute a Purchase Order and a Confirmation Date Notice. Manufacturer will then use its commercially reasonable efforts to comply with the manufacturing timeline set forth in the Purchase Order and will notify Client of the timeframe in which the Goods will be manufactured and shipped in accordance with Section 1.13 of this MFA. If such timeframe is accepted by Client and if Client has paid all costs previously owed and not in dispute, production shall be initiated in accordance with the terms of the Purchase Order. In the event of delays by Manufacturer's suppliers and/or subcontractors, adjustments to the Clinical Forecast will be made accordingly.

1.11 Client will either include all relevant terms in each Clinical Forecast to become a Purchase Order as described in Section 1.10 of this MFA or will deliver a Purchase Order to Manufacturer at the same time as its proposal for each update to the Clinical Forecast, as applicable. Purchase Orders will specify the Goods ordered, the quantity ordered and the requested delivery date(s) for each quantity. The Purchase Order will also specify the carrier who will collect the Goods from the manufacturing facility of Manufacturer.

1.12 If the terms and conditions of any Clinical Forecast, Purchase Order or any other document furnished by Client to Manufacturer under this MFA conflict with the terms and conditions of this MFA, the terms and conditions of the Purchase Order or Clinical Forecast will prevail.

1.13 Manufacturer will, within twenty (20) days of the receipt of any Purchase Order from Client, give written notice to Client of the dates by when manufacturing will be complete and the Goods subject to that Purchase Order will be shipped ("Delivery Date").

1.14 Manufacturer will supply quantities of Goods in batches based on the controlling Purchase Order made between Client and Manufacturer, but with a minimum batch size for any production run of four hundred (400) vials with each vial containing three hundred (300) Capsules. If for any reason, including, but not limited to, regulatory matters, cell functionality, cell number per Capsule or similar matters, Client requests a change in the quantity of Goods requested or the minimum size of any batch, Client and Manufacturer shall work to determine the feasibility of providing the requested quantity of Goods and whether there will be any adjustment in price as a result. In addition, Manufacturer will notify Client of the then-standard manufacturing and production batch size for Goods from time to time, although any change must be provided to Client at least 180 days prior to such change taking place in order for Client to be able to notify regulatory authorities and any other necessary individuals or groups.

1.15 Shipping will be by ex-works delivery to the carrier. Subject to *Force Majeure*, Manufacturer will deliver the Goods to the carrier within ten (10) Business Days of the Delivery Date specified in Manufacturer's confirmation of delivery dates under Section 1.13 of this MFA for such shipment. Client will be responsible for the full cost of any freight, postage, shipping, insurance charges and any other costs associated with shipment of the Goods. Manufacturer will work with Client to ensure clearance of each shipment of Goods through customs in the country of manufacture and in the country of destination, but it is Client's responsibility to obtain all necessary approvals or permits required for the Goods to leave the country of origin in accordance with Section 1.19 of this MFA. If the carrier refuses to accept Manufacturer's shipment for any reason related to Client's obligations to the carrier, Manufacturer shall not be in breach of the terms and conditions of this MFA as a result of such refusal, but will be obligated to receive the shipment back and to properly store such shipment to ensure its efficacy as long as feasible until such proper clearance can be accomplished if the Goods have not left the country of manufacture at Client's sole expense. Should Manufacturer have to store the shipment for such a period that the Goods expire, Client will be responsible of all and any loss.

1.16 Manufacturer will number each shipment with a vendor Lot number that allows the Parties to trace raw materials and/or components used to manufacture such shipment.

1.17 At least ten (10) days prior to shipment of Goods, Manufacturer will deliver to Client, on a Lot by Lot basis, a "Certificate of Analysis," which shall include a complete analysis of the Goods after their manufactory, including a lot number, specifications for the Capsules, the number of Cells and any other appropriate assessment of the Goods. The Certificate of Analysis shall also include a list of all adventitious agents that are not normal constituents of the Cells or Capsules, which shall include, but not be limited to, all bacteria, fungi, mold, mycoplasma, viruses, prions or similar agents.

1.18 Client is responsible for obtaining any necessary import permits to allow the importation of the Goods into the United States or its territories, or any other country of destination, for storage or clinical testing. Manufacturer shall cooperate with Client to ensure such clearance of each shipment of Goods in the country of destination, at Client's sole expense.

1.19 Client shall be responsible for the successful clearance of the Goods from the country of manufacture.

1.19.1 Manufacturer shall use commercially reasonable efforts to obtain GMP compliant release of the Goods according to Thai or other regulatory bodies of the country of manufacture. Manufacturer shall implement the necessary steps and systems to allow any required audits and certification to take place.

1.19.2 Any costs incurred for ensuring GMP compliant release of Goods from the country of manufacture will be shared equally between Manufacturer and Client.

1.19.3 Manufacturer shall not ship any Goods until it has received a signed written approval from Client. When Manufacturer releases the Goods, it shall provide Client with a Certificate of Analysis along with full documentation

1.20 The Goods to be manufactured and supplied to Client by Manufacturer under this MFA shall be delivered as frozen product on an ex-works basis. Client assumes all responsibility for and will bear all freight costs, tax and import duties and any import formalities or administrative tasks.

1.21 Once each shipment of Goods has been accepted by the carrier, Client shall be responsible for all further distribution and storage of the Goods in that shipment. Client shall store and distribute such quantities of the Goods in accordance with applicable industry norms and standards and with due regard to the specifications, to the extent applicable, and any and all relevant regulatory requirements.

1.22 Manufacturer and Client agree that the Goods are to be used only as a component part of a series of planned preclinical studies and clinical trials through Phase 2 trials and for no other purpose whatsoever.

1.23 Either Party may at any time request that the Goods be adapted/amended in order to comply with any applicable safety or other statutory requirements. If the changes induced by such adaptation/amendment materially affect the cost, nature or quality of the Goods, the Parties shall renegotiate in good faith the relevant provisions of this MFA. However any such adaptation/amendment may necessitate, through discussion between Manufacturer and Client, a new Setup study, the costs of which, as regulated in Section 2.1 of this MFA, will be the responsibility of Client. Any and all changes to the Specifications will be recorded in a new Appendix to this MFA as described in Section 1.5 of this MFA.

2. Payment

2.1 The costs for the Setup for the AI will be borne by Client and will be six hundred and forty seven thousand US dollars (USD 647,000) adjusted according to the year (see Section 2.4 of this MFA), of which 50% will be paid upon the Effective Date and the balance consisting of the remaining 50% will be paid within three months of the Effective Date.

2.2 Client will pay Manufacturer six hundred and forty seven US dollars (US$ 647) adjusted according to the year (see Section 2.4 of this MFA) per vial of encapsulated 22P1G cells shipped ex-factory.

2.3 Upon confirmation of the delivery date by Manufacturer pursuant to Section 1.13 of this MFA, Manufacturer will be entitled to submit invoices therefor to Client. Payment for the Goods will be in three parts: (i) one third of the total cost of the Purchase Order will be payable within thirty (30) days of receipt of the confirmed delivery date; (ii) one third will be payable within ninety (90) days of receipt of the confirmed delivery date; and (iii) the final one third will be payable within thirty (30) days of receipt of the Goods by the carrier ex-works.

2.4 Prices quoted for the Setup and the cost per vial are valid for 2014 and thereafter will be increased yearly according to the annual inflation rate in the country in which the Goods are manufactured according to the GDP Inflation Rate figures (http://www.gdpinflation.com). At the time of this MFA, the country of manufacture shall be Thailand.

2.5 At Effective Date and as publicized in website www.x-rates.com, 1 USD = 32.51Thai Baht ("Exchange Rate). Should the Exchange Rate differ by more than five percent (5%), Client and Manufacturer agree that prices mentioned in 2.1 and 2.2 above will be adjusted accordingly. At January 31, 2014, the Thai Consumer Index Price was 106.46 according to website www.gdpinflation.com. Should the CPI at moment of ordering the Goods, differ by more than 5 points compared to that as at January 31, 2014 of 106.46, Client and Manufacturer agree that the price mentioned 2.1 and 2.2 will be adjusted accordingly.

2.6 Any additional costs for adventitious agent testing, for non-standard substances, IPCs or release assays will be detailed in the specifications for the AI and billed to Client in addition to the agreed set-up fee and manufacturing costs/vial based on the determination of what constitutes standard and non-standard substances as noted in Section 1.8 of this MFA. A seven and one-half percent (7.5%) administration charge will be charged for third-party services contracted by Manufacturer on behalf of Client, such as testing or assay services.

2.7 Upon submission of each Client Purchase Order to Manufacturer, Client will disclose full details of the nature of the AI required to be manufactured. Further, Client will deliver at least ten (10) tubes of AI, each frozen tube containing at least 2 x 10^6 cells to be encapsulated that are from a fully tested and validated WCB, having already been produced from an MCB, and will provide the full testing and validation documentation for both the MCB and WCB from their respective manufacturers.

3. Late Payment and Interest

If payment is not made on the due date, Manufacturer shall be entitled, without limiting any other rights it may have, to charge Client interest on the outstanding amount (both before and after any judgment). Interest shall accrue on sums outstanding after the due date for payment at the rate of five percent (5%) per annum over the US FED base rate. Further, if payment is not made more than thirty (30) days after the due date, Manufacturer will have the right to suspend or cease production with an obligation to resume only upon further payment. Any payments already made by Client to Manufacturer will be deemed non-refundable if, once Client has made a decision to terminate a project, the project is not reopened within sixty (60) days of the written notice to Manufacturer of such termination.

4. Quality of the Goods

4.1 In entering into this MFA, Client relies on Manufacturer's expertise to manufacture the Goods, and Manufacturer accordingly warrants to Client that all Goods under this MFA shall:

4.1.1 Conform in all respects to the specifications agreed between the Parties as a result of the data gained in the Setup;

4.1.2 For a period of twenty-six (26) weeks following delivery of the Goods, so long as the Goods have been verifiably transported and stored according to Manufacturer's instructions, the Goods shall be warranted to meet the quality required by the specifications and to be free from defects in design, workmanship or materials. In case of delivery of defective or non-conforming Goods, Manufacturer shall remedy the defect or the non-conformity within thirty (30) days after receipt of a written notice from Client giving full particulars of the defect or the non-conformity, together with a transcript of the transport and storage conditions (e.g. by shipper's and Client data logger); and

4.1.3 If the defect or the non-conformity amounts to a material breach of any of the provisions of this MFA or a Purchase Order and Manufacturer fails to remedy the breach within ninety (90) days after receipt of written notice of the defective Goods, Client shall be entitled to receive a credit or terminate this MFA pursuant to Section 7.2.1 of this MFA, all at Client's sole discretion.

4.2 If any claim is made against Manufacturer by a third party arising out of or in connection with the manufacture of the Goods, Client shall indemnify Manufacturer against all damages or other compensation awarded against Manufacturer in connection with the claim or paid or agreed to be paid by Manufacturer in settlement of the claim which is approved by Client, which approval shall not be unreasonably withheld or delayed, and all reasonable legal or other expenses incurred by Manufacturer in or about the defense or settlement of the claim. Manufacturer shall notify Client as soon as practicable after becoming aware of the claim and take all action reasonably requested by Client to avoid, compromise or defend the claim and any proceedings in respect of the claim, subject to the Manufacturer being indemnified and secured to its reasonable satisfaction against all costs and expenses which may be incurred in doing so. Notwithstanding the foregoing, the indemnity obligations set forth in Section 4.2 of this MFA shall not apply to any claims based upon any manufacturing defect or defect in the specification or components made by Manufacturer so long as the claim refers to goods delivered less than 26 weeks previously by the manufacturer or are the result of the negligence, gross negligence or willful misconduct of Manufacturer.

4.4 Manufacturer and Client shall both obtain comprehensive liability insurance to protect all Parties prior to starting production of the Goods ordered by Client and will provide each other copies of their insurance policies following a written request by a Party to do so.

5. Intellectual Property

5.1 Intellectual Property ("IP") shall mean patentable inventions, marks (including trademarks, service marks, certification marks, and/or collective marks), whether registered or common law, materials in which copyrights exists and trade secrets. Client or its affiliates are the licensee owning an exclusive license to use the Cells in the field of oncology treatments in certain territories. For the period of this MFA and for the purposes of exercising its rights and performing its obligations under this MFA, Client grants Manufacturer a non-exclusive license to manufacture the Goods using the technology, subject to Client's or it's Affiliate's exclusive license.

5.1.1 Client is granted the non-exclusive right, to apply Manufacturer's "Cell-in-a-Box" trademark to the Goods during the term of this MFA.

5.2 All artwork supplied by Client from time to time for use in relation to the Goods or their labeling and packaging, and all of Client's or Client's Affiliate's Intellectual Property shall belong exclusively to Client, and Manufacturer shall acquire no rights therein.

5.3 Client shall, at the request and expense of Manufacturer, take all such steps as Manufacturer may reasonably require to assist Manufacturer in maintaining Manufacturer's trademarks. Client shall not represent that it has any title in or right of ownership to any of the trademarks other than the non-exclusive rights to use the Cell in a Box trademark granted by separate agreement or do or suffer to be done any act or thing which may in any way impair the rights of Manufacturer in any of the trademarks or bring into question the validity of its registration.

5.4 Client shall promptly notify Manufacturer of any actual or threatened infringement of any of the trademarks of which Client becomes aware or which Client suspects has occurred or may occur.

5.5. New IP generated during the term of this MFA shall be solely owned by Manufacturer if pertaining to Encapsulation and if generated solely by Manufacturer and shall be solely owned by Client if pertaining solely to the AI and if generated solely by Client. All other new IP involving arising during the term of this MFA as a direct result of work or intellectual input by both Client and Manufacturer ("Joint IP") shall be jointly-owned by Client and Manufacturer. The Parties will license their respective half of the Joint IP to each other for consideration of $1.00 US.

5.5.1 Disclosure of Inventions**.** A Party must promptly inform the other Party of all IP that it or its officers, employees, agents or consultants create as part of this MFA and that falls within the scope of this MFA.

5.5.2 Creation/Ownership. Creation/Ownership of new IP will be determined in accordance with Singapore patent law.

5.5.3 Filing, Prosecution and Maintenance Joint IP. Filing, prosecution and maintenance of Joint IP will be undertaken by Client as follows: (i) give Manufacturer a copy of any draft application before it is filed so that Manufacturer can give Client comments on the substance of the application; (ii) consult with Manufacturer regarding the countries in which patent applications should be filed; (iii) take all reasonable steps to prosecute all patent applications; (iv) respond to proceedings filed by third parties against the patent applications; (v) file all papers and, subject to Section 8.2 of this MFA, pay all fees necessary to maintain any granted patents; (vi) take all actions reasonably requested by Manufacturer to maintain any granted patents; (vii) give Manufacturer copies of all documents relating to the filing, prosecution and maintenance of patent applications and granted patents; (vii) upon written request by Manufacturer, give Manufacturer a report detailing the status of all patent applications and granted patents on or before December 31 of each year this MFA is in effect; and (viii) give Manufacturer prompt notice of any decision by Client to decline, defer, not file a patent application or to abandon a patent application(s) or a granted patent(s). After receiving this notice, Manufacturer may, at its sole cost and expense, take over the filing, prosecution or maintenance of the patent application(s) or granted patent(s). If this occurs, the relevant IP rights will be in assigned to Manufacturer.

5.5.4 Abandonment**.** If Client does not wish to continue to support the filing, prosecution or maintenance of any Joint IP, it shall immediately notify Manufacturer of such decision in writing. At that point, Manufacturer will have the right to keep or allow to lapse any and all rights to the Joint IP. All rights as described in the Asset Purchase Agreement supersede any described herein and shall survive the term or termination of this MFA.

5.6 Infringement. Each Party shall promptly notify the other of any third-party claim of infringement related to any IP. In the event any such claims are made, the Party owning the allegedly infringing IP shall be responsible for the defense of such claims and shall indemnify and hold harmless the other Party with respect to such claims. In the event an infringement claim is related to Joint IP, the Parties shall share equally in the defense of any such claim and in any damages related to such claim.

6. Cooperation of the Parties for Improvements and Modifications

6.1 Client and Manufacturer shall meet either physically or by way of a teleconference at least once per calendar quarter during the term of this MFA to review any matters likely to be relevant to the manufacture, sale, use or development of the Goods.

6.2 Without limiting the general scope of Section 6.1:

6.2.1 Client shall provide Manufacturer with details of any improvement belonging to Client that it wishes to be incorporated into the Goods or any other modification that it wishes to be made to the Goods from time to time; and

6.2.2 Manufacturer shall provide Client with details of any improvement that is made, developed or acquired by Manufacturer from time to time.

6.3 The term "improvement" as used in this MFA means any development, enhancement or derivative of the Goods, or its design or manufacturing process, which would make the Goods less expensive to manufacture, more effective, more useful, more valuable or would in any other way render the Goods preferable in commerce.

6.4 Title to any Intellectual Property rights with respect to any improvement made, developed or acquired by either Party shall belong to that Party, but Client may use any improvement which is made, developed or acquired by Manufacturer and any applicable Intellectual Property of Manufacturer relating to the subject matter of this MFA for its own purposes by way of a non-exclusive, royalty-free license during the term of this MFA and any extensions or renewals hereof.

6.5 Manufacturer shall not unreasonably withhold its consent to the incorporation into the Goods of any improvement belonging to Client or any other modification to the Goods referred to in Section 6.2.1 of this MFA, or of any improvement belonging to Manufacturer referred to in Sections 6.2.2 and 6.4 of this MFA. However, any such modification may necessitate, at the discretion of Manufacturer, a new Setup study, the costs of which, as regulated in Section 2.1 of this MFA, will be borne by Client.

7. Duration and Termination of the MFA

7.1 This MFA shall be effective as of the Effective Date. Unless sooner terminated pursuant to Sections 7.2 or 7.3, this MFA shall continue until terminated by either Party in accordance with the provisions of this MFA .

7.2 Either Party shall be entitled forthwith to terminate this MFA by giving written notice to the other if:

7.2.1 A Party commits any continuing and material breach of any of the provisions of this MFA and fails to remedy (or to commence and reasonably pursue a cure if the breach is not curable within sixty (60) days) the breach within sixty (60) days after receipt of a written notice giving the specific details of the breach and requiring it to be remedied.

7.2.2 A creditor takes possession or a receiver is appointed over any of the property or assets of the other Party;

7.2.3 A Party makes any voluntary arrangement with its creditors or becomes subject to an administration order related thereto;

7.2.4 The other party goes into liquidation (except for the purposes of an amalgamation, reconstruction or other reorganization and in such manner that the company resulting from the reorganization effectively agrees to be bound by or to assume the obligations imposed on that other party under this MFA); or

7.2.5 A Party ceases or threatens to cease to carry on its business.

7.3 Any waiver by either Party of a breach of any provision of this MFA shall not be considered as a waiver of any subsequent breach of the same or any other provision.

7.4 The rights to terminate this MFA shall not constitute a Party's ability to exercise any other right or seek any other remedy contained in this MFA or available by law.

8. Consequences of Termination

8.1 Upon the termination of this MFA for any reason, except for reason of non-payment by Client, Manufacturer shall be required to continue the manufacture of any Goods ordered pursuant to a Purchase Order then in effect, which manufacturing period shall continue until all Goods have been manufactured or three months, whichever is shorter ("Phase-Out Period"). During the Phase-Out Period, Client shall be permitted to sell all Goods that have been provided to Client pursuant to this MFA. At the end of the Phase-Out Period, Client shall offer to sell to Manufacturer all Goods which have been manufactured pursuant to this MFA, but not sold, and all usable but unused stocks of labeling and packaging for the Goods, at a price equal to their cost to Client (excluding any fees paid by the Client to Manufacturer above actual cost of the Goods), together with any necessary royalty-free licenses allowing Manufacturer to resell these Goods and to benefit exclusively from the financial proceeds of these sales.

8.2 Subject to Section 8.1, on the termination of this MFA for any reason Client shall:

8.2.1 Subject to Section 1.4 of this MFA, cease to sell the Goods or to use, either directly or indirectly, any of the technology referred to in Section 1.4 or Intellectual Property referred to in Section 5 of this MFA that is owned by Manufacturer and forthwith return to Manufacturer any documents in its possession or control which contain or record any part of any of that Intellectual Property.

8.3 Except as provided in Section 8 of this MFA and any accrued rights or obligations pursuant to this MFA, neither Party shall have any further obligation, contractual or otherwise, to the other.

8.4 The provisions of Section 9 of this MFA shall survive termination of the MFA, regardless of the reason for termination.

9. Confidentiality

9.1 Both Parties understand and acknowledge that, by virtue of this MFA, they may both receive or become aware of technology and information belonging or relating to the other Party, its business, business plans, affairs or activities which information is confidential and proprietary to the other Party and/or its manufacturers and/or customers and in respect of which they are bound by a strict duty of confidence ("Confidential Information").

9.2 As a consequence thereof, neither Party shall, either during the period of this MFA or at any subsequent time, disclose to any other person Confidential Information disclosed to it by the other Party under this MFA and shall use its best efforts to keep such Confidential Information (whether marked as such or not), except as provided by Section 9.3 or 9.4 of this MFA.

9.3 Any of the Confidential Information referred to in Section 9.1 of this MFA may be disclosed to:

9.3.1 Any contractor of or supplier to the Party in question of any equipment or products;

9.3.2 Any governmental or other authority or regulatory body; or

9.3.3 Any directors or employees or consultants and professional or legal advisers of the Party in question;

to such extent only as is necessary for the purposes of this MFA or as required by law, and subject in each case (other than under Section 9.3.2 of this MFA) to the Party in question first obtaining (and submitting to the other Party a copy of) a written undertaking from the person to whom the disclosure is made, as nearly as practicable in the terms of Section 9 of this MFA, to keep it confidential and to use it only for the purposes for which the disclosure is made.

9.4 Any of the Confidential Information referred to in Section 9.1 of this MFA may be used by the Party in question for any purpose, or disclosed by that Party to any other person, but only to the extent that any part of it is at the date of this MFA or subsequently becomes public knowledge through no fault of the Party in question; provided, however, that in so doing such Party does not disclose any part of Confidential Information which is not public knowledge.

9.5 This undertaking and the obligations contained in Section 9 of this MFA shall continue for a period of 10 years and shall survive termination of this MFA.

10. Force Majeure – excuse for non-performance

10.1 *"Force Majeure"* means war, emergency, accident, fire, earthquake, flood, storm, industrial strike or other impediment which the affected Party proves was beyond its control and that it could not reasonably be expected to have taken the impediment into account at the time of the execution of this MFA or to have avoided or overcome it or its consequences.

10.2 A Party affected by *Force Majeure* shall not be deemed to be in breach of this MFA, or otherwise be liable to the other Party, by reason of any delay in performance or the non-performance of any of its obligations under this MFA to the extent that the delay or non-performance is due to any *Force Majeure* of which it has notified the other Party in accordance with Section 10.3 of this MFA. The time for performance of that obligation shall be extended accordingly, subject to Section 10.4 of this MFA.

10.3 If any *Force Majeure* occurs in relation to either Party which affects or is likely to affect the performance of any of its obligations under this MFA, it shall notify the other Party within a reasonable time as to the nature and extent of the circumstances in question and their effect on its ability to perform.

10.4 If the performance by either Party of any of its obligations under this MFA is prevented or delayed by *Force Majeure* for a continuous period in excess of three (3) months, the other Party shall be entitled to terminate this MFA by giving written notice to the Party affected by the *Force Majeure.* However all reasonable costs committed by Manufacturer arising from a Purchase Order received will be reimbursed by Client.

11. Change of circumstances; Hardship

11.1 Where the performance of this MFA becomes more onerous than reasonably anticipated at the time of execution of this MFA for one of the Parties, that Party is nevertheless bound to perform its obligations subject to the following provisions.

11.2 If, during the term of this MFA, events occur that have not been contemplated by the Parties and which render the MFA fundamentally unfair to that a Party, thereby placing an excessive burden on one of the Parties in the performance of its contractual obligations ("Hardship"), that Party shall be entitled to request revision of this MFA provided that:

11.2.1 The events could not reasonably have been taken into account by the affected Party at the time of execution of this MFA;

11.2.2 The events are beyond the control of the affected Party; and

11.2.3 The risk of the events is not one which, according to this MFA, the Party affected should be required to bear (an increase in the cost of performance for a Party shall not constitute a hardship hereunder).

11.3 Each Party shall in good faith consider any proposed revision seriously put forward by the other Party in the interests of the relationship between the Parties.

12. No Partnership or Agency

Nothing in this MFA shall: (i) be deemed to constitute a partnership in law between the Parties; (ii) make either Party the agent of the other for any purpose; or (iii) entitle either Party to commit or bind the other Party in any manner.

13. Assignment and Subcontracting

13.1 Subject to Section 1.2, this MFA is personal to the Parties, and neither Party shall, without the prior written approval of the other:

13.1.1 Assign, mortgage, charge or otherwise transfer or deal in, or create any trust over, any of its rights; or

13.1.2 Subcontract, except by Manufacturer to its sub-contractors or otherwise delegate the whole or any part of its rights or obligations under this MFA to another person; provided, however: a Party may, without the permission of the other Party, assign this MFA to: (i) its Affiliates; (ii) any purchaser of all or substantially all of its assets; or (iii) any successor corporation resulting from any merger or consolidation of such Party with or into such corporations.

14. Notices

14.1 Any notice under this MFA shall be in writing (which may include e-mail) and may be served by leaving it or sending it to the address of the other party as specified in Section 14.2 of this MFA, in a manner that ensures receipt of the notice can be proved.

14.2 For purposes of Section 14.1 of this MFA, notification details are the registered addresses as set forth at the beginning of this MFA, unless other details have been duly notified in accordance with Section 14 of this MFA.

15. Entire Agreement

15.1 This MFA and the Asset Purchase Agreement constitute the entire agreement between the Parties with regard to the subject matter hereof. Neither Party has entered into this MFA in reliance upon any representation, warranty or undertaking of the other Party that is not expressly set out or referred to in this MFA or the Asset Purchase Agreement. This shall not preclude any liability for fraudulent misrepresentation. In the event of a conflict between the Asset Purchase Agreement and this MFA, the terms of this MFA shall control and shall supersede any previous agreement or understanding relating to its subject matter; however, it is the intent of the parties that the Asset Purchase Agreement and the MFA be read and interpreted together, giving meaning to all terms and conditions wherever and whenever possible.

15.2 This MFA may not be varied except by a signed written agreement between the Parties. If any provision of this MFA is held by any court or other competent authority to be invalid or unenforceable in whole or in part, this MFA shall continue to be valid as to its other provisions and the remainder of the affected provision, unless it can be concluded from the circumstances that, in the absence of the provision found to be null and void, the Parties would not have executed this MFA. The Parties shall use all reasonable efforts to replace all provisions found to be null and void by provisions that are valid under the applicable law and come closest to their original intention.

16. Dispute resolution

Any dispute arising under this MFA which cannot be resolved by consultation, negotiation and mediation between the Parties shall within ninety (90) days of commencement of discussions related to the dispute, shall be referred to and finally resolved by arbitration in London, England in accordance with the Arbitration Rules of the London International Arbitration Centre for which rules are deemed to be incorporated by reference into Section 16 of this MFA. The language of the arbitration shall be English. Any such arbitration award shall be final and binding upon the Parties and judgment on such award may be entered into any court or tribunal having jurisdiction thereof.

17. Applicable Law

The validity and interpretation of this MFA and the legal relations of the Parties to it shall be governed by the laws of Singapore. The United Nations Convention on Contracts for the International Sale of Goods (Vienna Sales Convention of 1980−CISG) is specifically not applicable to this MFA.

18. Miscellaneous

18.1 Binding Effect. This MFA is binding upon and inures to the benefit of a Party's legal representatives, successors and permitted assigns.

18.2 Counterparts. This MFA may be executed in two or more counterparts, each of which will be deemed an original and all of which shall constitute together the same document.

18.3 Amendment. This MFA may be amended only by a written agreement between the Parties.

18.4 Waiver. A Party's compliance with the terms of this MFA may only be waived by written notice from the other Party. Unless stated otherwise, a waiver will not be deemed an ongoing waiver. The delay or failure of a Party to require performance of a term of this MFA will not prevent the Party from enforcing the same term later.

18.5 Third Party Beneficiaries. It is the intention of the Parties that no third party will have, and no third party has, any rights under this MFA.

SIGNED by	)
	)
	)
for and on behalf of the Manufacturer	) Dr. Brian Salmons) CEO, Austrianova Singapore Pte. Ltd.
	)
	)
	)
	)
in the presence of:-	)
	)

SIGNED by	)
	)
	)
for and on behalf of the Client	) Kenneth L. Waggoner) Chief Executive Officer and President of Nuvilex, Inc.
	)
	)
	)
	)
in the presence of:-	)
	)

Appendix A: Specifications for Encapsulated 22P1G Cells

Parameter	Method	Specification Limits
Visual appearance	EP	Clear, coloured £ BG4
Number of Capsules per vial	Manual Scanner	300 ± 20 %
Viability	AlamarBlue Assay	³ 20000 cell equivalents (corresponds to metabolism activity of 20000 not encapsulated HEK 22PIG cells)
Enzymatic activity	Resorufin Assay	Activity detectable
Sterility	Membrane Filtration (EP 2.6.1)	sterile
Purity testing - mycoplasma	Fluorescence method	not detected
Purity testing - mycoplasma	Co-Culture, PCR	not detected
Endotoxins	LAL test	£ 10 EY / mL
pH of supernatant	EP	7.5 ± 0.5
Freezing rate	MFGVII-PA-12-103	-0.3 to -1.0^0 C/min
Osmolality of supernatant	QC-PA-10-049/03	Report only
DMSO assay of supernatant	QC-PA-10-049/Annex01/01	9-11 %

Exhibit A: Clinical Forecast

Study Information **Accrual Metrics** **Subject Accrual Performance**

		P	**A**
Study No.:	Total No. Sites:		
Study Short Name:	Total No. Subjects:		
Registration No.:	Monthly Subject Accrual:		
Test Article:			
Study Type:			
Study Status: Planned			

Study Milestones Timeline

Exhibit 10.4

MASTER SERVICES AGREEMENT

THIS MASTER SERVICES AGREEMENT ("Agreement") is made as of this 7th day of April, 2014 ("Effective Date") by and among ViruSure GmbH, an Austrian corporation, with a business address at Tech Gate Science Part, Donau City Strasse 1, A-1220, Vienna, Austria ("VIRUSURE") and Nuvilex, Inc., a Nevada corporation, with a business address at 12510 Prosperity Drive, Suite 310, Silver Spring, Maryland 20904 U.S.A. ("COMPANY").

BACKGROUND

VIRUSURE is a contract research organization engaged in providing products and services including, without limitation, discovery and development services, preclinical, clinical and commercial testing services, scientific and regulatory consulting and research models and related services. COMPANY desires VIRUSURE to provide and VIRUSURE agrees to provide the services described in this Agreement ("Services") pursuant to the terms and conditions of this Agreement. The Services shall consist of individual studies or consultations (each, a "Study") defined in the Supporting Documents (as hereinafter defined). In consideration of the mutual promises and covenants set forth herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties, intending to be legally bound, agree as follows:

1. The Study. VIRUSURE shall render the Services as set forth in a Protocol and/or Statement of Work, Letter of Payment Authorization, Letter of Agreement, Letter of Commitment, Work Order, Purchase Order or Consulting Services Letter (the Protocol and/or Statement of Work, Letter of Payment Authorization, Letter of Agreement, Letter of Commitment, Work Order, Purchase Order and Consulting Services Letter are collectively referred to in this Agreement as the "Supporting Documents"). A "Protocol" and/or "Statement of Work" shall mean an attachment to this Agreement describing the nature, design and scope of the Study and the schedule of work to be performed or consulting services to be provided during the course of an individual Study conducted by VIRUSURE for COMPANY. A "Letter of Payment Authorization", "Letter of Agreement", "Work Order" or "Purchase Order" shall mean an attachment to this Agreement that describes with respect to a particular Study the price, fees and payment schedule for that Study and any modifications of the terms of this Agreement as applied to a particular Study. A "Letter of Commitment" shall mean an attachment to this Agreement that describes a commitment of space and resources by VIRUSURE. A Consulting Services Letter shall mean an attachment to this Agreement that describes VIRUSURE's consulting services and pricing for such services. In the event of a conflict between the terms contained in the Supporting Documents and this Agreement, the terms of this Agreement shall control, unless specifically agreed upon to the contrary in the Supporting Documents. The Supporting Documents when signed by VIRUSURE and COMPANY shall be incorporated into and made a part of this Agreement.

2. Conduct of Services.

2.1. VIRUSURE will maintain industry standards of professional conduct in the performance of the Study and in the preparation of all related reports. VIRUSURE and COMPANY will adhere to all material government laws, rules and regulations applicable to the conduct of the Study ("Applicable Law"). If applicable, and as set forth in the Supporting Documents, VIRUSURE will perform the Study in compliance with the current Good Laboratory Practices ("GLP") or Good Manufacturing Practices ("GMP") of the appropriate governmental regulatory agencies.

2.2. VIRUSURE will conduct the Study in accordance with the Supporting Documents, which may be amended from time to time upon the mutual agreement of VIRUSURE and COMPANY. VIRUSURE agrees not to intentionally change or deviate in any material manner from the Supporting Documents without COMPANY's prior approval. Deviations from the Supporting Documents may be made in an emergency without COMPANY's approval, provided that VIRUSURE shall use commercially reasonable efforts to obtain COMPANY's verbal approval, which shall be subsequently confirmed by COMPANY in writing. The parties acknowledge that during the course of performing the Study in accordance with the Supporting Documents, additional costs may be incurred by VIRUSURE as a result of procedural changes which do not amount to or require a change in the Supporting Documents, but which are deemed necessary by VIRUSURE to successfully perform said Study, and which could not be foreseen at the time of the preparation of the Supporting Documents. If such procedural changes occur, VIRUSURE shall advise COMPANY prior to their implementation and obtain COMPANY's prior written approval as to the necessity and additional cost thereof. Should such changes be urgent, and VIRUSURE is unable to obtain COMPANY's written approval in advance, VIRUSURE shall use commercially reasonable efforts to obtain COMPANY's verbal approval, which shall be subsequently confirmed by COMPANY in writing. Upon obtaining such approval, COMPANY agrees that in order to maintain the integrity of the Study, VIRUSURE may proceed accordingly and be entitled to recover such additional costs from COMPANY upon presentation of an explanation of such procedural changes, urgency and the necessity thereof. VIRUSURE shall not subcontract all or a part of the Services to a third party without obtaining prior written consent of COMPANY.

2.3. After the Study has been completed, VIRUSURE may be requested by COMPANY to provide additional consultation services concerning the Study. Upon such a request by COMPANY, VIRUSURE will provide the requested services and will be paid an amount mutually agreed to between COMPANY and VIRUSURE. These consultation services will be subject to the provisions on Confidentiality and Ownership set forth in Sections 8 and 13 of this Agreement, respectively.

3. Test Articles. If applicable, COMPANY will provide VIRUSURE with sufficient amounts of all compounds, materials, or other substances meeting relevant specifications ("Test Articles") with which to perform the Study, as well as such complete and accurate data as is necessary to apprise VIRUSURE of the identity, strength, purity, stability and composition or other appropriate characteristics of each batch, proper storage and safe handling requirements of Test Articles, including a Material Safety Data Sheet ("MSDS") or equivalent documentation (e.g. Genetically Modified Organism ("GMO") assessment), such as Sample Submission Form that is provided and requested by VIRUSURE. In addition, COMPANY will provide VIRUSURE certification that the methods of synthesis, fabrication, or derivation of Test Articles had been documented by COMPANY. COMPANY will arrange shipments of Test Articles. All costs associated with shipping Test Articles to VIRUSURE shall be the responsibility of COMPANY, and VIRUSURE shall not be responsible for any loss, damage or destruction of the Test Articles while in transit.

4. Personnel. VIRUSURE will arrange for qualified personnel to support VIRUSURE's obligations under this Agreement. To the best of VIRUSURE's knowledge, VIRUSURE represents that none of its employees who are to participate in a Study have been debarred and none of such employees are under consideration to be debarred by the U.S. Food and Drug Administration from working in or providing services to any pharmaceutical or biotechnology company under the Generic Drug Enforcement Act of 1992, as amended.

5. Inspections.

5.1. Upon reasonable advance notice, VIRUSURE will permit COMPANY, during normal business hours and at mutually agreeable times, to visit the VIRUSURE facilities where the Study is taking place to monitor VIRUSURE's performance of the Study.

5.2. VIRUSURE will notify COMPANY as soon as practical in the event of any regulatory inspection of VIRUSURE's facilities that directly impacts a Study. In the event of an inspection of COMPANY's Study by a regulatory or administrative agency, VIRUSURE will to the extent permissible under Applicable Law, consult with and allow COMPANY to review and comment on any responses to such agency related to the inspection.

5.3. To the extent that COMPANY engages a third party to perform any services related to a Study, COMPANY shall provide all information requested by VIRUSURE regarding such services, including without limitation all information regarding regulatory and quality assurance sufficient to enable VIRUSURE to comply with its own regulatory and/or quality assurance obligations.

6. Records and Reports.

6.1. VIRUSURE will keep complete and accurate records of the status and progress of the Study as required by the Supporting Documents.

6.2. Provided that COMPANY is not in default hereunder or under any of the Supporting Documents, VIRUSURE will furnish a report or data containing information specified in the Supporting Documents. All reports will be prepared in the standard format of the VIRUSURE unless otherwise specified in the Supporting Documents or as otherwise agreed to by the parties.

6.3. All raw data, study documentation, protocols, interim and final reports, specimens generated as a result of a preclinical, clinical and/or commercial Study ("Deliverables") are COMPANY's property. At COMPANY's cost and expense, if Applicable Law or COMPANY requires COMPANY's property to be held by VIRUSURE, VIRUSURE shall store COMPANY's property as agreed upon in the Supporting Documents and in accordance with VIRUSURE's standard archiving terms and conditions set forth on Exhibit A attached to this Agreement and made a part hereof. Upon reasonable advance notice, provided that COMPANY is not in default under this Agreement or under any of the Supporting Documents, COMPANY shall have reasonable access to such material, and shall have the right to obtain photocopies of the raw data and supporting documentation, at COMPANY's expense. Upon request and at the expense of COMPANY, VIRUSURE will assist COMPANY in transferring any of COMPANY's property to a third party as instructed by COMPANY.

6.4. In the event VIRUSURE provides electronic access to the Study data, records, reports and other documentation and COMPANY elects to use such electronic access, the use of such electronic access shall be governed by VIRUSURE's standard electronic access terms and conditions which may be accessed via VIRUSURE's website.

7. Compensation.

7.1. COMPANY will pay VIRUSURE as set forth in the Supporting Documents ("Study Price"). All invoices are due and payable thirty (30) days from the date of Company's receipt of the invoice, and COMPANY agrees to pay all invoices submitted. All amounts not paid by COMPANY when due shall accrue interest from the applicable due date until paid, at the rate of one and one half percent (1.5%) per month. VIRUSURE may elect to cease or suspend work on a Study or withhold required reports or other deliverables if COMPANY does not make payments when due and payable.

7.2. All applicable termination, delay, suspension or cancellation fees will be set forth in the Supporting Documents.

7.3. COMPANY and VIRUSURE agree that neither COMPANY nor VIRUSURE should receive a benefit or a detriment from differences arising from variations between foreign currency exchange rates for the currencies used for this project and those existing at the dates of the actual invoices, as published in the Wall Street Journal. If such a difference is larger than +/- 5%, COMPANY and VIRUSURE have the right to request a re-evaluation of the future billing rates based on the work performed by VIRUSURE after such a difference is observed.

7.4. All Value Added Taxes, sales taxes and any other taxes required by Applicable Law shall be paid by COMPANY.

8. Confidentiality. The parties may exchange proprietary and confidential information during the term of this Agreement, including, without limitation, the existence and terms of this Agreement. The parties will identify, in writing, such information as confidential and/or proprietary. If a party intends to disclose confidential information to the other party orally, the disclosing party shall: (i) alert the other party of the confidential nature of the disclosure prior to the disclosure; and (ii) provide written notice to the other party of the confidential nature and contents of such disclosure within ten (10) days of the original disclosure. Each party will use its commercially reasonable efforts to maintain such information in confidence and will employ reasonable and appropriate procedures to prevent its unauthorized publication or disclosure. Except as expressly authorized in writing, neither party shall use the other party's proprietary or confidential information for any purpose other than in performance of this Agreement. The obligations of confidentiality set forth in Section 8 of this Agreement will survive the termination or expiration of this Agreement for a period of five (5) years. The confidentiality provisions of Section 8 of this Agreement shall not apply to any part of such information, which:

a) is known to the receiving party at the time it was obtained from the disclosing party;

b) is acquired by the receiving party from a third party, and such third party did not obtain such information directly or indirectly from the disclosing party under an obligation not to disclose;

c) is or becomes published or otherwise in the public domain other than by violation of this Agreement by the receiving party;

d) is independently developed by the receiving party without reference to or reliance upon the information provided by the disclosing party; and

e) is required to be disclosed by the receiving party to comply with applicable laws or governmental regulations; provided that the receiving party provides prompt written notice of such disclosure to the disclosing party and cooperates with the disclosing party's reasonable and lawful actions to avoid and/or minimize the extent of such disclosure.

9. Use of Names.

Neither party will use the other party's name or the name of any employee of the other party in any advertising, packaging, promotional material, or any other publicity relating to this Agreement, without the prior written approval of the other party.

10. Warranties.

10.1. COMPANY warrants that it owns all rights, title and interest in or otherwise has the right to use the Test Articles and the intellectual property related thereto, and that, to the best of COMPANY's knowledge, VIRUSURE's use of any and all such Test Articles in connection with any Study will not infringe the intellectual property rights of any third party.

10.2. VIRUSURE warrants that the Services shall conform to the specifications set forth in the Supporting Documents, Applicable Law and the current material applicable standards, regulations and procedures of the appropriate regulatory agencies. VIRUSURE neither warrants nor represents that the results of the Study will be acceptable to any regulatory or governmental agency to which they are presented nor that the results of the Study will enable COMPANY to further develop, market or otherwise exploit the Test Articles or any other product or service.

10.3. ***THE WARRANTY BY COMPANY SET FORTH IN SECTION 10.2 ABOVE IS IN LIEU OF ANY AND ALL OTHER REPRESENTATIONS OR WARRANTIES, EXPRESS, IMPLIED OR STATUTORY INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR FOR NON-INFRINGEMENT OF A PATENT, TRADEMARK OR OTHER INTELLECTUAL PROPERTY RIGHT.***

11. Limitation of Liability.

11.1. In as far as no other terms or conditions have been agreed, the VIRUSURE's liability in the event of any claim is limited to the performance of the Services. VIRUSURE is exempt from honouring compensation, in particular for any damages beyond the performance of the Services, unless gross negligence or wilful misconduct can be proven. This clause shall continue to be effective without limit of time after the expiration or termination of the Services.

11.2. VIRUSURE will not be liable for penalties or liquidated damages or for special, indirect, consequential, punitive, exemplary or incidental damages of any type or kind (including, without limitation, lost profits) regardless of whether any such losses or damages are characterized as arising from breach of contract, breach of warranty, tort, strict liability or otherwise, even if VIRUSURE is advised of the possibility of such losses or damages, or if such losses or damages are foreseeable.

11.3. VIRUSURE's liability under this Agreement, regardless of the form of action, shall be limited to actual damages and shall not exceed the total amount paid for the Protocol or Statement of Work under which such liability arises, except to the extent caused by gross negligence or wilful misconduct of the VIRUSURE. In no event shall either VIRUSURE be liable for any damages arising from or in connection with any decision by COMPANY or any third party, made independently of the Services or VIRUSURE's confidential information provided under this Agreement, to further research, develop or market Test Articles or any derivative or product or service related thereto or the use of Test Articles or any product or derivative or service related thereto.

11.4. Subject to the limitations set forth in this Section 11, in the event that VIRUSURE commits a breach of the warranty set forth in Section 10.2 above, VIRUSURE's sole liability, and COMPANY's sole remedy, shall be for VIRUSURE to perform, at VIRUSURE's cost and expense, the affected work or portion of the research affected by the breach to the relevant specification.

12. Indemnities.

12.1. Subject to the limitations of liability contained in Section 11 of this Agreement above, VIRUSURE will defend, indemnify, save and hold harmless COMPANY and its parent, subsidiaries and affiliates, and their respective directors, officers, employees and agents, from and against any claims, demands, lawsuits, actions, causes of action, losses, damages, fines and liabilities, including, without limitation, reasonable attorneys' fees and any costs and expenses associated with each party's compliance with a subpoena or other similar legal request related to a Study ("Claims") arising out of or in connection with or attributable to VIRUSURE's breach of this Agreement, gross negligence or wilful misconduct in performance of the Study and will pay any costs and damages which may be assessed against them, provided that VIRUSURE is given written notice of the Claims within ten (10) days of the date of notice to COMPANY and is given information, reasonable assistance and sole authority to defend the Claims, provided that no settlement of such Claims may be effected by VIRUSURE without COMPANY's written consent (which consent will not be unreasonably withheld).

12.2. COMPANY will defend, indemnify, save and hold harmless VIRUSURE and its parent, subsidiaries and affiliates, and their respective directors, officers, employees and agents, from and against any Claims arising out of or in connection with or attributable to: (i) the research, development, manufacture, distribution, use, sales or other disposition by COMPANY, or any distributor, collaborator, customer, sub-licensee, contractor, subcontractor, representative or agent of COMPANY, of the Test Articles and/or any other substances upon which the services of VIRUSURE were performed, except to the extent such Claims arise from VIRUSURE's breach of this Agreement, or gross negligence or wilful misconduct of VIRUSURE; or (ii) any infringement of any third party's patent rights or unauthorized use or misappropriation of its know-how related to the Study, except to the extent such Claims arise from or in connection with the intellectual property, confidential information or other techniques of VIRUSURE employed in the performance of the Services; or (iii) COMPANY's breach of this Agreement, gross negligence or wilful misconduct in connection with this Agreement and will pay any costs and damages which may be assessed against them, provided that COMPANY is given written notice of the Claims within ten (10) days of the date of notice to VIRUSURE and is given information, reasonable assistance and sole authority to defend the Claims, provided that no settlement of such Claims may be effected by the VIRUSURE without COMPANY's written consent (which consent will not be unreasonably withheld).

13. Ownership. Any inventions and/or techniques for carrying out the Services which relate to the conduct of VIRUSURE's business are and shall remain VIRUSURE's exclusive property, including, but not limited to; present and future documentation, scientific and technical data, test procedures and other information that is owned or licensed by VIRUSURE and that is not developed hereunder. Subject to the terms and conditions hereof, VIRUSURE shall have the right to use concurrent control data as part of its general historical database. Any data, discoveries or inventions developed or generated pursuant to this Agreement which directly relate to any information or materials (including Test Articles) provided by COMPANY under this Agreement or those relating to Deliverables, including, without limitation, new data, uses, processes or compositions directly relating to the information or materials (including Test Articles) provided under this Agreement or those relating to Deliverables shall be the exclusive property of COMPANY. VIRUSURE agrees to assist COMPANY in securing for COMPANY any patents, copyrights or other proprietary rights in such data, discoveries or inventions and to perform all acts that may be reasonably required to vest in COMPANY all right, title and interest in such data, discoveries or inventions, and VIRUSURE shall be reasonably compensated for such assistance. All costs and expenses associated with establishing COMPANY's rights therein shall be COMPANY's responsibility.

14. Force Majeure. Except with respect to the payment of monies due under this Agreement, neither party shall be considered in default of the performance of any obligation hereunder to the extent that the performance of such obligation is prevented or delayed by fire, flood, earthquake, hurricane, explosion, disease, contamination, strike, acts of terrorism, war, insurrection, embargo, government requirement, civil or military authority, act of God, or any other event, occurrence or condition which is not caused, in whole or in part, by that party, and which is beyond the reasonable control of that party.

15. Term and Termination.

15.1. This Agreement will commence on the Effective Date and will continue for five (5) years from the Effective Date or until terminated by the parties as set forth below.

15.2. COMPANY shall have the right to terminate an on-going Study at any time without cause upon thirty (30) days prior written notice to VIRUSURE. In the event a Study is terminated without cause, VIRUSURE shall be paid for all Services rendered through the effective date of termination, together with any additional expenses incurred in connection with the shutdown of the Study, including, without limitation, any irrevocably committed costs incurred by VIRUSURE.

15.3. Either party may terminate this Agreement upon thirty (30) day's notice to the other party, provided that VIRUSURE completes all Studies in progress and COMPANY makes all payments due to VIRUSURE through the effective date of termination date as set forth in Section 16.2.

15.4. Upon termination, neither party will have any further obligations under this Agreement, except that: (i) the liabilities accrued through the effective date of termination; and (ii) the obligations which by their terms survive termination, including the applicable confidentiality, record keeping, regulatory compliance, intellectual property and indemnification provisions of this Agreement, shall survive termination.

16. Employee Solicitation. COMPANY agrees that, during the term of a Study and for a period of one hundred eighty (180) days thereafter, COMPANY will not solicit for hire or hire as an employee, or engage as an independent contractor, any person who has been involved in rendering services on the Study, without the prior written consent of VIRUSURE. In the event of such solicitation, hiring or engagement, in addition to any other remedy VIRUSURE may have, COMPANY shall pay to VIRUSURE an amount equal to such employee's annual salary.

17. Dispute Resolution. The parties shall attempt, in good faith, to resolve through negotiations any controversy, claim, or dispute arising out of this Agreement. In the event that negotiations are not successful, the controversy, claim or dispute shall be submitted to third party mediation upon terms reasonably acceptable to the parties. If such claim, controversy or dispute is not resolved through mediation, upon written demand of either party, the claim, controversy or dispute shall be submitted to arbitration. Such arbitration shall take place and proceed in accordance with the laws of Austria and rules of Conciliation and Arbitration of the International Chamber of Commerce. A record and transcript of the proceedings shall be maintained. Any award shall be made in writing and in reasonable detail, setting forth the findings of fact and conclusion of law supporting the award. The determination of a majority of the panel of arbitrators shall be the decision of the arbitrators, which shall be binding regardless of whether one of the parties fails or refuses to participate in the arbitration. The decision shall be enforceable by a court of law, provided that the decision is supported by substantial fact and is without material error of law. All costs of such arbitration, except expert fees and attorneys' fees, shall be shared equally by the parties.

18. Miscellaneous.

18.1. Notices. All notices from one party to the other will be in writing and will be delivered by addressing the same to the addresses first set forth above, or at such other address as either party may specify in writing to the other. Notices shall be sent by overnight courier, certified mail, return receipt requested, or by other means of delivery requiring a written acknowledged receipt. All notices shall be effective upon receipt.

18.2. Independent Contractor. The business relationship of VIRUSURE to COMPANY is that of an independent contractor and not of a partner, joint venture, employer, employee or any other kind of relationship. VIRUSURE will be solely responsible for expenses and liabilities associated with the employment of its employees.

18.3. Assignment. This Agreement, and the rights and obligations under this Agreement, may not be assigned or transferred by either party without the prior written consent of the other party, except that either party may assign this Agreement to an affiliated company or in connection with the merger, consolidation or sale of substantially all assets related to the Study.

18.4. Entire Agreement. This Agreement, together with the Supporting Documents, sets forth the entire agreement and understanding between the parties, superseding any and all previous statements, negotiations, documents agreements and understandings, whether oral or written, as to the subject matter of the Agreement. No modification or waiver of the provisions of this Agreement shall be valid or binding on either party unless in writing and signed by both parties. No waiver of any term, right or condition under this Agreement on any one occasion shall be construed or deemed to be a waiver or continuing waiver of any such term, right or condition on any subsequent occasion or a waiver of any other term, right or condition hereunder.

18.5. Severability. In the event that any one or more of the provisions contained in this Agreement is for any reason, held to be invalid, illegal or unenforceable in any respect, that invalidity, illegality or unenforceability will not affect any other provisions of this Agreement, and all other provisions will remain in full force and effect. If any provision of this Agreement is held to be excessively broad, it will be reformed and construed by limiting and reducing it so as to be enforceable to the maximum extent permitted by law.

18.6. Applicable Law. This Agreement will in all events and for all purposes be governed by, and construed in accordance with, the laws of Austria without regard to any choice of law principle that would dictate the application of the law of another jurisdiction.

18.7. Counterparts. This Agreement may be executed in counterparts, which taken together shall constitute a single legal document.

18.8. Language of Agreement. The parties acknowledge that it is their express wish that this Agreement and all notices and other documents to be given or executed pursuant hereto be in English.

IN WITNESS WHEREOF, duly authorized representatives of the parties have executed and delivered this Agreement as of the Effective Date.

ViruSure
By: /s/ Andy Bailey
Print Name: Andy Bailey
Title: CEO/Operations Director
Date: April 7, 2014

Nuvilex, Inc.
By: /s/ Kenneth L. Waggoner
Print Name: Kenneth L. Waggoner
Title: Chief Executive Officer and President
Date: April 7, 2014

Exhibit A

Archive Terms and Conditions

1. All raw data, study documentation, protocols, interim and final reports, specimens generated as a result of a preclinical Study or case histories generated as a result of a clinical or commercial Study that COMPANY requests be held in VIRUSURE's archive facility or that Applicable Law requires be held in VIRUSURE's archive facility shall hereinafter be referred to as "Materials." VIRUSURE agrees to comply with industry standards in connection with the storage of the Materials and adhere to all Applicable Law with respect to the storage of the Materials.

2. VIRUSURE shall store the Materials at its current storage rates, which may be increased on an annual basis upon agreement between VIRUSURE and COMPANY. If the Materials require additional and/or special storage requirements, additional charges for storage shall be assessed and invoiced to COMPANY. Invoices shall be due and payable thirty (30) days from the date of the invoice and COMPANY agrees to pay all invoices submitted.

3. VIRUSURE's liability for archival services under this Agreement, regardless of the form of action, shall not exceed the fee paid for one year's storage of the Materials, except to the extent caused by the breach of this Agreement, the gross negligence or wilful misconduct byVIRUSURE. In no event shall VIRUSURE be liable for penalties or liquidated damages or for special, indirect, consequential punitive, exemplary or incidental damages of any type or kind (including, without limitation, lost profits) in connection with the storage of the Materials. VIRUSURE shall have no liability for loss of the Materials beyond its reasonable control, including losses caused by loss of refrigeration.

4. The Materials shall be archived for the period set forth in the Supporting Documents ("Retention Period"). Upon the expiration of the Retention Period, VIRUSURE shall contact COMPANY to determine disposition of the Materials as follows: (i) extended storage of the Materials; (ii) return of the Materials to COMPANY at COMPANY's expense to be archived in accordance with Applicable Law or (iii) where offered by VIRUSURE , disposal of Materials at COMPANY's expense. If COMPANY requests VIRUSURE to continue to store the Materials and VIRUSURE agrees, the cost for storage of the Materials shall continue to be invoiced to COMPANY at VIRUSURE's then current rates. If COMPANY fails to give such instructions, VIRUSURE shall so notify COMPANY, and if such instructions are still not forthcoming within thirty (30) days of said notification, then VIRUSURE shall have the option of (i) continuing storage of the Materials, which will be deemed to have been authorized for an additional period of not less than one (1) year, or (ii) VIRUSURE may return the Materials to COMPANY at COMPANY's expense or (iii) dispose of the Materials at COMPANY's expense provided regulatory retention periods have expired. If COMPANY intends to go out of business or to transfer ownership of the Materials, COMPANY will provide notice to VIRUSURE with instructions for disposition of the Materials. If COMPANY fails to give such instructions, VIRUSURE shall dispose of the Materials at COMPANY's expense provided regulatory retention periods have expired. COMPANY agrees that VIRUSURE shall have access to the Materials at all times in order to comply with Applicable Law. COMPANY shall be liable for storage charges until the Materials are returned to COMPANY. At any time while the Materials are in transit to COMPANY, all risk of loss or exposure to the Materials shall be borne by VIRUSURE.

5. VIRUSURE will not release the Materials to any third party, without COMPANY's written permission unless such disclosure is compelled by valid subpoena or Applicable Law. If such disclosure is requested, VIRUSURE shall use its commercially reasonable efforts to provide COMPANY with written notice prior to such release. Prior to release or inspection of any Materials by COMPANY or its agents, COMPANY shall provide all reasonable documentation requested by VIRUSURE.

Exhibit 10.6

CONSULTING AGREEMENT

This Consulting Agreement ("Agreement") is made as of 1 April 2014 ("Effective Date") between Vin-de-Bona Trading Company Pte Ltd, having its principal place of business at 26 Kandahar Street, Singapore 198888 ("Consultant") and Nuvilex, Inc. ("Company"), having its principal place of business at 12510 Prosperity Drive, Suite 310, Silver Spring, Maryland 20904 United States of America.

RECITALS

A. The Company has need of consulting services, assistance and advice and the Consultant has information, know how, expertise and knowledge relating to such services, assistance and advice which Consultant is willing to provide to the Company, as set forth in Schedule 1 attached to this Agreement and incorporated herein by this reference; and

B. The Company desires to engage the Consultant to provide such services, assistance and advice on the terms and conditions set forth in this Agreement.

AGREEMENT

1. Engagement

The Company hereby engages the Consultant to provide and the Consultant hereby agrees to provide such advice, consulting and other services to the Company or any affiliated company as the Company shall from time to time determine in accordance with Schedule 1 attached to this Agreement or any subsequent Schedule(s) agreed to between the parties in writing (collectively, "Services").

1.1 Services shall be provided for as agreed by the parties in in Schedule 1 and any subsequent written Schedule or Schedules agreed to between the parties to this Agreement.

1.2 The Consultant shall, in the discharge of Services, observe and comply with all governmental regulations to the best of its knowledge and with all reasonable requests and directions from time to time made or given to the Consultant by the Company.

1.3 The Consultant shall provide and carry out Services with reasonable care and skill and to the best of the ability of those individuals working for the Consultant.

2. Term

The Term of this Agreement shall commence on 1 April 2014 and shall, subject to the provisions of Section 10 of this Agreement, last for an initial period of twelve (12) months from that effective date ("Term"). Thereafter, the Term shall continue for additional periods of twelve (12) months (each an "Additional Term"), but any Additional Term may be terminated at any time by either party by giving not less than thirty (30) days' prior Notice (defined below) to the other party.

*** 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. Fees

3.1 The Company will pay the Consultant for the satisfactory provisions of Services at the rate of USD [*******] per hour for such Services ("Fees"). Payments shall be due and payable within fifteen (15) days after the month in which Services have been rendered to the Company and the Company is in receipt of an invoice describing such Services.

3.2 The amounts referred to above are stated exclusive of any Value Added Tax (" VAT") which shall be paid by the Company in addition to all other fees and Expenses (defined below) upon delivery to the Company of a valid VAT invoice. Such VAT invoice shall be paid within fifteen (15) days after the Company is in receipt thereof.

4. Expenses

All reasonable travel, accommodation and other expenses properly and reasonably incurred by the Consultant in performing approved Services ("Expenses") shall be reimbursed to the Consultant. The Consultant shall submit details of Expenses to the Company. Expenses shall be paid by the Company within fifteen (15) days of the Company's receipt of the written details of Expenses.

5. Confidential Information and Restrictions

5.1 Company's Confidential Information means all lists of customers notes memoranda records and writings made by the Consultant in relation to the Company or in relation to the Services (defined below) and all information and materials disclosed by the Company to the Consultant pursuant to or in contemplation of this Agreement and arising out of the Services provided by the Consultant to the Company, including, but not limited to, any technical and commercial data, drawings, patent applications, structures, models, techniques, processes, samples, compositions, compounds and apparatus relating to the same specifications, know-how, prototypes, trade secrets and other information of a confidential nature relating to the business, products or affairs of the Company or its customers, collaborators or suppliers.

5.2 The Company's Confidential Information shall be regarded as confidential to the business of the Company and shall be held for the benefit of the Company and, except for the purposes of performing Services, the Consultant shall not disclose the Company's Confidential Information to any third party nor use the same for any purpose without the prior written consent of the Company.

5.3 The provisions of Section 5.1 of this Agreement shall not apply to information which:

(a) is, or subsequently becomes, part of the public domain otherwise than by any breach of this Agreement;

(b) is shown by written record to have been known to the Consultant at the time of disclosure to it by or on behalf of the Company; or

(c) is hereafter disclosed to the Consultant by a third party with the lawful right to make such disclosure.

*** 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.

5.4 As the Consultant will, in the course of its engagement, have dealings with customers, employees and suppliers of the Company, in order to protect the goodwill of the Company the Consultant (without prejudice to any other duty implied by law or equity) hereby covenants that, during the Term and any Additional Term and for a period of twelve (12) months after the date of termination or expiration of the Term or any Additional Term, the Consultant shall not, directly or indirectly, and whether on its own account or as partner employee or on behalf of another person firm or company without the prior written consent of the Company:

(a) interfere with or endeavour to entice away from the Company any person firm or company with whom or which the Consultant had dealings and who or which during the period of twelve (12) months prior to the termination of this Agreement or expiration of the Term or any Additional Term of this Agreement (" Relevant Period") was a supplier client or customer or a prospective customer of the Company with whom the Company was in serious negotiations;

(b) solicit or entice away or endeavour to solicit or entice away from the Company any person who shall be a director, officer, manager, senior employee, agent or contractor of the Company with whom the Consultant had dealings during the Relevant Period ; or

(c) offer or procure the offer of employment to any director, officer, manager, senior employee, agent or contractor of the Company with whom the Consultant had dealings in the Relevant Period whether or not such person would commit any breach of contract by reason of leaving.

5.5 The provisions of this Section 5 shall survive termination of this Agreement or expiration of the Term or any Additional Term for any reason for a period of two (2) years from the effective date of the termination of this Agreement of expiration of the Term or any Additional Term.

6. Other Activities

6.1 The Consultant shall be at liberty to engage in other business activities.

6.2 The Consultant recognizes that it owes a duty of good faith to the Company and shall not knowingly enter into any arrangement or carry out any activity, which might create a conflict of interest with any of its obligations under this Agreement.

6.3 If it is brought to the attention of the Company that the Consultant is in breach of Section 6.2 of this Agreement, the Company shall notify the Consultant of the breach and, upon receipt of such Notice, the Consultant shall immediately cease the activity or activities which are the subject of such Notice or terminate this Agreement.

7. Status of Consultant

7.1 This Agreement is not a contract of employment, and nothing contained in this Agreement shall be construed to create the relationship of employer and employee between the Company and the Consultant. The Consultant is an independent contractor and not the servant, employee, partner, representative or agent of the Company and has no power or authority to enter into any contract on behalf of the Company. The Consultant shall be free to exercise judgement and discretion with regard to performing Services.

7.2 The Consultant shall bear exclusive responsibility for the discharge of any income tax national insurance contributions, VAT and other taxation liability arising out of remuneration paid to the Consultant pursuant to this Agreement and shall keep the Company fully indemnified (that indemnity to include any legal and accounting costs which the Company incurs) against all losses costs damages or expenses suffered by the Company, including, but not limited to, any payments which it may be required to make by any taxing authority in any of the countries in which the Consultant conducts business' or any other third party as a result of a breach of this Section 7 or otherwise in relation to the remuneration paid to the Consultant pursuant to this Agreement.

7.3 The Consultant warrants and represents that, by entering into and performing this Agreement, the Consultant: (i) will not be in breach of any fiduciary or other contractual duty to any third party; (ii) will not be creating any conflict of interest; (iii) has the full and unfettered power to enter into this Agreement; and (iv) has obtained all necessary approvals to enter into this Agreement.

8. Assignment or Subcontracting

The Consultant shall not assign or subcontract any of the Consultant's rights or duties under this Agreement. The Company shall have the right to assign this Agreement at its sole discretion and at any time during the Term or any Additional Term, so long as the Company remains liable for all Fees and Expenses incurred by the Consultant prior to the effective date of the Company's assignment of this Agreement.

9. Termination

9.0 Summary Termination. Without prejudice to any of the rights under this Agreement and notwithstanding any other provisions of this Agreement, the Company shall have the right at any time to terminate this Agreement in any of the following events:

(a) The Consultant commits any material breach of any of the provisions of this Agreement and, in the case of a breach capable of remedy, fails to remedy the same within thirty (30) days after the Consultant's receipt of a Notice from the Company setting forth the full particulars of the breach and requiring it to be remedied; or

(b) Consultant refuses or neglects to comply with any lawful orders or directions given to it by the Company.

9.2 Termination upon Acquisition. If the Company (or substantially all of its assets) should be acquired during the Term or any Additional Term, then this Agreement will terminate upon the effective date of the acquisition.

9.3 Consultant may terminate this Agreement by giving the Company three months' prior Notice of Termination.

10. Intellectual Property Rights

All information, documents, reports, plans, drawings or other such materials generated specifically for the Company during performance of the Services and paid for by the Company shall belong to and be the exclusive property of the Company. Upon termination of this Agreement or expiry of the Term or any Additional Term of this Agreement, the Consultant shall deliver to the Company all the above Company specific and paid for information, documents, reports, plans, drawings or other material, irrespective of whether such information or documentation is completed or partially completed.

11. Waiver

A waiver by one party of a breach by the other of any term of this Agreement shall not prevent the subsequent enforcement of that term and shall not be deemed a waiver of any subsequent breach.

12. Notices

Any Notice required or permitted to be given under this Agreement ("Notice") shall be in writing and may be sufficiently given if sent by prepaid registered post addressed to the party to whom the Notice is to be given at its address as set forth at the beginning of this Agreement or such other address as such party may hereafter designate by written Notice to the other. Any Notice so mailed shall be deemed to have been given on the second business day following the date of mailing.

13. Entire Agreement

This Agreement shall constitute the entire agreement between the parties in respect of the performance of the Services and any terms and conditions referred to in correspondence or elsewhere and any other conditions or stipulations to the contrary are hereby excluded.

14. Severability

Each of the obligations contained in the provisions this Agreement shall be construed as separate and severable obligations but if at any time any one or more of the obligations is or becomes invalid illegal or unenforceable in any respect under law, but would be valid if some part thereof were deleted or the period or area of application reduced, such obligation shall apply with such modification as may be necessary to make it valid and effective. The validity, legality and enforceability of the remaining clauses and provisions of this Agreement shall not in any way be affected or impaired thereby.

15. Governing Law and Jurisdiction

This Agreement shall be governed by and interpreted in accordance with the laws of England without regard to its conflicts of laws principles. The parties hereby submit to the exclusive jurisdiction of the Courts of England to resolve any dispute arising out of or related to 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.

16. Counterparts

This Agreement may be executed by any party by PDF, facsimile or signature by counterparts, each of which shall be deemed to be an original as against any party whose signature appears on this Agreement, and all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the parties have executed this Agreement on the date indicated below.

Nuvilex Inc.

/s/ Kenneth L. Waggoner
By: Kenneth L. Waggoner
Title: Chief Executive Officer and President
Date: 23 April 2014

Vin-de-Bona Trading Company Pte Ltd

/s/ Walter H. Gunzburg
By: Walter H. Gunzburg
Title: Managing Director
Date: 05 May 2014

*** 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.

Schedule 1 to the Agreement

The Services the Consultant shall provide to the Company during the Term and any Additional Term(s) shall consist of the following: (i) 'without prejudice' and non-patentable advice on new and existing products in the field of cellular therapies using the "Cell-in-a-Box®" technology; (ii) support of Nuvilex in collecting scientific information and writing scientific reports or other activities needed to obtain any and all Ethic Committee approvals for clinical trials in the areas licensed by Nuvilex; (iii) review and evaluation of new product ideas and developments, market trends and competitive activity in the field in the areas licensed by Nuvilex; (iv) assessment of protocols and procedures in the field in the areas licensed by Nuvilex; (v) review of marketing materials and educational programs in the field in the areas licensed by Nuvilex; (vi) advice to Nuvilex clinical personnel regarding preclinical studies and clinical trials in the areas licensed by Nuvilex; (vii) consultation with and advice to Nuvilex on current issues arising out of or related to the Phase 2b clinical trials Nuvilex will be conducting in Australia for advanced, inoperable pancreatic cancer using the "Cell-in-a-Box®" technology; and (viii) any other Services the parties agree to arising out of or related to the business affairs of the Company in the areas licensed by Nuvilex. The location for providing such Services shall be mutually agreed between the parties to the Agreement.

Exhibit 10.7

MASTER CONSULTANCY AGREEMENT

Between

Nuvilex, Inc.

And

BB Biotech Consulting GmbH

*** 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.

MASTER CONSULTANCY AGREEMENT

This Master Consultancy Agreement ("Agreement") is made as of 15 April 2014 ("Effective Date") between BB Biotech Consultant GmbH, Klosterhofstr, 12, D-69469 Weinheim, Germany ("Consultant") and Nuvilex, Inc. ("Company"), having its principal place of business at 12510 Prosperity Drive, Suite 310, Silver Spring, Maryland 20904 United States of America.

RECITALS

A. The Company has need of consultancy services, assistance and advice and the Consultant has information, know how, expertise and knowledge relating to such services, assistance and advice which Consultant is willing to provide to the Company as set forth in Schedule 1 attached to this Agreement and incorporated herein by this reference; and

B. The Company desires to engage the Consultant to provide such services, assistance and advice on the terms and conditions set forth in this Agreement.

AGREEMENT

1. Definitions. In this Agreement the following expressions shall (unless the context otherwise requires) have the following meanings:

"Associated Company" means any company which for the time being is a subsidiary or holding company or other legal entity of the Company or any subsidiary (other than the Company) of any such holding company.

"Company's Confidential Information" means all lists of customers notes memoranda records and writings made by the Consultant in relation to the Company or in relation to Services (defined below) and all information and materials disclosed by the Company to the Consultant pursuant to or in contemplation of this Agreement and arising out of the Consultant providing Services to the Company, including, but not limited to, any technical and commercial data, drawings, patent applications, structures, models, techniques, processes, samples, compositions, compounds and apparatus relating to the same specifications, know-how, prototypes, trade secrets and other information of a confidential nature relating to the business, products or affairs of the Company or its customers, collaborators or suppliers.

"Consultant's Confidential Information" means all confidential information and materials disclosed by the Consultant to the Company pursuant to or in contemplation of this Agreement, including, but not limited to, any technical and commercial data, drawings, patent applications, specifications, know-how, prototypes, processes, trade secrets and other information of a confidential nature relating to the business, products or affairs of the Consultant or its customers, collaborators or suppliers.

*** 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.

2. Appointment.

The Company hereby engages the Consultant to provide and the Consultant hereby agrees to provide such advice, consultancy and assistance to the Company or any Associated Company as the Company shall from time to time determine in accordance with Schedule 1 attached to this Agreement or any subsequent Schedule(s) agreed to between the parties in writing (collectively, "Services"). The Consultant agrees that Services shall be performed in such location(s) as is specified in Schedule 1.

2.1 Services shall be provided for as agreed by the parties in in Schedule 1 and any subsequent written Schedule or Schedules.

2.2 The Consultant shall, in providing Services, observe and comply with all governmental regulations and with all reasonable requests and directions from time to time made or given to the Consultant by the Company.

2.3 The Consultant shall provide and carry out Services with reasonable care and skill and to the best of his ability.

3. Term.

The Consultant's appointment shall commence on 15 April 2014 and shall, subject to the provisions of Section 10 of this Agreement, last for an initial period of 12 months from that Effective Date ("Term"). Thereafter, the appointment shall continue for additional periods of 12 months (each an "Additional Term"), but any Additional Term may be terminated at any time by either party on giving not less than one month's Notice (defined below) to the other party.

4. Fees.

4.1 The Company will pay the Consultant for the satisfactorily providing Services to the Company at the rate of ****** per hour up to a maximum of ****** per day. Payments for Services shall be due and payable within fifteen (15) days after the month in which Services have been rendered to the Company and the Company is in receipt of an invoice describing such Services.

4.2 The amounts referred to above are stated exclusive of any Value Added Tax (" VAT") which (if appropriate) shall be paid by the Company in addition to all other Fees and Expenses (defined below) upon delivery to the Company of a valid a VAT invoice. Such VAT invoice shall be paid within fifteen (15) days after the Company is in receipt of such VAT invoice.

4.3 The payments provided for in this Section 4 shall represent the Company's entire financial commitment under this Agreement (except for any sums that may be payable to the Consultant under Section 5 of this Agreement); without prejudice to the generality of the foregoing, the Consultant is not entitled to receive any further payment for any work done for any Associated Company unless specifically authorised by the Company.

*** 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.

5. Expenses.

5.1 All reasonable travelling, accommodation and subsistence expenses properly and reasonably incurred by the Consultant in providing Services to the Company, being approved by the Company in writing in advance ("Expenses"), shall be reimbursed to the Consultant. The Consultant shall submit details of Expenses (including in the case of car journeys the mileage covered) to the Company together with VAT invoices where applicable. Expenses shall be paid by the Company within fifteen (15) days of the Company's receipt of the written details of Expenses. Otherwise, the Consultant shall be responsible for all Expenses incurred in providing Services to the Company.

6. Confidential Information and Restrictions.

6.1 The Company's Confidential Information shall be regarded as confidential to the business of the Company and shall be held for the benefit of the Company and, except for the purposes of providing Services to the Company, the Consultant shall not disclose the Company's Confidential Information to any third party nor use the same for any purpose without the prior written consent of the Company.

6.2 The provisions of Section 6.1 of this Agreement shall not apply to information which:

(a) is or subsequently becomes part of the public domain otherwise than by any breach of this Agreement;

(b) is shown by written record to have been known to the Consultant at the time of disclosure to it by or on behalf of the Company; or

(c) is hereafter disclosed to the Consultant by a third party with the lawful right to make such disclosure.

6.3 As the Consultant will in the course of its engagement have dealings with customers, employees and suppliers of the Company, in order to protect the goodwill of the Company the Consultant (without prejudice to any other duty implied by law or equity) hereby covenants that during the Term and any Additional Term and for a period of twelve (12) months after the date of termination of the Term or any Additional Term the Consultant shall not, directly or indirectly, and whether on its own account or as partner employee or on behalf of another person firm or company without the prior written consent of the Company:

(a) solicit for the benefit of a business similar to or likely to compete with that of the Company or interfere with or endeavour to entice away from the Company any person firm or company with whom or which the Consultant had dealings and who or which during the period of twelve (12) months prior to the termination of this Agreement or expiry of the Term or any Additional Term of this Agreement ("Relevant Period") was a supplier client or customer or a prospective customer of the Company with whom the Company was in serious negotiations;

*** 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.

(b) take any action likely to result in any supplier of the Company ceasing or reducing its trade with the Company;

(c) render or offer to render any services to any person firm or company with whom the Consultant had dealings and who or which during the Relevant Period was a supplier client customer or a prospective customer of the Company with whom the Company was in serious negotiations;

(d) solicit or entice away or endeavour to solicit or entice away from the Company any person who shall be a director, officer, manager, senior employee, agent or contractor of the Company with whom the Consultant had dealings during the Relevant Period ; or

(e) offer or procure the offer of employment to any director, officer, manager, senior employee, agent or contractor with whom the Consultant had dealings in the Relevant Period whether or not such person would commit any breach of contract by reason of leaving.

6.4 Each of the obligations set forth in Section 6.3 of this Agreement shall be construed as separate and severable obligations.

6.5 The provisions of this Section 6 shall survive termination of this Agreement or expiry of the Term or any Additional Term for any reason for a period of five (5) years from the effective date of the termination of this Agreement of expiry of the Term or any Additional Term.

7. Other Activities.

7.1 The Consultant shall be at liberty to engage in other business activities provided that such activities do not prevent or impair the proper performance by the Consultant of its obligations under this Agreement.

7.2 The Consultant recognizes that it owes a duty of good faith to the Company and shall not enter into any arrangement or carry out any activity, which might create a conflict of interest with any of its obligations under this Agreement.

7,2 If it is brought to the attention of the Company that the Consultant is in breach of Sections 7.1 or 7.2 of this Agreement, the Company shall notify the Consultant of the breach and, upon receipt of such Notice, the Consultant shall immediately cease the activity or activities which are the subject of such Notice.

8. Status of Consultant.

8.1 This Agreement is not a contract of employment, and nothing contained in this Agreement shall be construed to create the relationship of employer and employee between the Company and the Consultant. The Consultant is an independent contractor and not the servant, employee, partner, representative or agent of the Company and has no power or authority to enter into any contract on behalf of the Company. The Consultant shall be free to exercise judgement and discretion with regard to providing Services.

*** 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.

8.2 The Consultant shall bear exclusive responsibility for the discharge of any income tax national insurance contributions, VAT and other taxation liability arising out of remuneration paid to the Consultant pursuant to this Agreement and shall keep the Company fully indemnified (that indemnity to include any legal and accounting costs which the Company incurs) against all losses costs damages or expenses suffered by the Company, including, but not limited to, any payments which it may be required to make by the Inland Revenue or any other third party as a result of a breach of this Section 8 or otherwise in relation to the remuneration paid to the Consultant pursuant to this Agreement.

8.3 The Consultant warrants and represents that, by entering into and performing this Agreement, the Consultant: (i) will not be in breach of any fiduciary or other contractual duty to any third party; (ii) will not be creating any conflict of interest; (iii) has the full and unfettered power to enter into this Agreement; and (iv) has obtained all necessary approvals to enter into this Agreement.

9. Assignment or Subcontracting.

The Consultant shall not assign or subcontract any of the Consultant's rights or duties under this Agreement. The Company shall have the right to assign this Agreement at its sole discretion and at any time during the Term or any Additional Term, so long as the Company remains liable for all Fees and Expenses incurred by the Consultant prior to the effective date of the Company's assignment of this Agreement.

10. Termination of the Agreement.

10.1 Summary Termination. Without prejudice to any of the rights under this Agreement and notwithstanding any other provisions of this Agreement, the Company shall have the right at any time to terminate this Agreement in any of the following events:

(a) The Consultant commits any material breach of any of the provisions of this Agreement and, in the case of a breach capable of remedy, fails to remedy the same within thirty (30) days after the Consultant's receipt of a Notice from the Company setting forth the full particulars of the breach and requiring it to be remedied;

(b) The Consultant is found to be guilty of dishonesty, violence or serious misconduct whether or not in connection with its duties under this Agreement;

(c) The Consultant or any of its directors, officers or employees is convicted of any criminal offense other than an offense which, in the reasonable opinion of the Company, does not affect the Consultant's engagement with the Company;

(d) Professor Dr. Matthias Löhr becomes of unsound mind or becomes a patient for any purpose of any statute relating to mental health;

(e) The Consultant or Professor Dr. Matthias Löhr files a bankruptcy petition or is determined to be bankrupt or compound with the creditors of the Consultant or Professor Dr. Matthias Löhr;

*** 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.

(f) The Consultant commits any persistent breach of the terms of this Agreement; or

(g) The Consultant refuses or neglects to comply with any lawful orders or directions given to it by the Company.

10.2 Termination upon Acquisition. If the Company (or substantially all of its assets) should be acquired during the Term or any Additional Term, then this Agreement will terminate upon the effective date of the acquisition.

11. Intellectual Property Rights.

11.1 All industrial or intellectual property rights, including, but not limited to, design rights (whether registered or not), patents, trademarks and copyrights which may arise in any invention, document or report, including, but not limited to, any proprietary materials, drawings or graphic works which may be discovered or produced during or related to providing Services to the Company, whether by the Consultant alone or jointly with the Company, shall be assigned by the Consultant and shall vest exclusively in the Company. The Consultant hereby grants to the Company an assignment of future rights which it may acquire by operation of law or otherwise in any intellectual or industrial property rights arising out of or related to providing Services to the Company.

11.2 All information, documents, reports, plans, drawings or other such materials related to providing Services to the Company shall belong to and be the exclusive property of the Company. Upon termination of this Agreement or expiry of the Term or any Additional Term, the Consultant shall deliver to the Company all information, documents, reports, plans, drawings, emails or other material in any form (collectively, "Documents") irrespective of whether such Documents are completed or partially completed.

12. Publicity.

The Consultant shall not at any time make any untrue statement in relation to the Company and shall not, after expiration of the Term or any Additional Term or termination of this Agreement, wrongly represent itself as having been or being engaged by or connected with the Company.

13. Waiver.

A waiver by one party of a breach by the other of any term of this Agreement shall not prevent the subsequent enforcement of that term and shall not be deemed a waiver of any subsequent breach.

14. Relationship between the Parties.

Nothing contained in this Agreement shall be construed or have effect as constituting any relationship of employer and employee representative partner or agent and principal between the Company and the Consultant.

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15. Notices.

Any notice, approval, consent or other communication in connection with this Agreement ("Notice") must be in writing and either hand-delivered or sent by express air courier service to the addressee as the address at the beginning of this Agreement or such other address as such party may hereafter designate by written Notice to the other. Any Notice made pursuant to this Section 15 shall be deemed to have been received upon delivery in the event of hand delivery or delivery by air courier.

16. Entire Agreement.

This Agreement shall constitute the entire agreement between the parties with respect to providing Services to the Company. Any terms and conditions referred to in correspondence or elsewhere and any other conditions or stipulations to the contrary are hereby excluded.

17. Severability.

Each of the obligations contained this Agreement shall be construed as separate and severable obligations, but if at any time any one or more of the obligations is or becomes invalid illegal or unenforceable in any respect under law but would be valid if some part thereof were deleted or the period or area of application reduced, such obligation shall apply with such modification as may be necessary to make it valid and effective. The validity, legality and enforceability of the remaining clauses and provisions of this Agreement shall not in any way be affected or impaired thereby.

18. Governing Law and Jurisdiction.

This Agreement shall be governed by and interpreted in accordance with the laws of Germany without regard to its conflicts of laws principles. The parties hereby submit to the exclusive jurisdiction of the Courts of England to resolve any dispute arising out of or related to this Agreement.

[The balance of this page has been left blank intentionally.]

*** 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.

19. Counterparts

This Agreement may be executed by any party by PDF, facsimile or signature by counterparts, each of which shall be deemed to be an original as against any party whose signature appears on this Agreement and all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the parties have executed this Agreement (but not delivered as a Deed until the date written below) as follows:

Nuvilex Inc.

_/s/ Kenneth L. Waggoner_____
By: Kenneth L. Waggoner
Title: Chief Executive Officer and President
Date: April 30, 2014

BB Biotech Consulting GmbH

_/s/ Professor Dr. Matthias Löhr_____
By: Professor Dr. Matthias Löhr
Title: Managing Director
Date: April 30, 2014

***** 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.**

Schedule 1 to the Agreement

Services the Consultant shall provide to the Company during the Term and any Additional Term shall consist of the following: (i) provide advice on, and evaluation and testing of, new and existing products in the field of cellular therapies using the "Cell-in-a-Box®" technology; (ii) support the Company in collecting information, writing scientific reports or other activities needed to obtain any and all Ethic Committee approvals for clinical trials; (iii) review and evaluation of new product ideas and developments, market trends and competitive activity in the field; (iv) assessment of protocols and procedures in the field; (v) review of marketing materials and educational programs in the field; (vi) provide advice to the Company clinical personnel regarding preclinical studies or clinical trials; (vii) consultation with and advice to the Company, by telephone or in person, and on current issues arising out of or related to the Phase 2b clinical trials the Company will be conducting in Australia for advanced, inoperable pancreatic cancer using the "Cell-in-a-Box®" technology; and any other Services the parties agree to in writing arising out of or related to the business affairs of the Company. The location for providing such Services shall be nationally and internationally, as mutually agreed between the parties to the 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.

Exhibit 10.9

MEMORANDUM OF UNDERSTANDING

THIS MEMORANDUM OF UNDERSTANDING, dated and effective as of January 31, 2011, is made and entered into by and between Nuvilex, Inc., a Nevada corporation (the "Company"), and Robert F. Ryan, M.S., Ph.D. ("Dr. Ryan"), serving as President and Chief Executive Officer of Nuvilex, Inc. (NVLX), to set forth compensation terms for the period of one (1) year commencing February 1, 2011 and ending January 31, 2012 ("Compensation Term"), and provides basic compensation coverage as follows:

1. Compensation; Incentives; Restricted Stock.

(a) Compensation: Part 1, Sign-On Compensation. For joining Nuvilex as its President and Chief Executive Officer, the Company shall issue to Dr. Ryan a total of Six Million (6,000,000) restricted shares delivered as Five Hundred Thousand (500,000) restricted shares on a monthly basis during the Compensation Term defined herein. Such shares are deemed to have been earned on the first day of each respective month with the Company, commencing on February 1, 2011, and are based on the market closing stock price on January 28, 2011 of $0.018.

(b) Compensation: Part 2, Temporary Salary Equivalent. In lieu of a standard salary, as agreed to by the Chairman and CFO of Nuvilex and in recognition of the quantity and extent of work performed and as a result of insufficient operating capital in the Company and until there is sufficient operating capital, the Company shall issue to Dr. Ryan Two Hundred Fifty Thousand (250,000) restricted shares on a monthly basis from February 1 through May 2011 and Four Hundred Fifteen Thousand (415,000) each month starting June 1, 2011 through the end of the Compensation Term defined herein. Such shares are deemed to have been earned on the last day of each respective month and are based on the market closing share price on the last day of such month.

(c) Incentives: Part 1. The Company offers the following performance-based incentives to Dr. Ryan as a supplement to his income during the Compensation Term. The price is based on the closing stock price on the day the performance is completed:

- Three Million (3,000,000) restricted shares upon completion of the acquisition of SG Austria. These shares are deemed to have been earned at the Closing of the acquisition of SG Austria, or related entity, by Nuvilex, Inc.

- Two Million (2,000,000) restricted shares upon completion of the acquisition of Nature Bright, Wellness Builder, Advanced Medical Sciences, Semorex or other comparable company. These shares are deemed to have been earned at the Closing of the acquisition.

- One Million (1,000,000) restricted shares for the commercialization of Oraphyte, Citroxin, or another of the company's products from the existing product line or addition of any other entity to Nuvilex. These shares are deemed to have been earned at either the sale of the product to a third party, or through the arrangement of a distribution channel where sales are imminent or sales to any entity where the sales are anticipated to be greater than $50,000.

- One Million (1,000,000) restricted shares for the completion of any major event, such as, but not limited to, the following:
  - IND filing and issuance,
  - clinical trial initiation or completion,
  - NDA filing,
  - NDA approval,
  - commercialization or monetization of any new product, or
  - acquisition of additional products or companies.

This MEMORANDUM OF UNDERSTANDING, dated and effective as of January 31, 2011, represents an agreement by and between Dr. Robert F. Ryan, M.S., Ph.D. and Nuvilex, Inc.

NUVILEX, INC.

By:	/s/ Patricia Gruden	/s/ Robert F. Ryan, M.S., PhD
	Patricia Gruden	Robert F. Ryan, M.S., PhD
	Chairman and CFO	President and CEO

Exhibit 10.10

January 31, 2012

EMPLOYMENT AGREEMENT

THIS AGREEMENT is made the 31st day of January Two Thousand and Twelve (2012)

BETWEEN: Nuvilex, Inc. ("Nuvilex") "The Company"), a Nevada corporation having the International Headquarters located at Meadows Corporate Park I, 12510 Prosperity Dr., Suite #310, Silver Spring, MD 20904, USA;

AND: Dr. Robert F. Ryan ("Dr. Ryan" "the Employee"), living at 2306 Falling Creek Rd., Silver Spring, MD 20904.

WHEREBY IT IS AGREED as follows:

1. EMPLOYMENT

The Company hereby appoints and employs the Employee as President, Chief Executive Officer, and Interim Chief Financial Officer, and the Employee hereby accepts the appointment and employment, upon the terms and conditions of this Agreement. The employment shall continue seamlessly under this new contract from 1st February 2012 and shall continue through January 31, 2016, and after that point until terminated by either party, as provided below.

2. DUTIES

(a) Subject to the overall direction of the Board of Directors of the Company ("the Board") the Employee shall manage the Affairs of the Company to the best of his ability and in the best interest of the Company and its shareholders and in a proper and business like manner.

(b) The Employee shall also hold office as its President, Chief Executive Officer (CEO), and Interim Chief Financial Officer (CFO) of the subsidiaries of the Company as appropriate, including but not limited to, Freedom-2, Inc., Freedom-2 GmbH, Freedom-2 Holdings, Inc., and Freedom-2 Creditor Partners, and perform all usual and incidental duties in such capacity for any subsidiary that does not have a specifically appointed member as President and/or CEO and/or CFO.

(c) During the continuance of this Agreement, the Employee shall:-

(1) Faithfully and diligently, perform such duties and exercise such powers in relation to the business of the Company as may from time to time be vested in him.

(2) Personally attend to his duties during such times as may be reasonably required (during regular office hours, as well as beyond such hours, as necessary) except in case of incapacity through illness or accident in which case he shall forthwith notify the Board of such incapacity and shall furnish to the Board such evidence thereof as they may require.

(3) Carry out his duties from any location that he deems suitable – specifically these may be anywhere in the United States, in Asia (Singapore, Malaysia, Thailand, Indonesia etc), Europe (Germany, Austria, United Kingdom etc), Japan or Australia for example, with special regard to the company's collaborative activities, business development activities etc.

(d) During the continuance of this Agreement, the Employee shall, subject to the prior written approval of the Board, which shall not be unduly withheld, be permitted to be directly or indirectly engaged, employed, concerned or interested in other businesses provided that those businesses are not deemed by the Board to be in direct competition to the Company and that these activities do not in any way interfere with the Employee's ability to carry out his duties for the Company. Specifically the Employee shall be permitted to be engaged in the following activities for no greater than ten percent (10%) time:

o President and CEO, RFR Consulting

(e) The Employee shall render to the Board reports as the Employee may consider desirable or as the Board may from time to time reasonably require.

3. POWERS

(a) The Employee shall have the usual powers of President, CEO, and CFO of a business similar to the Company's business and shall have power to enter into contracts in the ordinary course of the Company's business and also to exercise such powers authorities and discretions of the Board as the Board may from time to time delegate to the Employee.

(b) Subject to any directions that may from time to time be given by the Board, the Employee shall be entitled to engage and dismiss any and all employees of the Company without the previous approval of the Board, but in most cases it is anticipated that the Employee shall consult with the Board and Legal Counsel prior to undertaking such a course of action.

4. REMUNERATION

(A) Present Company Condition Temporary Compensation,

1) Compensation: Temporary Salary Equivalent, President and CEO. In lieu of a standard salary, as agreed to by the Chairman of Nuvilex and in recognition of the quantity and extent of work performed and as a result of insufficient operating capital in the Company and until there is sufficient operating capital, the Company shall issue to Dr. Ryan Four Hundred Fifteen Thousand (415,000) shares in Nuvilex Common Stock each month starting January 31, 2012 through the end of the Compensation Term defined herein and except as changed as indicated herein. Such shares are deemed to have been earned on the last day of each respective month and are based on the market closing share price on the last day of such month accordingly.

2) Compensation: Temporary Salary Equivalent, Interim CFO. In lieu of a standard salary, as agreed to by the Chairman of Nuvilex and in recognition of the quantity and extent of work performed and as a result of insufficient operating capital in the Company and until there is sufficient operating capital, the Company shall issue to Dr. Ryan Three Hundred Fifty Thousand (350,000) shares in Nuvilex Common Stock each month starting August 1, 2012 through and until a CFO has been appointed for the Company, including, but not limited to all day to day financial activities, Bank account assessment and maintenance, completion of all transfers of information to the Quicken or other financial software, interactions with the present Company CPA or any other CPA hired for the position, any and all SEC Financial and compliance reporting issues including but not limited to Forms 3, 4, 8-K, 10-K, 10Q, and all other Financial activities that come before the Company. This compensation to Dr. Ryan shall be through and until the end of the Compensation Term defined above and as indicated herein. Such shares are deemed to have been earned on the last day of each respective month and are based on the market closing share price on the last day of such month accordingly.

(B) Incentives; Restricted Stock.

Incentives: The Company offers the following performance-based incentives to Dr. Ryan as a supplement to his income during the Compensation Term. The price is based on the closing stock price on the day the performance is completed:

- Three Million (3,000,000) restricted shares upon completion of the acquisition of SG Austria. These shares are deemed to have been earned at the Closing of the acquisition of SG Austria, or related entity, by Nuvilex, Inc.
- Two Million (2,000,000) restricted shares upon completion of the acquisition of any other comparable company to Austrianova Singapore Pte. Ltd. These shares are deemed to have been earned at or upon the Closing of the acquisition.
- One Million (1,000,000) restricted shares for the commercialization of Oraphyte, Citroxin, or another of the company's products from the existing product line or addition of any other entity to Nuvilex. These shares are deemed to have been earned at either the sale of the product to a third party, or through the arrangement of a distribution channel where sales are imminent or sales to any entity where the gross sales or revenue generation are anticipated to be greater than $50,000.
- One Million (1,000,000) restricted shares for the completion of any major event, such as, but not limited to, the following:
    - IND filing and issuance,
    - clinical trial initiation or completion,
    - NDA filing,
    - NDA approval,
    - commercialization or monetization of any new product, or
    - completion of any contract with a new organization greater than $50,000
    - acquisition of additional products or companies.

(C) Compensation: Permanent Salary.

1. Once funding has been completed for the Company and the acquisition of Austrianova Singapore Pte. Ltd. has been finished and brought into Nuvilex permanently; the Company shall pay the Employee during his employment hereunder a monthly remuneration in the first year of $10,000 USD payable on the last business day of each month. The subsequent yearly increases are at a minimum based on the table below which has been incorporated into the business plan and is part of the Private Placement Memorandum being worked on for financing. Compensation can be higher than described below, as determined by performance and the Board of Directors.

Executive Team Compensation	2012 (Year 1)	2013 (Year 2)	2014 (Year 3)	2015 (Year 4)	2016 (Year 5)	2017 (Year 6)
Dr. Robert Ryan (+ 2,980,000 NVLX shares Yr 1)	($120,000)	($169,600)	($206,032)	($222,515)	($240,316)	($269,154)
Yearly Nuvilex Common Shares Compensation	2,980,000	2,950,000	2,940,000	2,975,000	3,000,000	3,500,000
Benefits for Dr. Robert Ryan (Insurance, Phone, Internet, Etc.)	($20,000)	($33,920)	($41,206)	($44,503)	($48,063)	($53,831)

2. In addition to the salary, the Employee shall receive Nuvilex Common Stock in the amount of shares per month for the first year as indicated in the table above. Additional years will decrease as the salary increases, also as indicated in the table.

3. Permanent Salary Equivalent, Interim CFO. Once funding has been completed for the Company and the acquisition of Austrianova Singapore Pte. Ltd. has been finished and brought into Nuvilex permanently and until a new CFO has been hired to take on the position, the Company shall pay the Employee during his employment hereunder a monthly remuneration in the first year of $8,000 USD payable on the last business day of each month through and until a CFO has been appointed for the Company, the duties of which include, but are not limited to all day to day financial activities, Bank account assessment and maintenance, completion of all transfers of information to the Quicken or other financial software, interactions with the present Company CPA or any other CPA hired for the position, any and all SEC Financial and compliance reporting issues including but not limited to Forms 3, 4, 8-K, 10-K, 10Q, and all other Financial activities that come before the Company. This compensation to Dr. Ryan shall be through and until the end of the Compensation Term defined above and as indicated herein. Such remuneration shall be prorated in the event the new CFO has been chosen and is in place during a payment period. Compensation shall be biweekly.

4. Employee will be entitled to an annual bonus based on performance of the Company and Employee, in conjunction with achievement of objectives set annually by the Company and the Employee.

5. Once funding has been acquired, the Company shall acquire Workmen's Compensation Insurance and any other Insurance as required by law for the Employee and pay for it directly to the Insurance Company as a standard benefit for the Employee.

6. The Company will not provide the Employee with nor bear the cost of Medical, Dental, Long-Term Care, or Life Insurance coverage unless required by law or requested by the Employee, which will then be negotiated between the Employee and the Company.

7. The Employee shall be entitled to participate in all Share Option Plans of the Company and its subsidiaries.

8. The Company shall be responsible for making the payments for any agreed upon or negotiated medical insurance for the Employee directly to the medical insurance company. However, the Company hereby guarantees to make said payments to the Employee or to the medical insurance company in the event that the payments have not been paid in a timely manner by the Company if the Employee has requested to receive insurance under the terms set forth herein. If for any reason, beyond the Company's control, funds are not available to make the payments described in this paragraph, then the Employee hereby agrees to accept payment in the form of common stock of the Parent Company for an amount up to 100% of the Employees remuneration, including amounts that might be due for medical insurance, for a period not to exceed 2 months.

5. ANNUAL LEAVE

(a) The Employee shall be entitled to 25 working days leave for each calendar year. Except with the Nuvilex Board's consent, leave may not be carried over beyond the end of any calendar year, and any leave not consumed by then shall be forfeited. The Employee shall not take leave during any period when his absence would adversely affect the Company's interests.

(b) If, in any calendar year, the Employee has not been employed for the full twelve months, his leave entitlement shall be pro-rated accordingly.

(c) If the Employee is dismissed by the Company for misconduct or breach of duty, his outstanding annual leave will be forfeited.

(d) No leave will be undertaken for greater than 2 weeks at a time unless approved by the Board.

6. EXPENSES / TRAVELING

(a) The Company shall reimburse the Employee for all reasonable out-of-pocket traveling, lodging, entertainment and/or other expenses properly and necessarily incurred by him in the performance of his duties for the Company. The Employee will be entitled to Business Class travel on air, rail or other journeys of more than two (2) consecutive hours. The Employee shall submit vouchers and invoices in support of any such item of expenditure to the Company that has been paid by the Employee in order to be reimbursed.

(b) The Company will further provide and reimburse the cost of telephone, iPhone, Blackberry, computer and internet services worldwide for the Employee.

(c) The Company will provide and ensure maintenance of the Director's & Officer's Insurance to cover this position and this employee at all times as long as this agreement is in effect. The total amount of said insurance shall be no less than $3 million USD.

7. TERMINATION

(a) If the Employee shall:-

(1) be convicted of a criminal offense (excluding any traffic violation for which he is sentenced to a term of imprisonment of less than 3 days; or

(2) be or become bankrupt or compound with all his creditors or enters into any deed of arrangement with all his creditors; or

(3) commit any material breach of any of his duties or obligations under this Agreement; or

(4) refuse or neglect to comply with any lawful and reasonable orders or directions given to him by the Company; or

(5) be or become of unsound mind; or

(6) be or become incapacitated from any cause whatsoever including the imposition of any court order from efficiently performing his duties hereunder for sixty (60) working days in aggregate in any period of twelve (12) consecutive months; or

(7) becomes prohibited by law or any order from any regulatory body or government authority from being a director of a company;

(8) then the Company shall be entitled by notice in writing to the Employee to determine forthwith his employment under this Agreement whereupon the Employee shall cease to be in the employ of the Company and in whatever capacity shall have no claim against the Company for damages or payment in lieu of notice or otherwise by reason of such determination other than as expressly provided for in this Agreement.

(b) Without prejudice to all rights accrued to both parties, either party may terminate this Agreement by giving 12 months' prior notice in writing to the other party without assigning any reason therefore.

(1) Once either party has given notice of termination the Company may at any time and for any period require the Employee to cease performing his duties and/or exclude him from entering any of the premises of the Company. During any such period of "garden leave", the Company will continue to pay the Employee's salary and provide all benefits provided for in this Agreement.

(2) The Company reserves the right to make a payment in lieu of notice for any unexpired period of notice. This right shall apply whether the Company or the Employee gives notice of termination.

(c) In the event that this Agreement shall be terminated pursuant to Clause 7.(b) above, or the employment of the Employee shall be terminated or cease for any reason other than as provided in Clause 7.(a) above, the Employee shall receive a severance payment equivalent to twelve (12) months of salary plus an amount equivalent to twelve (12) months of benefits and bonuses which shall be calculated based on the benefits at the time of termination.

(d) In the event that this Agreement shall be terminated pursuant to a change in control in Nuvilex, the Employee shall receive a severance payment equivalent to twenty-four (24) months of salary plus an amount equivalent to three twenty-four (24) months of benefits and bonuses which shall be calculated based on the benefits at the time of termination.

8. INTELLECTUAL PROPERTY RIGHTS

The Employee acknowledges and agrees that:

(a) any and all inventions, original works of authorship, development, concepts, improvements, designs, discoveries, ideas, and trade secrets, whether or not patentable or can be registered under copyright or similar laws, in the field of "encapsulation of living cells, gene therapy, antibodies, protein expression of any kind and therapeutic drugs, to name but a few, in cellulose and polymers thereof, and in addition, the new and novel encapsulation equipment design and its operating know-how", which may be solely or jointly conceived or developed or reduced to practice, or cause to be conceived or developed or reduced to practice by the Employee in the course of his employment with the Company or any affiliates ("Company Intellectual Property") and all rights, title and interest therein and thereto shall belong to the Company and the Employee shall therefore undertake to assign and transfer to the Company the entire legal and beneficial interest of the Employee to such Company Intellectual Property, all his rights, title and interest in and to which shall be vested in the Company;

(b) in the course of employment, the Employees shall maintain adequate and current records (in the form of computer or written notes, sketches, drawings or any other format as may be stipulated by the Company) of all Company Intellectual Property, such records to be the sole and unrestricted property of the Company;

(c) following the cessation of the Employee's employment with the Company, the Employee shall, for a period of 12 months from the date of such cessation, declare in writing to the Company all intellectual property protection applications sought by the Employee, including but not limited to, design protection, trademark protection and patent protection and shall provide the Company with all information requested by the Company in order to enable to Company to ascertain whether such protection sought involves or comprises, whether all or in part, any Company Intellectual Property; and

(d) he will do all things and take all action as may be necessary to ensure that all legal and beneficial rights, title and interest in and to the Pre-Employment Intellectual Property and the Company Intellectual Property shall be vested in the Company.

9. CONFIDENTIALITY

(a) The Employee shall not except as authorized or required by his duties, either during the continuance of this Agreement or after its termination, divulge to any person or to any body corporate or unincorporated and shall use all reasonable endeavors to prevent the unauthorized publication or disclosure of any trade secrets or any confidential information concerning the business or finances of the Company or any of its subsidiaries or associated companies or any of its dealings, transactions or affairs which may come to his knowledge. For the avoidance of doubt, such trade secrets and confidential information shall include lists of customers, agents or dealers, price lists and any other documents or information designed and marked in writing by the Company as trade secrets or confidential information.

(b) Forthwith upon the termination of this Agreement, the Employee shall deliver to the Company all documents (including correspondence, list of customers, agents and/or dealers, specifications and other documents of whatsoever nature), or samples delivered to or in the possession of the Employee concerning the business of the Company or of any of its subsidiaries or associated companies. For the avoidance of doubt, it is hereby declared that the property in all such specifications, documents, and samples as aforesaid shall at all times be vested in the Company or such subsidiary or associated company, as the case may be.

10. NOTICE

Any notice to be given hereunder shall be given in writing and may be given either personally or may be sent by post addressed in the case of the Company to its registered office and in the case of the Employee to him at his last known place of residence and any notice given by post shall be deemed to have been served at the expiration of Twenty-Four (24) hours after the same was posted.

11. SEVERABILITY

If any term, provision, stated alternative, clause or paragraph of this Agreement shall be void, invalid, illegal or unenforceable for any reason whatsoever, such term, provision, stated alternative, clause or paragraph shall be severable and shall not affect the enforceability or otherwise of any other term, provision, stated alternative, clause or paragraph of this Agreement

12. GOVERNING LAW AND DISPUTE RESOLUTION

(b) Any dispute arising out of or in connection with this Agreement, including any question regarding its existence, validity or termination, shall be referred to and finally resolved by arbitration in Nevada in accordance with the Arbitration Rules of the American Association for Arbitration for the time being in force, which rules are deemed to be incorporated by reference in this clause. The Tribunal shall consist of a single arbitrator to be appointed by the American Association for Arbitration. The language of the arbitration shall be English. The award of the arbitrator shall be final and binding upon the parties.

13. DISABILITY

In the event that the Employee cannot perform the duties because of illness or incapacity for a period of more than eight (8) weeks, the compensation otherwise due during said illness or incapacity will be reduced by fifty percent (50%). The Employee's full compensation will be reinstated upon return to work. However, if the Employee is absent from work for any reason for a continuous period of over six (6) months, the Company may terminate the Employee's employment, and the Company's obligations under this agreement will cease on that date.

14. DEATH BENEFIT

Should Employee die during the term of employment, the Company shall pay to Employee's estate any compensation due through the end of the month in which death occurred.

15. RESTRICTION ON POST EMPLOYMENT COMPENSATION

For a period of two and a half (2 ½) years after the end of employment, the Employee shall not control, consult to or be employed by any business similar to that conducted by the company, either by technology transfer, knowledge sharing, information exchange, training of any kind, soliciting any of its accounts or by operating within Employer's general trading area.

16. ASSISTANCE IN LITIGATION

Employee shall upon reasonable notice, furnish such information and proper assistance to the Company as it may reasonably require in connection with any litigation in which it is, or may become, a party either during or after employment.

17. EFFECT OF PRIOR AGREEMENTS

This Agreement supersedes any prior agreement between the Company or any predecessor of the Company and the Employee, except that this agreement shall not affect or operate to reduce any benefit or compensation inuring to the Employee of a kind elsewhere provided and not expressly provided in this agreement.

18. LIMITED EFFECT OF WAIVER BY COMPANY

Should Company waive breach of any provision of this agreement by the Employee, that waiver will not operate or be construed as a waiver of further breach by the Employee.

19. ASSUMPTION OF AGREEMENT BY COMPANY'S SUCCESSORS AND ASSIGNEES

The Company's rights and obligations under this agreement will inure to the benefit and be binding upon the Company's successors and assignees.

20. ORAL MODIFICATIONS NOT BINDING

This instrument is the entire agreement of the Company and the Employee. Oral changes have no effect. It may be altered only by a written agreement signed by the party against whom enforcement of any waiver, change, modification, extension, or discharge is sought.

21. MISCELLANEOUS

(1) This Agreement constitutes the entire agreement between the parties hereto in respect of the subject matter hereof and shall supersede all prior agreements or arrangements (oral or otherwise) made between the Company and the Employee.

(2) The expiration or termination of this Agreement whosoever arising shall not operate to affect such of the provisions hereof as in accordance with their terms are expressed to operate or have effect thereafter.

IN WITNESS WHEREOF, this Agreement has been executed, signed and agreed on the day and year first above written.

/s/ Robert Ryan, PhD
Dr. Robert Ryan, PhD

for and on behalf of Nuvilex, Inc.

Accepted

/s/ Patricia Gruden
Patricia Gruden
Chairman of the Board

Exhibit 21.1

List of Subsidiaries

Name of Subsidiary	Jurisdiction of Organization
Bio Blue Bird AG	Lichtenstein
Medical Marijuana Sciences, Inc.	Nevada

EXHIBIT 31.1

CERTIFICATION

I, Kenneth L. Waggoner, certify that:

1. I have reviewed this Annual Report on Form 10-K 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. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this Report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States;

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

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

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: August 1, 2014

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

EXHIBIT 31.2

CERTIFICATION

I, Patricia Gruden, certify that:

1. I have reviewed this Annual Report on Form 10-K 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. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this Report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States;

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

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

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: August 1, 2014

By: /s/ Patricia Gruden
Name: Patricia Gruden
Title: Chief Financial Officer and Board Chairman

EXHIBIT 32.1

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

In connection with Annual Report of Nuvilex and its subsidiaries ("Company") on Form 10-K 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 of the Company, certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13a-14(b) or 15d-14(b) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 1, 2014

By: /s/ Kenneth L. Waggoner
Name: Kenneth L. Waggoner
Title: Chief Executive 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.

EXHIBIT 32.2

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

In connection with Annual Report of Nuvilex, Inc. and its subsidiaries ("Company") on Form 10-K for the period ended April 30, 2014 as filed with the Securities and Exchange Commission on the date hereof ("Report"), the undersigned, Patricia Gruden, Chief Financial Officer of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13a-14(b) or 15d-14(b) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 1, 2014

By: /s/ Patricia Gruden
Name: Patricia Gruden
Title: 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.