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

FORM 10-K/A
(Amendment No. 2)

(Mark One)

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

For the fiscal year ended April 30, 2013

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)

(240) 696-6859
(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 30, 2012: $6,326,212.

As of July 29, 2013, the registrant had 509,931,348 outstanding shares of Common Stock.

DOCUMENTS INCORPORATED BY REFERENCE
None

Explanatory Note

We are filing this amendment to our annual report on Form 10-K for the year ended April 30, 2013 (the "10-K") to amend Part I, Item 1 – Business, Part II, Item 5. Market For Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities and Part III, Item 11. Executive Compensation and Item 13 Certain Relationships and Related Transactions, and Director Independence, in the original 10-K filed with the Securities and Exchange Commission ("SEC"), in response to comments from the staff of the SEC. Except as aforesaid, the information in this Form 10-K/A has not been updated to reflect events that occurred after July 29, 2013, the filing date of the 10-K. Accordingly, this Form 10-K/A should be read in conjunction with the 10-K and our filings made with the SEC subsequent thereto. Except as set forth above, all other information in the 10-K remains unchanged. The Company has included as exhibits to this Form 10-K/A an updated certification from the Company's Principal Executive and Financial Officer pursuant to Sections 302 and 906 of the Sarbanes Oxley Act of 2002.

Forward-Looking Statements

This Amendment No. 2 to the Annual Report on Form 10-K includes "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "1933 Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements other than statements of historical fact are "forward-looking statements" for purposes of this Amendment No. 2 to Annual Report on Form 10-K/A, 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 herein 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 Nuvilex, Inc. files with the Securities and Exchange Commission. Our future financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risk and uncertainties, including, but not limited to, the risk factors set forth in "Part I, Item 1A – Risk Factors" below and for the reasons described elsewhere in this Amendment No. 2 to Annual Report on Form 10-K/A. 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 accept as required by law or applicable regulations. Except where the context otherwise requires, in this Amendment No. 2 to Annual Report on Form 10-K/A, the "Company," "Nuvilex," "we," "us" and "our" refer to Nuvilex, Inc., a Nevada corporation, and, where appropriate, its subsidiaries.

PART I

ITEM 1 - BUSINESS

Overview

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

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

Cancer Treatments

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

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

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

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

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

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

Diabetes Studies

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

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

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

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

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

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

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

Current Business of the Company

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

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

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

Strategy

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

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

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

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

Cell Therapy Product Development

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

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

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

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

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

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

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

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

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

Market Opportunity and the Competitive Landscape

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

Live Cell Encapsulation

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

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

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

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

Dates of Trial and Location

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

Identity of Trial Sponsors

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

Trial Design

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

Patient Information

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

Trial Criteria

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

Duration of Treatment and Dosage Information

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

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

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

Specific Clinical Endpoints

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

Observational Metrics Utilized and Actual Results Observed

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Comparisons to Standard of Care

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

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

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

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

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

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

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

Conclusions

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

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

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

Manufacturing

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

Medical Marijuana

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

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

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

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

Government Regulations

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

Clinical Development

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

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

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

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

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

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

Review and Approval by Regulatory Agencies

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

Expedited Programs for Serious Conditions

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

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

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

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

Orphan Drug Status

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

Patents, Intellectual Property and Trade Secrets

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

Patents and Intellectual Property Agreements

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

- License Ageement Relating to Encapsulated Cells Producing Viral Particles and Encapsulated Cells Expressing Biomolecules ("Bavarian Nordic/GSF License"). The licensors are Bavarian Nordic and GSF – Forschungszentrum fur Umwelt u. Gesundheit GmbH. The licensee is Bio Blue Bird. The License Agreement was signed in July 2005. The Licensors have rights to terminate the license in the event that the annuity and upkeep fees are not paid to Bavarian Nordic, there is not proper reporting or there is not a clearly documented effort to commercialize this technology;
- The Bavarian Nordic/GSF License relates to the patent US 6893634 B1 that claims "A capsule comprising a porous membrane formed by a polyelectrolyte complex which encapsulates cells which express cytochrome P450 as a cell membrane bound protein, wherein the porous membrane of the capsule is permeable to prodrug molecules and the cells are retained within the capsule" and further claims based on this;
- The Company has an exclusive license to the US Patent US 6,776,985 B1 that claims "Encapsulated retroviral packaging cells producing retroviral vectors, comprising capsules having a porous capsule wall which is permeable to said retroviral particles" and further claims based on this. This patent would be broadly applicable to the delivery of retroviral vectors by encapsulated packaging cells for a variety of indications;
- Third Addendum to Asset Purchase Agreement between the Company and SG Austria effective as of June 25, 2013 ("Third Addendum"). The Third Addendum resulted in the Company acquiring 100% ownership of Bio Blue Bird, the licensee of the patents identified above; and
- Licensing Agreement between the Company and Austrianova Singapore effective as of June 25, 2013 relating to diabetes. The Company has an exclusive license world-wide to use the Cell-in-a-Box® technology with genetically modified or non-modified non-stem cell lines and IPS stem cells specifically designed to produce insulin or other critical components for the treatment of diabetes. The Company must enter into a research program involving European academic research partners providing a total funding of at least US$400,000 within three years of June 25, 2013 and must enter clinical trials within 7 years of June 25, 2013 to retain the exclusive world-wide license.

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

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

Third Addendum to Asset Purchase Agreement with SG Austria

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

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

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

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

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

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

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

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

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

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

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

Diabetes Licensing Agreement

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

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

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

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

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

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

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

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

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

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

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

All major countries provide for patent term extension.

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

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

Encapsulated Cells Producing Retroviral Particles

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

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

All major countries provide for patent term extension.

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

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

Sources and Availability of Raw Materials

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

Employees

The Company as of April 30, 2013, had four employees, including all subsidiaries. Nuvilex also utilizes consultants and independent contractors in finance, accounting, and other capacities.

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 via 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, 2013 and 2012. 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 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
FY 2012	HIGH	LOW
First Quarter	$ 0.07	$ 0.05
Second Quarter	$ 0.06	$ 0.05
Third Quarter	$ 0.06	$ 0.03
Fourth Quarter	$ 0.07	$ 0.03

At April 30, 2013, the market price of the Company's common stock was $0.09 per share.

As of April 30, 2013, there were 509,931,348 issued and outstanding shares of common stock held by 2,496 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 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 during the year ended April 30, 2013.

SECURITIES AUTHORIZED FOR ISSUANCE UNDER EQUITY COMPENSATION PLANS. The Company currently does not maintain any equity compensation plans.

Recent Issuance of Unregistered Securities

On January 31, 2011, 5,000,000 shares of common stock were issued to Dr. Robert F. Ryan for $100,000 cash received.

During the year ended April 30, 2011, 3,750,000 shares of common stock were issued to Dr. Robert F. Ryan, Ms. Patricia Gruden and Dr. Gerald W. Crabtree, officers of the Company for compensation. Shares were valued using the closing stock price on the day of issuance for a total expense of $92,250.

During the year ended April 30, 2011, the company authorized the issuance of 1,375,000 shares of common stock for compensation to its officers. These shares were all issued during the year ended April 30, 2012.

In order to provide a form of security for Cornerstone Bank, The Board of Directors agreed to provide the original collateral offer of 14,605,614 shares of stock to the Bank. They will have the potential to sell this stock in the future under a 10B5 plan under specific conditions unable to be associated with developments in the company. When all of the funds due and payable to Cornerstone Bank have been remitted, any remaining shares provided as collateral will be returned to Nuvilex.

On June 21, 2011 500,000 shares of common stock were issued to an unaffiliated accredited investor for $21,000 cash received.

During the year ended April 30, 2012, 23,575,000 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 $1,160,880.

During the year ended April 30, 2012, 8,550,000 shares of common stock were issued to consultants for various services. Shares were valued using the closing stock price on the day of issuance for a total expense of $409,400.

During the year ended April 30, 2012, 9,250,000 shares of common stock were issued to an existing public company stockholder in exchange for $600,000 in cash advances to the Company. In addition, another 1,650,000 shares were issued as incentive for providing the cash advances to the Company. These additional shares were value at $101,750 and charged to interest expense.

During the year ended April 30, 2012, 1,025,000 shares of common stock were issued to unaffiliated lending institutions to settle various debts. The shares were valued using the closing stock price on the day of issuance for a total expense of $55,725.

During the year ended April 30, 2013, 8,771,429 shares of common stock were issued to consultants to the Company 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 unaffiliated lending institutions 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 to an unaffiliated accredited investor for $10,000 cash.

The shares were held in escrow until on or about July 10, 2013, the completion of the purchase of BBB by the Company and SG Austria returned the shares to the respective Company Treasuries (refer to Note 5 of the Financial Statements contained in Item 8). During the quarter ended July 31, 2012, the Company issued 100,000,000 shares of restricted common stock to Austrianova Singapore Pte. Ltd. (ASPL).

During the year ended April 30, 2013 the company issued 39,622,400 shares of common stock to accredited investors 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, 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.

PART III

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, 2013 and 2012. There were no other forms of compensation provided to the 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
Robert F. Ryan, M.S., Ph.D. (1) (3)	President, Chief Executive Officer and Chief Financial Officer	5/1/2011 - 4/30/2012	$ –	10,480,000	$ 545,714	$ 545,714
Robert F. Ryan, M.S., Ph.D. (1) (3)	President, Chief Executive Officer and Chief Financial Officer	5/1/2012 - 4/30/2013	$ –	8,130,000	$ 384,659	$ 384,659
Patricia Gruden (1) (3)	Chairman, Board of Directors; Interim Chief Financial Officer	5/1/11 - 4/30/2012	$ –	5,250,000	$ 289,875	$ 289,875
Patricia Gruden (1) (3)	Chairman, Board of Directors	5/1/2012 - 4/30/2013	$ –	–	$ –	$ –
Gerald W. Crabtree, M.S., Ph.D. (2)	Chief Operating Officer	5/1/11 - 4/30/2012	$ 9,000	5,285,000	$ 268,286	$ 276,286
Gerald W. Crabtree, M.S., Ph.D. (2)	Chief Operating Officer	5/1/2012 - 4/30/2013	$ 17,500	3,986,668	$ 201,769	$ 219,269
Robert Bowker	President of Knock-Out Technologies, Ltd	5/1/11 - 4/30/2012	$ –	2,500,000	$ 114,000	$ 114,000
Robert Bowker	President of Knock-Out Technologies, Ltd	5/1/2012 - 4/30/2013	$ –	3,500,000	$ 98,000	$ 98,000
Richard Goldfarb, M.D., FACS	President of MedElite, Inc	5/1/11 - 4/30/2012	$ –	500,000	$ –	$ 35,000
Richard Goldfarb, M.D., FACS	President of MedElite, Inc	5/1/2012 - 4/30/2013	$ –	–	$ –	$ –
Timothy Matula	Director	5/1/11 - 4/30/2012	$ –	3,000,000	$ 1,000	$ 81,000
		5/1/2012 - 4/30/2013	$ –	–	$ –	$ –

(1) On January 31, 2011, the Company accepted the resignations of Patricia Gruden as Interim President and Interim Chief Executive Officer. Ms. Gruden will continue to serve as Interim Chief Financial Officer, Interim Secretary and Interim Chairman of the Board of Directors. Effective as of the same date, to fill the vacancies created by Ms. Gruden's resignations, the Board of Directors appointed Dr. Robert F. Ryan, M.S., Ph.D., as President and Chief Executive Officer.

(2) On February 24, 2011, the Board of Directors appointed Dr. Gerald W. Crabtree, M.S., Ph.D., Chief Operating Officer.

(3) On January 19, 2012, the Company accepted the resignation from Patricia Gruden as the Company’s Interim Chief Financial Officer. Effective as of the same date, to fill the vacancy created by Ms. Gruden's resignation, the Board of Directors appointed Dr. Robert F. Ryan, M.S., Ph.D., President and Chief Executive Officer, as the Company's Interim Chief Financial Officer.

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, 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.

Nuvilex, Inc. Directors are compensated for their participation on the Board of Directors for performance of their duties as directed by the Chairman of the Company. The Board of Directors 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.

NUVILEX EMPLOYMENT AGREEMENTS

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

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 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

As of April 30, 2013 and 2012, the Company owed a shareholder $393,158 and $337,408; respectively, for operating expenses. All loans bear interest at 6% and are due within one to three years.

As of April 30, 2013 and 2012, the Company owed Directors and a shareholder $26,425 and $22,700; respectively, the loan bears interest at 8% and is due on demand.

As of April 30, 2013 and 2012, the Company owed Dr. Robert Ryan, our former Chief Scientific Officer, $201,143 (including $15,080 of accrued expenses) and $185,862; respectively, at 8% interest, to provide for payment of operating expenses. Dr. Ryan loaned an additional $96,000 during the fiscal year ended April 30, 2013. The highest amount outstanding during the fiscal year ended April 30, 2013 was $261,862 and the highest amount outstanding during the fiscal year ended April 30, 2012 was $185,862. During the fiscal year ended April 30, 2012, the Company made no payments in respect of principal and interest in respect of this loan. During the fiscal year ended April 30, 2013, the Company made principal payments totaling $95,600 and no interest payments in respect of this loan.

The Board of Directors has determined that none of the Company's Directors and none of the Audit Committee or Compensation Committee Members satisfies the definition of "Independent Director" as established in the NASDAQ Marketplace Rules, including for Audit Committee Members the additional independence requirements mandated by the NASDAQ Marketplace Rules.

PART IV - OTHER INFORMATION

ITEM 15. EXHIBITS

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

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

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

Exhibit No.	Description	Location
10.5	Licensing Agreement between the Company and Austrianova Singapore dated June 25, 2013.	Incorporated by reference from the Company's Report on Form 8-K filed with the SEC on July 18, 2013.
10.6	Consulting Agreement between Vin-de-Bona Trading Company Pte. Ltd. and Registrant effective as of April 1, 2014.	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the SEC on August 4, 2014.**
10.7	Master Consultancy Agreement between BB Biotech Consulting GmbH and Registrant dated as of April 15, 2014.	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the SEC on August 4, 2014.**
10.8	Financial Advisory, Offering and At the Market Offering Engagement Letter between Chardan Capital Markets, LLC and the registrant dated May 28, 2014.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on May 29, 2014.
10.9	Memorandum of Understanding dated as of January 31, 2011 between the Company and Robert F. Ryan, M.S., Ph.D.	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the SEC on August 4, 2014.
10.10	Employment Agreement made the 31st day of January 2012 between the Company and Robert F. Ryan, M.S., Ph.D.	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the SEC on August 4, 2014.
10.11	Collaborative Research Agreement between University of Veterinary Medicine Vienna and the Company effective as of July 1, 2014.	Incorporated by reference from Amendment No. 1 to the Company's Annual Report on Form 10-K/A filed with the SEC on October 16, 2014.**
10.12	Licence Agreement between University of Technology, Sydney and Nuvilex Australia Pty Ltd effective as of October 13, 2014.	Incorporated by reference from Amendment No. 1 to the Company's Annual Report on Form 10-K/A filed with the SEC on October 16, 2014.**
10.13	Master Services Agreement between ViruSure GmbH and the Company effective as of August 23, 2014.	Incorporated by reference from Amendment No. 1 to the Company's Annual Report on Form 10-K/A filed with the SEC on October 16, 2014.**
10.14	Settlement Agreement dated as of September 19, 2014, by and between Nuvilex, Inc. and Robert F. Ryan, M.S., Ph.D.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on September 25, 2014.
10.15	Asset Purchase Agreement dated as of September 19, 2014, by and between Nuvilex, Inc. and Robert F. Ryan, M.S., Ph.D.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on September 25, 2014.
10.16	Consulting Agreement, dated September 29, 2014, between Nuvilex, Inc. and Patricia Gruden.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on October 3, 2014.
10.17	Stock Option Agreement, dated September 29, 2014, between Nuvilex, Inc. and Patricia Gruden.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on October 3, 2014.
10.18	Consulting Agreement, dated September 29, 2014, between Nuvilex, Inc. and Timothy Matula.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on October 3, 2014.
10.19	Stock Option Agreement, dated September 29, 2014, between Nuvilex, Inc. and Timothy Matula.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on October 3, 2014.
10.20	Consulting Agreement, dated September 29, 2014, between Nuvilex, Inc. and Richard M. Goldfarb.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on October 3, 2014.
10.21	Stock Option Agreement, dated September 29, 2014, between Nuvilex, Inc. and Richard M. Goldfarb.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on October 3, 2014.
14.1	Nuvilex, Inc. Code of Business Conduct and Ethics.	Incorporated by reference from the Company's Current Report on Form 8-K filed with the SEC on September 25, 2014.
21.1	List of Subsidiaries.	Incorporated by reference from Amendment No. 1 to the Company's Annual Report on Form 10-K/A filed with the SEC on October 16, 2014.
31.1	Certification of Chief Executive and Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under Sarbanes-Oxley Act of 1934, as amended.	Filed herewith.
32.1	Certification of Chief Executive and Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002*.	Filed herewith.
101	Interactive Data Files for Nuvilex, Inc. Form 10-K for the period ended April 30, 2014	Incorporated by reference from the Company's Annual Report on Form 10-K filed with the SEC on August 4, 2014.

*Exhibit 32.1 is being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall such exhibit be deemed to be incorporated by reference in any registration statement or other document filed under the Securities Act of 1933, as amended, or the Securities Exchange Act, as amended, except as otherwise stated in such filing.

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

SIGNATURES

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

NUVILEX, INC

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

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

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

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

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

EXHIBIT 31.1

CERTIFICATION

I, Kenneth L. Waggoner, certify that:

1. I have reviewed this Amendment No. 2 to the Annual Report on Form 10-K/A of Nuvilex, Inc. ("Report") and its subsidiaries for the fiscal year ended April 30, 2013;

2. Based on my knowledge, this Report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this Report;

3. Based on my knowledge, the financial statements, and other financial information included in this Report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this Report;

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me by others within those entities, particularly during the period in which this Report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States;

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

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

5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: October 16, 2014

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

EXHIBIT 32.1

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

In connection with Amendment No. 2 to the Annual Report of Nuvilex and its subsidiaries ("Company") on Form 10-K/A for the year ended April 30, 2013 as filed with the Securities and Exchange Commission on the date hereof ("Report"), the undersigned, Kenneth L. Waggoner, Chief Executive Officer, President and Chief Financial Officer of the Company, certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13a-14(b) or 15d-14(b) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: October 16, 2014

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

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