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

FORM 10-K

(Mark one)

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

For the fiscal year ended December 31, 2015

☐ **TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____to _____.

Commission file number 000-24477

DIFFUSION PHARMACEUTICALS INC.

(Exact name of registrant as specified in its charter)

Delaware	**30-0645032**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
2020 Avon Court, #4 **Charlottesville, Virginia**	**22902**
(Address of principal executive offices)	(Zip Code)

(434) 220-0718
(Registrant's telephone number, including area code)

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

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, par value $0.001 per share
(Title of each class)

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 of this chapter) during the preceding 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 of this chapter) 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 definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

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

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

The aggregate market value of the registrant's common stock, excluding shares beneficially owned by affiliates, computed by reference to the closing sale price at which the common stock was last sold as of June 30, 2015 (the last business day of the registrant's second fiscal quarter) as quoted by the OTCQX on that date was approximately $26.2 million. For purposes of this computation, all directors, executive officers and 10% beneficial owners of the registrant as of such date are deemed to be affiliates.

As of March 21, 2016, 101,578,512 shares of common stock of the registrant were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this annual report on Form 10-K incorporates by reference information (to the extent specific sections are referred to herein) from the registrant's definitive proxy statement for its 2016 Annual Meeting of Stockholders or an amendment to this Annual Report on Form 10-K, in any case, to be filed within 120 days of the end of the period covered by this Annual Report.

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This annual report on Form 10-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and are subject to the safe harbor created by those sections. For more information, see "Part I. Item 1. Business — Cautionary Note Regarding Forward-Looking Statements."

As previously disclosed, on January 8, 2016, Diffusion Pharmaceuticals Inc. (f/k/a RestorGenex Corporation), a Delaware corporation (the "Company"), completed the merger (the "Merger") of its wholly owned subsidiary, Arco Merger Sub, LLC ("Merger Sub"), with and into Diffusion Pharmaceuticals LLC, a Virginia limited liability company ("Diffusion LLC"), in accordance with the terms of the Agreement and Plan of Merger, dated as of December 15, 2015, among the Company, Merger Sub and Diffusion LLC (the "Merger Agreement"). As a result of the Merger, Diffusion LLC, the surviving company in the Merger, became a wholly owned subsidiary of the Company and, following the Merger, the Company changed its corporate name from RestorGenex Corporation ("RestorGenex") to Diffusion Pharmaceuticals Inc.

For accounting purposes, the Merger is treated as a "reverse acquisition" under generally acceptable accounting principles in the United States ("U.S. GAAP") and Diffusion LLC is considered the accounting acquirer. Accordingly, Diffusion LLC's historical results of operations will replace the Company's historical results of operations for all periods prior to the Merger and, for all periods following the Merger, the results of operations of the combined company will be included in the Company's financial statements.

This annual report on Form 10-K relates to the Company's year ended December 31, 2015, which was prior to the completion of the Merger, and therefore contains the historical financial statements of RestorGenex and does not include the historical financial statements of Diffusion LLC. The first periodic report that will include results of operations for the combined company, including Diffusion LLC, will be the Company's quarterly report on Form 10-Q for the quarter ending March 31, 2016.

Unless the context otherwise requires, references to the "Company," the "combined company" "we," "our" or "us" in this report refer to Diffusion Pharmaceuticals Inc. and its subsidiaries, references to "Diffusion" refer to the Company following the completion of the Merger, references to "RestorGenex" refer to the Company prior to the completion of the Merger and references to "Diffusion LLC" refer to Diffusion Pharmaceuticals LLC, the Company's wholly-owned subsidiary following the Merger.

Except as otherwise noted, references to "common stock" in this report refer to common stock, par value $0.001 per share, of the Company.

All share and per share amounts have been adjusted to reflect the one-for-100 reverse split of outstanding common stock effective March 7, 2014.

This report contains the following trademarks, trade names and service marks of ours: RestorGenex and Diffusion. All other trade names, trademarks and service marks appearing in this Annual Report on Form 10-K are the property of their respective owners. We have assumed that the reader understands that all such terms are source-indicating. Accordingly, such terms appear without the trade name, trademark or service mark notice for convenience only and should not be construed as being used in a descriptive or generic sense.

PART I

ITEM 1. BUSINESS

We are a clinical stage biotechnology company focused on extending the life expectancy of cancer patients by improving the effectiveness of current standard-of-care treatments, including radiation therapy and chemotherapy. We are developing our lead product candidate, *transcrocetinate sodium*, also known as *trans sodium crocetinate* ("TSC"), for use in the many cancer types in which tumor oxygen deprivation ("hypoxia") is known to diminish the effectiveness of current treatments. TSC is designed to target the cancer's hypoxic micro-environment, re-oxygenating treatment-resistant tissue and making the cancer cells more susceptible to the therapeutic effects of standard-of-care radiation therapy and chemotherapy. Our lead development programs target TSC against cancers known to be inherently treatment-resistant, including brain cancers and pancreatic cancer. A Phase 1/2 clinical trial of TSC combined with first-line radiation and chemotherapy in patients newly diagnosed with primary brain cancer ("glioblastoma" or "GBM") was completed in 2015. This trial provided evidence of efficacy and safety in extending overall survival without the addition of toxicity. Based on these results, an End-of-Phase 2 meeting was held with the U.S. Food and Drug Administration ("FDA") in August 2015, resulting in agreement on the design of a single 400 patient pivotal Phase 3 registration study which, if successful, would be sufficient to support approval. Discussions with the FDA regarding extension of the TSC development program from first line GBM into first-line pancreatic cancer treatment are currently underway. TSC has been granted Orphan Drug designation for the treatment of GBM.

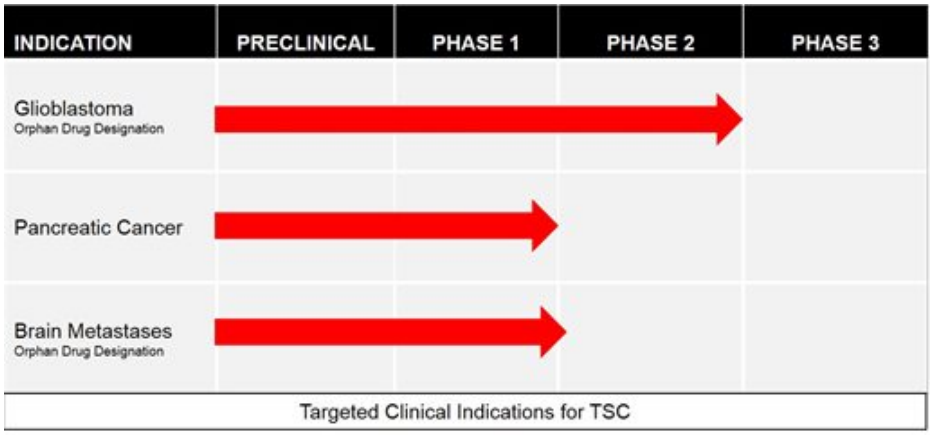
In addition to cancer, TSC also has potential applications in other indications involving hypoxia, such as hemorrhagic shock, stroke, peripheral artery disease and neurodegenerative diseases.

On January 8, 2016, we entered into a business combination whereby a wholly-owned subsidiary of the Company merged with and into Diffusion LLC, with Diffusion LLC surviving as our wholly-owned subsidiary (the "Merger"). In connection with the Merger, the Company issued to the holders of outstanding units of Diffusion LLC an aggregate of approximately 82.9 million shares of the Company's common stock ("Common Stock") and, as a result, immediately following the completion of the Merger, the former equity holders of Diffusion LLC owned approximately 84.1% of the Common Stock and the stockholders of RestorGenex immediately prior to the Merger owned approximately 15.9% of the Common Stock, in each case, on a fully-diluted basis (subject to certain exceptions and adjustments). Also in connection with the Merger, the pre-Merger directors and officers of the Company tendered their resignations and the pre-Merger directors and officers of Diffusion LLC were appointed as the new directors and officers of the Company, and our corporate headquarters was moved from Buffalo Grove, Illinois to Charlottesville, Virginia. Following the completion of the Merger, the Company changed its corporate name from "RestorGenex Corporation" to "Diffusion Pharmaceuticals Inc." and changed the trading symbol of the Company's common stock from "RESX" to "DFFN."

For accounting purposes, the Merger is treated as a "reverse acquisition" under generally acceptable accounting principles in the United States ("U.S. GAAP") and Diffusion LLC is considered the accounting acquirer. Accordingly, Diffusion LLC's historical results of operations will replace the Company's historical results of operations for all periods prior to the Merger and, for all periods following the Merger, the results of operations of the combined company will be included in the Company's financial statements.

Summary of Current Product Candidate Pipeline

The following table summarizes the targeted clinical indications for Diffusion's lead molecule, *trans sodium crocetinate*:



In addition to the TSC programs depicted in the table, we are exploring alternatives regarding how best to capitalize upon the legacy RestorGenex product candidates, which include RES-529, a novel PI3K/Akt/mTOR pathway inhibitor which has completed two Phase I clinical trials for age-related macular degeneration and was in preclinical development in oncology, specifically GBM, and RES-440, a “soft” anti-androgen compound for the treatment of acne vulgaris.

Diffusion Technology Overview

Diffusion’s proprietary technology is targeted at overcoming treatment-resistance in solid cancerous tumors by combining our lead product candidate, TSC, with standard-of-care radiation and chemotherapy regimens, thus effecting a better patient survival outcome without the addition of harmful side effects.

Under normally oxygenated cellular conditions, radiation and chemotherapy would have a powerful killing effect upon cancerous tumor tissue. However, in many solid tumor types cellular oxygen deprivation occurs as the result of too-rapid tumor growth, causing parts of the tumor to outgrow its blood supply. When tumor tissue becomes hypoxic, it is up to three times more resistant to the cancer-killing power of the standard therapies (radiation and chemotherapy) currently used in the treatment of the vast majority of cancer patients. Cancerous tumor cells are known to thrive under hypoxic conditions, as the resultant changes in the tumor microenvironment confer “treatment-resistance” to radiation and chemotherapy within the cell.

Many solid cancerous tumor types are hypoxic and therefore subject to this treatment-resistance. TSC safely re-oxygenates treatment-resistant hypoxic tumor tissue via a novel mechanism of action, without affecting the oxygenation of normal tissue, thereby increasing therapeutic effectiveness. To date, no addition of serious harmful side effects, or exacerbation of the known side effects of standard-of-care treatments, has been observed in our clinical studies.

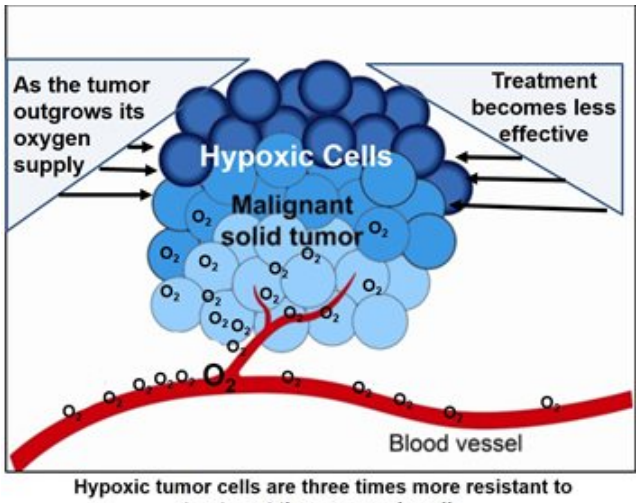
TSC’s distinctive re-oxygenation capabilities derive from its mechanism of action, which promotes enhanced diffusion of oxygen through blood plasma and into the hypoxic tumor microenvironment. Disruption of the treatment-resistance syndrome by re-oxygenation promotes enhanced cancer-killing power from radiation and chemotherapy, thereby safely extending patient survival. Because of the characteristics of this novel mechanism, oxygen levels of normal tissue remain unaffected, thereby avoiding side effects related to the syndrome referred to as “oxygen toxicity.” We believe this avoidance of oxygen toxicity confers a significant advantage to TSC’s diffusion-based approach over previous attempts to diminish treatment-resistance based on enhancing the oxygen concentration levels of the blood.

Our clinical development plan targets TSC at the radiation and chemotherapy sensitization of hypoxic tumor types, with an initial focus on primary brain cancer (“glioblastoma” or “GBM”), pancreatic cancer, and brain metastases. We have been granted orphan drug designations by the FDA for the treatment of brain cancers based on the acknowledged unmet medical need and number of patients affected. Such orphan drug designations allow certain favorable treatments under FDA regulations in connection with exclusivity periods and the new drug approval process.

Tumor Hypoxia

We believe that our breakthrough small molecule approach to overcoming solid tumor treatment-resistance by the reduction of cellular hypoxia may have significant implications for the improved treatment of cancer. Hypoxia is a deficiency in the supply of oxygen. It is well known that tumors are especially susceptible to developing hypoxia, driven by a combination of rapid cellular growth, structural abnormalities of the tumor microvessels and disturbed circulation within the tumor. There are a number of known treatment-resistance consequences conferred by tumor hypoxia, including increases in:

- Resistance to ionizing radiation;
- Clinically aggressive phenotype;
- Potential for more invasive growth; and,
- Regional and distal tumor spreading.



Hypoxic tumor cells are three times more resistant to treatment than normoxic cells

The above-described phenomenon of hypoxia-related “treatment-resistance” has been known to the scientific and clinical communities for over half a century. The challenge has been to find an approach that can effectively mitigate treatment-resistance without the addition of toxic side effects or exacerbation of the side effects associated with radiation and chemotherapy treatments. We believe that TSC embodies such an approach.

Trans Sodium Crocetinate

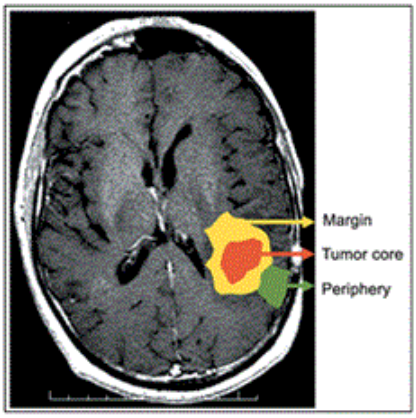
Dr. John Gainer, our Chief Scientific Officer, one of our directors and Professor Emeritus of Chemical Engineering at the University of Virginia, was the first to propose the use of chemical compounds specifically to facilitate the diffusion of oxygen through blood plasma for the purpose of re-oxygenating hypoxic tissues. Dr. Gainer's early laboratory work systematically examined various means to alter the diffusivity of oxygen through the use of small molecules that would affect the intermolecular forces existing in blood plasma. He originally identified crocetin, a natural carotenoid compound, as a molecule that could increase oxygen diffusion through the plasma, and crocetin was shown to be an effective treatment in a rat model of atherosclerosis and other indications. This work continued from the 1970s into the mid-1990s with various animal models, including radiation sensitization and hemorrhagic shock.

Because crocetin is an isomeric mixture, Dr. Gainer examined whether it was the *trans*-isomer which was responsible for eliciting the therapeutic benefit. These experiments led to his development of a pure *trans*-isomer salt compound, which he named *trans sodium crocetinate*. (The USAN designated name is *transcrocetinate sodium*). TSC has been shown to be more effective than crocetin in a severe model of hemorrhagic shock in both rats and pigs. It also demonstrated safety and efficacy in animal models of stroke and myocardial infarction, as well as in enhancing the response of hypoxic tumors to the therapeutic effects of radiation and chemotherapy.

It has been proposed that TSC works by altering the molecular arrangement of the water molecules in blood plasma (which is composed of 90% water), with the altered structure being less dense – and thus less resistant to oxygen diffusion – than untreated blood plasma. Water is composed of two hydrogen atoms and one oxygen atom, with a net positive charge found on the hydrogen atoms and a net negative charge found on the oxygen atom. This results in the formation of hydrogen bonds, which are an attraction between the net-negatively charged oxygen of one water molecule and the net-positively charged hydrogen atoms of another water molecule. Theoretically, one water molecule can form four hydrogen bonds with neighboring water molecules. However, the literature on the subject indicates that a water molecule actually forms, on average, two to 3.6 hydrogen bonds. By promoting an increase in the average number of hydrogen bonds among the water molecules comprising the bulk of blood plasma, TSC enhances the ability of oxygen to diffuse through the plasma and into hypoxic tissue.

Trans Sodium Crocetinate Increases Oxygenation of Hypoxic Cancerous Tumors

While earlier studies focused on improved treatments for hemorrhagic shock, ischemia, and traumatic brain injury, the use of TSC as an agent to re-oxygenate hypoxic cancerous tumors became a central area of research for Diffusion LLC following its founding in 2001. Because tumor hypoxia is a leading cause of solid tumor resistance to both radiation and chemotherapy, it was believed that an agent such as TSC – one that could safely increase the oxygenation of hypoxic tumor tissue – could prove effective in treatment-resistant cancers when combined with standard-of-care regimens of radiation and/or chemotherapy. This belief led to the development of preclinical and clinical development programs targeted against treatment-resistance in various cancers, with a focus on brain cancer types (both GBM and metastatic) and pancreatic cancer, all of which are known to be significantly hypoxic. The Company's longer term goal is to use TSC against treatment-resistance in the entire range of hypoxic cancers now treated with radiation and chemotherapy.



MRI of GBM tumor indicating sampling areas.
Source: Wei *et al.*, 2010

Glioblastoma Program

Diffusion's lead program is targeted against newly diagnosed primary brain cancer, also known as glioblastoma. Glioblastoma is a grade IV brain tumor, characterized by a heterogeneous cell population, with a number of negative attributes. GBM cells are typically genetically unstable (and thus prone to mutation), highly infiltrative, angiogenic, and resistant to radiation and chemotherapy. The mutations typically found in GBM allow the tumor to grow and thrive in a hypoxic environment. GBM is classified into two major subclasses, primary or secondary, depending upon the clinical properties as well as the chromosomal and genetic alterations that are unique to each class. Primary GBM arises *de novo* from normal glial cells and typically occurs in those over the age of 40, while secondary GBM arises from transformation of lower grade tumors and is usually seen in younger patients. Primary GBM is believed to account for approximately 95% of all GBM diagnoses.

While GBM is the most common form of primary brain tumor involving glial cells it is still relatively rare, as approximately 24,000 people in the United States were diagnosed with some form of malignant brain cancer in 2014. Gliomas account for approximately 80% of malignant brain cancers, with GBM accounting for approximately 45% of gliomas. The median age of GBM diagnosis is approximately 65 years, with the incidence of GBM in those over 65 increasing rapidly as shown by a doubling in incidence from 5.1 per 100,000 in the 1970s to 10.6 per 100,000 in the 1990s. Those diagnosed with the disease have a grim prognosis, with the median survival time of untreated patients being 4.5 months. Current standard-of-care treatment only provides 12-14 months of survival time after diagnosis.

Current Treatments for GBM

The standard-of-care for GBM tumors generally begins with surgical resection, unless the tumor is deemed inoperable due to its location near vital centers of the brain. This surgery is performed both to alleviate the symptoms associated with the disease as well as to facilitate treatment of residual tumor cells. Even with advances in surgical technique, complete removal of the tumor with clean margins is difficult to achieve, as the tumors are highly infiltrative and typically extend into the normal brain parenchyma. Due to this, almost all GBM patients have recurrence of the tumor, with 90% of such recurrence occurring at the primary site.

Due to the invasive nature of the tumors, surgical resection is promptly followed by radiotherapy coupled with the use of chemotherapeutic agents. Radiotherapy involves the administration of irradiation to the whole brain. While nitrosoureas were historically a commonly used chemotherapeutic agent, temozolomide (“TMZ”) was approved in 2005 and is now a mainstay of the standard-of-care. This is based on a clinical trial that showed the addition of TMZ to surgery and radiation increased median survival in newly diagnosed GBM patients to 14.6 months compared to 12.1 months for the surgery and radiation only group.

Most chemotherapeutic drugs have a limited ability to cross the blood brain barrier, thus a strategy to attempt to circumvent this was the development of Gliadel®, dissolvable chemotherapy wafers that could be placed in the tumor bed following surgical resection. Gliadel® contains the nitrosourea chemotherapeutic agent carmustine that is released for several weeks, in contrast to systemically administered carmustine that has a very short half-life. While Gliadel® wafers were shown to be safe, the drugs’ addition to radiation and TMZ did not result in a statistically significant increase in survival.

GBM tumors show increased expression of vascular endothelial growth factor (“VEGF”), and the anti-angiogenesis drug bevacizumab has been approved by the FDA for the treatment of recurrent GBM. A Phase 2 study found that bevacizumab treatment in patients with recurrent GBM increased six-month progression-free survival from a historical 9-15% to 25% with overall six-month survival of 54%. Another Phase 2 study showed that recurrent GBM patients treated with bevacizumab at a lower dose but a higher frequency had even higher six-month progression-free survival of 42.6%.

While bevacizumab has shown success in recurrent GBM, it is not utilized in newly diagnosed patients, our target patient population, as two separate clinical trials showed no difference in overall survival in patients treated with radiation, TMZ, and bevacizumab compared to patients treated with only radiation and TMZ. Bevacizumab treatment did result in an increase in progression free survival in both studies; however, the reason why this increase in progression free survival did not translate to an increase in overall survival is unclear. In addition, certain studies have reported that patients treated with bevacizumab had an increased symptom burden, a worse quality of life, and a decline in neurocognitive function.

GBM Therapies Under Development

There are a number of companies developing GBM therapies. For example, a search on the website www.clinicaltrials.gov yields over 300 results for "glioblastoma multiforme" and "open trials." Most of these trials focus on the recurrent patient population, whereas our target population will be newly diagnosed patients. In addition to the therapeutics previously mentioned, current GBM trials include Northwest Therapeutics' DCVax®-L, Celldex Therapeutics' Rindopepimut, Bristol-Myers Squibb's Nivolumab/Ipilimumab and AbbVie's Veliparib. In addition, the medical device company Novocure has been developing a novel approach called Tumor Treating Fields ("TTFields") using low intensity, alternating electric fields within the intermediate frequency range. TTFields are believed to disrupt cell division through physical interactions with key molecules during mitosis.

GBM is an Orphan Disease

Malignant brain cancers are diagnosed in approximately 24,000 individuals every year, making it an "orphan disease." The Orphan Drug Act of 1983 was designed to provide financial incentives for, and to reduce the costs associated with, developing drugs for rare diseases and disorders. A "rare disease or disorder" is defined by the Orphan Drug Act of 1983 as affecting fewer than 200,000 Americans at the time of designation or one for which "there is no reasonable expectation that the cost of developing and making available in the United States…will be recovered from sales in the United States." A sponsor must request that the FDA designate a drug currently under development for a "rare disease or condition" as an orphan drug, and if the FDA agrees that the drug and indication meet the criteria set forth in the Orphan Drug Act of 1983, certain financial and marketing incentives become available.

In July 2011, we announced that TSC was granted Orphan Drug Designation by the FDA for the treatment of GBM.

Trans Sodium Crocetinate Phase 1/2 Clinical Trial in GBM

We have evaluated TSC in 148 human subjects in various Phase 1 and Phase 2 clinical trials to date, with no serious adverse events attributable to TSC observed. Our Phase 1/2 clinical trial of TSC in patients with newly diagnosed GBM completed in 2015 is described in more detail below. TSC is targeted for testing against newly diagnosed GBM in an upcoming Phase 3 clinical trial that, assuming the availability of funding resources and the completion of certain manufacturing and animal toxicology guidelines mandated by the FDA agreement, could begin within the next 12 months.

Our Phase 1/2 clinical trial in GBM enrolled 59 newly diagnosed patients who received TSC in conjunction with radiation and TMZ. In the Phase I portion of the trial, TSC was initially administered three times per week at half-dose to three patients prior to radiation. Subsequently, six additional patients received full-dose TSC for six weeks in combination with radiation. No dose-limiting toxicities were identified in the nine patients during the Phase I portion of the trial, nor were any serious adverse events relating to the drug observed. Fifty additional patients were enrolled in the Phase II trial and received full-dose TSC in combination with TMZ and radiation therapy. Four weeks after completion of radiation therapy, all patients underwent chemotherapy with higher doses of TMZ for five days every four weeks, but no further TSC was administered.

We presented initial results from the trial at the 2015 American Society of Clinical Oncology ("ASCO") Annual Meeting in June 2015, which discussed data from the 18 trial sites covering the first 21 months. Preliminary results were then announced in July 2015. We presented the results in relation to a historical control group from a 2005 study which showed that the addition of TMZ to standard-of-care (surgery plus radiation) increased overall survival from 12.1 months to 14.6 months. We reported that:

- TSC plus radiation and TMZ increased the patients' chance of survival at two years by 37% compared to the historical control group. The overall survival at two years was 36.3% in the TSC group compared to 26.5% in the historical control group.

- In the subgroup of patients considered inoperable, the chance of survival at two years for those who received TSC was increased by over 100%, as 40% in the TSC group were alive at two years compared to less than 20% in the control.

- 71% of those treated with TSC were alive at one year compared to 61 percent of those in the historical control group.

- No serious negative safety findings attributed to TSC were observed in the TSC study and adverse events were consistent with those seen in previous trials of GBM featuring radiation and TMZ.

End-of-Phase 2 FDA Meeting and Plans for TSC Phase 3 GBM Clinical Trial

Following the announcement of the results of the 2015 Phase 1/2 clinical trial in GBM, we held an end of Phase 2 meeting with the FDA in August 2015 to discuss planning for a Phase 3 clinical trial. At the meeting, an agreement was reached on a trial design for the Phase 3 study, including:

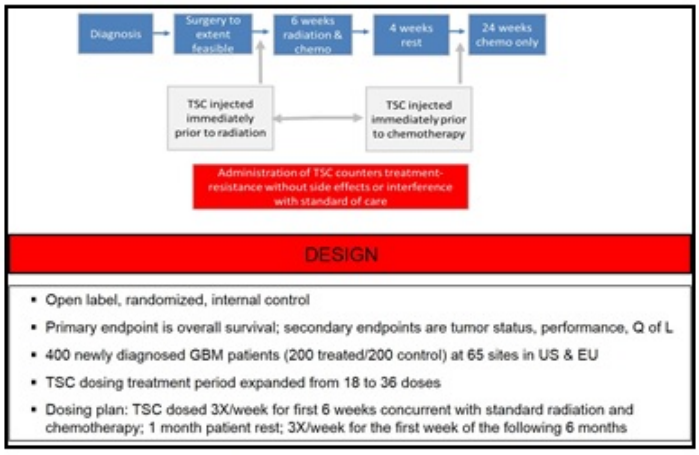
- A single, successful, randomized open-label trial of the agreed upon design can serve as the basis for an application for approval.

- The trial will consist of 400 newly diagnosed GBM patients with half given TSC in conjunction with standard-of-care radiation and TMZ and half receiving standard-of-care radiation and TMZ only.

- Based on the Phase 1/2 safety results with supporting toxicology, TSC's dosing exposure will be substantially increased, which means that TSC can now be used for both the radiation + chemotherapy and subsequent TMZ chemotherapy-only phase of GBM treatment.

- Diffusion will provide certain expanded information on animal toxicology, pharmacokinetics and manufacturing practices before initiating the trial.

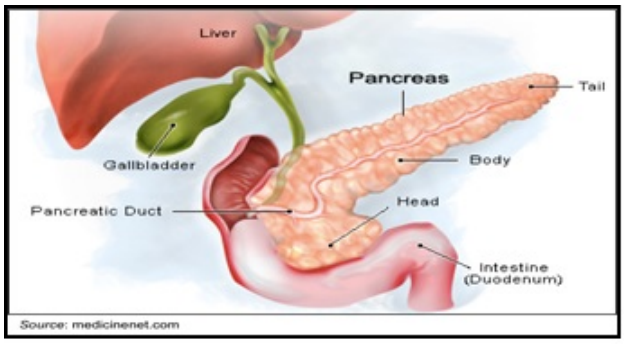
One of the major differences between the Phase 3 trial and the Phase 1/2 trial is the addition of TSC doses after the completion of the radiation/chemotherapy phase of treatment into the chemotherapy only phase. In the Phase 1/2 trial, TSC was only given prior to radiation (18 doses total). In the Phase 3 study, we are planning to give the patients 36 total doses of TSC, 18 in conjunction with radiation/chemotherapy and 18 in conjunction with chemotherapy alone. The following figure gives a graphical representation of our planned Phase 3 trial, which, assuming the availability of financial resources and the completion of certain manufacturing and animal toxicology guidelines mandated by the FDA agreement, we intend to commence within the next 12 months.



Pancreatic Cancer Program

One of the most hypoxic of all the solid cancers, and therefore one of the most treatment-resistant, is pancreatic cancer. According to the American Cancer Society, pancreatic cancer is responsible for 7% of all cancer deaths in both men and women, making it the fourth leading cause of cancer death in the U.S. Estimates are that 40% of pancreatic cancer cases are sporadic in nature, 30% are related to smoking and 20% may be associated with dietary factors, with only 5-10% of cases hereditary in nature.

Pancreatic cancer is difficult to diagnose in early stages because initial symptoms are often nonspecific and subtle in nature, and include anorexia, malaise, nausea, fatigue, and back pain. Approximately 75% of all pancreatic carcinomas occur within the head or neck of the pancreas, 15-20% occur in the body of the pancreas, and 5-10% occur in the tail.



The only potential curative therapy for pancreatic cancer is complete surgical resection. Unfortunately, this is only possible for approximately 20% of cases, and even of those patients whose cancer is surgically resected, 80% will develop metastatic disease within two to three years following surgery. Patients with unresectable pancreatic cancer have a median overall survival of 10 to 14 months while patients diagnosed with Stage IV disease (indicative of metastases) have a 5-year overall survival of just 1%.

Multiple studies have confirmed that pancreatic cancers are highly hypoxic. A study reporting the direct measurement of oxygenation in human pancreatic tumors prior to surgery showed dramatic differences between tumors and normal tissue. The partial pressure of oxygen (“pO2”) ranged between 0-5.3 mmHg in tumors but in adjacent normal tissue it ranged from 9.3-92.7 mmHg. Hypoxic areas are also frequently found when examining tissue from mouse models of pancreatic cancer.

Current Treatment Options for Pancreatic Cancer

Surgery remains the primary mode of treatment for patients with pancreatic cancer. However, there is an important role for chemotherapy and/or radiation in an adjuvant setting (given to prevent recurrence) or neoadjuvant setting (given before surgery to shrink the tumor to make complete resection more probable), as well as in patients with unresectable disease.

Since its approval in 1996, gemcitabine has been partnered with approximately 30 different agents in late-stage clinical trials in an attempt to improve upon the effectiveness of gemcitabine alone in treating patients with metastatic pancreatic cancer. Only two of these trials have led to an FDA approval – erlotinib (Tarceva®) and nab-paclitaxel (Abraxane®).

In patients with metastatic disease, the use of erlotinib with gemcitabine led to a significantly higher one-year survival rate than with the use of gemcitabine alone (23% vs. 17%, $P = 0.023$) as well as an increased median overall survival (6.24 months vs. 5.91 months, $P = 0.038$). A more recent study showed that the addition of nanoparticle albumin-bound (nab)-paclitaxel to gemcitabine significantly improved overall survival in treatment naïve patients with metastatic cancer, as overall survival was approximately two months longer in patients treated with combination therapy (8.5 vs. 6.7 months).

The Folfirinox (leucovorin + 5-fluorouracil + oxaliplatin + irinotecan) regimen was shown to significantly improve overall survival compared to treatment with gemcitabine (11.1 months vs. 6.8 months). While dramatically improving overall survival, the Folfirinox treatment was accompanied by serious adverse events and thus is only recommended for patients with good performance status.

Other combinations of gemcitabine with cisplatin, oxaliplatin, irinotecan or docetaxel tested in Phase 3 trials have not been of superior benefit to gemcitabine alone. The combination therapy nab-Paclitaxel and gemcitabine was recently approved by the FDA as an additional standard-of-care for the treatment of patients with untreated pancreatic adenocarcinoma. However, the improvements were modest, and treatment of pancreatic cancer remains an area of intense research, with 92 products in all stages of clinical development with 14 of them in Phase 3 at this time according to clinicaltrials.gov.

Just recently, the FDA approved Onivyde® (irinotecan liposome injection) in combination with fluorouracil and leucovorin, to treat patients with metastatic pancreatic cancer who were previously treated with gemcitabine-based chemotherapy. In the pivotal clinical trial, patients treated with Onivyde® plus fluorouracil/leucovorin lived an average of 6.1 months, compared to 4.2 months for those treated with only fluorouracil/leucovorin.

Pancreatic Cancer Market Analysis

It is estimated that in 2016 approximately 49,000 people will be diagnosed with pancreatic cancer in the United States. More than half of these patients will be diagnosed with metastatic disease. The five-year survival rates for patients with pancreatic cancer are dismal (<14%) and are particularly bad for those with metastatic disease (~1%).

The current standard-of-care for patients with metastatic pancreatic cancer includes gemcitabine combined with either erlotinib or nab-paclitaxel. Gemzar® (gemcitabine) is now available as a generic, however prior to losing patent protection the drug generated peak revenues of approximately $700 million in the United States for Eli Lilly. Tarceva® (erlotinib), which is approved for the treatment of metastatic non-small cell lung cancer and metastatic pancreatic cancer, is marketed by Roche and Astellas and sales of the drug generated $1.4 billion in revenue in 2014. Abraxane® (nab-paclitaxel), which was approved for the treatment of breast cancer in 2005 and non-small cell lung cancer in 2012, was approved by the FDA in 2013 for the treatment of metastatic pancreatic cancer. Sales of Abraxane® totaled $848 million in 2014 for all indications.

TSC in Pancreatic Cancer

We believe that targeting hypoxia in pancreatic cancer with TSC, especially in combination with standard-of-care therapies involving gemcitabine and nab-paclitaxel, may be beneficial in the treatment of pancreatic cancer. Pancreatic cancer is one of the most hypoxic malignant tumors, making it one of the most resistant tumors to therapy. Patients with advanced pancreatic cancer of exocrine origin have few therapeutic options and, for patients with advanced cancers, the overall survival rate of all stages is less than 1% at 5 years, with most patients dying within 1 year. Gemcitabine remains to-date, the backbone of treatment of pancreatic cancer.

The antitumor efficacy of gemcitabine is known to be hindered by a number of hypoxia-related factors including, but not limited to:

- *Limited Delivery of Gemcitabine to Intracellular Tumor Microenvironment.* Hypoxia has been associated with resistance to nucleoside analogs such as gemcitabine by decreasing the expression of the human cross-cell membrane equilibrative nucleoside transporter 1 (hENT1), thereby decreasing transport of gemcitabine and other nucleoside analogues into tumor cells.

- *Gemcitabine Intratumor Cell Inhibition of Ribonucleotide Reductase Compromised.* Hypoxia has been associated with a decrease in intracellular tumor ribonucleotide reductase, an enzyme required for the antitumor effect of gemcitabine. Indeed, this decrease leads to cell cycle arrest in G1 or G2 phase, thereby allowing DNA repair before progression to S or M phase.

- *Increased Breakdown of Gemcitabine*. It has been also observed that under hypoxic conditions, intratumor cell levels of cytidine deaminase are substantially increased. Cytidine Deaminase is the main enzyme responsible for the breakdown of gemcitabine and similar nucleosides. As a result of this, the gemcitabine antitumor effect is substantially decreased under hypoxic conditions.

- *Nab-paclitaxel Potentiates Gemcitabine by Decreasing Cytidine Deaminase.* One of the ways nab-paclitaxel decreases cytidine deaminase has been observed to be through increasing reactive oxygen species (“ROSs”) which has been shown to deactivate cytidine deaminase.

Taken together, the four factors above are believed to explain, at least in part, the limitations of gemcitabine in hypoxic conditions and the efficacy observed with the gemcitabine plus nab-paclitaxel combination regimen for the treatment of pancreatic cancer. They also suggest that correction of hypoxia with an anti-hypoxia agent such as TSC may significantly improve the efficacy of the gemcitabine plus nab-paclitaxel combination regimen for the treatment of pancreatic cancer, including for the following reasons:

- TSC has been shown to improve the cytotoxic effect of gemcitabine in a pre-clinical rat model.

- By correcting hypoxia, TSC may improve delivery of gemcitabine to intracellular tumor microenvironment by increasing levels of hENT-1.

- By reversing hypoxia-induced cell cycle arrest via reactivation of ribonucleotide reductase, TSC may restore gemcitabine’s antitumor effect.

- By reversing the hypoxia-induced increase of cytidine deaminase, TSC may increase intratumoral gemcitabine levels. Addition of TSC to the gemcitabine plus nab-paclitaxel regimen could further improve the efficacy of the combination by further decreasing cytidine deaminase. Of note, hypoxia has also been implicated in conferring tumor resistance to taxane-based therapies.

Proposed Plans for TSC Phase 2/3 Clinical Trial in Pancreatic Cancer

The planned Phase 2/3 clinical trial for TSC in pancreatic cancer is based on preclinical safety and efficacy data, and findings from the Phase 1/2 clinical trial in GBM, as well as the facts noted above. Global experts in the field agree that pancreatic cancer is an appropriate target for expansion of the use of TSC, and a clinical advisory committee of these key opinion leaders has been assembled to facilitate the Diffusion pancreatic cancer clinical development program. We are currently in discussions with the FDA regarding trial design, end-points, and patient numbers. Assuming the availability of financial resources, we anticipate beginning enrollment in this trial in the first half of 2017.

Brain Metastases Program

In contrast to the relative rarity of primary brain cancers, life-threatening cancers that metastasize to the brain are much more common and represent a serious complication in the treatment of many cancer types. Up to 30% of adult cancer patients will suffer from brain metastases. There are approximately 170,000 cases of metastatic brain cancer every year in the United States. Incidence of brain metastases varies depending upon the primary tumor type, although lung cancer appears to carry the greatest risk. The prognosis for patients with brain metastases is very grim, with current treatment options only resulting in median overall survival times of less than one year.

Treatment for brain metastases involves both controlling the symptoms associated with the condition as well as attacking the cancer directly. Brain metastases typically result in edema that can be controlled with the use of steroids; however, long-term use of steroids typically results in side effects that diminish a patient's quality of life. Approximately 25-45% of patients will experience seizures and require the use of anti-epileptic drugs. Surgery is only utilized in patients with a solitary brain metastatic lesion. Radiation therapy remains the standard-of-care for the vast majority of patients with brain metastases. There is very limited evidence for the use of chemotherapy, as few clinical trials have been conducted. There are no medications currently approved for the treatment of brain metastases.

Plans for TSC Phase 2/3 Clinical Trial in Metastatic Brain Cancer

We are planning to conduct a Phase 2/3 clinical trial in metastatic brain cancer after further discussions with the FDA regarding trial design, end-points, and patient numbers.

In December 2012, the FDA granted us Orphan Drug Designation for the use of TSC in brain metastases.

Description of Other Indications/Products

We have rights to and own technologies and potential products beyond those described above, including analog molecules as backups to TSC. It is our strategy to focus at the current time on our TSC for oncology, specifically GBM and pancreatic cancer, as described herein. Beyond those described herein, we also intend to continue to review our technologies and potential products on a regular basis and consider internal development in the future and the potential to out-license portions of our technology and potential products to other biopharmaceutical companies with greater focus and resources than ours, or potentially in-license late stage products which are in or ready for human clinical trials.

As a result of the Merger, we acquired product candidates for ophthalmology, oncology and dermatology. One such product candidate is RES-529, a novel PI3K/Akt/mTOR pathway inhibitor which has completed two Phase I clinical trials for age-related macular degeneration and is in preclinical development in oncology, specifically GBM. The novel inhibition of the PI3K/Akt/mTOR pathway and targeting of the androgen receptor have also shown potential in a number of additional indications. The legacy RestorGenex pipeline also includes RES-440, a "soft" anti-androgen compound for the treatment of acne vulgaris. Subject to prioritization and available resources, we may expand or out-license one or more of the products acquired in the Merger. Prior to the completion of the Merger, we distributed contingent value rights ("CVRs") to our stockholders as of the close of business on January 7, 2016 giving those holders the right to potentially receive certain cash payments of up to $50 million in the aggregate in the event we receive net cash payments during the five-year period after the Merger as a result of the sale, transfer, license or similar transaction relating to RES-440.

Competition

Our industry is highly competitive and subject to rapid and significant change. Potential competitors in the United States are numerous and include major pharmaceutical and specialty pharmaceutical companies, universities and other institutions. We generally divide our competition in the pharmaceutical industry into four categories: (1) corporations with large research and developmental departments that develop and market products in many therapeutic areas; (2) companies that have moderate research and development capabilities and focus their product strategy on a small number of therapeutic areas; (3) small companies with limited development capabilities and only a few product offerings; and (4) university and other research institutions. Many of our competitors have longer operating histories, greater name recognition, substantially greater financial resources and larger research and development staffs than we do, as well as substantially greater experience than us in developing products, obtaining regulatory approvals, and manufacturing and marketing pharmaceutical products. A significant amount of research is carried out at academic and government institutions. These institutions are aware of the commercial value of their findings and are aggressive in pursuing patent protection and negotiating licensing arrangements to collect royalties for use of technology that they have developed.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Our commercial opportunity could be reduced or eliminated if our competitors develop or market products or other novel therapies that are more effective, safer or less costly than our current or future product candidates, or obtain regulatory approval for their products more rapidly than we may obtain approval for our product candidates. In addition, the first product to reach the market in a therapeutic or preventative area is often at a significant competitive advantage relative to later entrants in the market and may result in certain marketing exclusivity as per federal legislation. Acceptance by physicians and other health care providers, including managed care groups, also is critical to the success of a product versus competitor products. Our success will be based in part on our ability to identify, develop and manage a portfolio of product candidates that are safer and more effective than competing products.

There are several firms currently marketing or developing products that may be competitive with our products. We believe TSC is a first-in-class novel small molecule that re-oxygenates hypoxic tissue, enhancing efficacy of radiation and chemotherapy without harmful side effects. Other companies are also developing drugs to enhance the efficacy of radiation and chemotherapy, notably, NuvOx Pharma LLC.

Research and Product Development

RestorGenex spent approximately $3.9 million in 2015 and $2.9 million in 2014 on research and product development activities that related primarily to activities associated with the synthesis and formulations of its products then in development, additional preclinical studies and planning for Phase I/Phase II studies. Diffusion LLC spent approximately $3.9 million in 2015 and $2.0 million in 2014 on research and product development activities. We anticipate that our research and development expenses during 2016 will increase compared to 2015 and will consist primarily of expenses associated with the initiation of our glioblastoma and pancreatic cancer human clinical trials.

Intellectual Property

Our success depends and will continue to depend in part upon our ability to maintain proprietary protection for our products and technologies, to preserve our proprietary information, trademarks and trade secrets and to operate without infringing the proprietary rights of others. Our policy is to attempt to protect our technology by, among other things, filing patent applications on inventions that are important to the development and conduct of our business with the U.S. Patent and Trademark Office ("USPTO"), and its foreign counterparts or obtaining license rights for technology that we consider important to the development of our business.

As of March 21, 2016, we own 14 issued U.S. patents and 46 issued foreign patents, which include granted European, Japanese, Chinese and Indian patent rights, and over 50 pending patent applications worldwide, covering the product candidates we currently intend to develop. While U.S. Patent 6,060,511 originally assigned to the University of Virginia, will expire this year, the expiration will not have a material impact on the business. The majority of our patents expire between 2026 and 2031. TSC has been granted Orphan Drug Designation for the treatment of both GBM and metastatic brain cancer and an application is pending for pancreatic cancer. A formulation patent provides protection for the TSC oral drug product until 2031 with extensions possible.

Patents extend for varying periods according to the date of patent filing or grant and the legal term of patents in various countries where patent protection is obtained. The actual protection afforded by a patent, which can vary from country to country, depends on the type of patent, the scope of its coverage and the availability of legal remedies in the country.

In addition to patents, we use other forms of protection, such as trademark, copyright and trade secret protection, to protect our intellectual property, particularly where we do not believe patent protection is appropriate or obtainable. We aim to take advantage of all of the intellectual property rights that are available to us and believe that this comprehensive approach will provide us with proprietary positions for our product candidates, where available.

We also protect our proprietary information by requiring our employees, consultants, contractors and other advisors to execute nondisclosure and assignment of invention agreements upon commencement of their respective employment or engagement. Agreements with our employees also prevent them from bringing the proprietary rights of third parties to us. In addition, we also require confidentiality or service agreements from third parties that receive our confidential information or materials.

Government Regulation

FDA Drug Approval Process

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act (the "FDC Act") and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending new drug applications ("NDAs"), warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

Pharmaceutical product development for a new product or certain changes to an approved product in the United States typically involves preclinical laboratory and animal tests, the submission to the FDA of an investigational new drug application ("IND") which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including good laboratory practices. The results of preclinical testing are submitted to the FDA as part of an IND, along with other information, including information about product chemistry, manufacturing and controls and a proposed clinical trial protocol. Long term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin.

Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (1) in compliance with federal regulations; (2) in compliance with good clinical practice ("GCP") an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors; and (3) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary or permanent discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board ("IRB") for approval at each site at which the clinical trial will be conducted. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

Clinical trials to support new drug applications ("NDAs") for marketing approval are typically conducted in three sequential phases, but the phases may overlap, especially in cancer indications. In Phase 1, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess pharmacological actions, side effects associated with increasing doses and, if possible, early evidence on effectiveness. Phase 2 usually involves trials in a limited patient population to determine metabolism, pharmacokinetics, the effectiveness of the drug for a particular indication, dosage tolerance and optimum dosage, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 clinical trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In most cases the FDA requires two adequate and well-controlled Phase 3 clinical trials with statistically significant results to demonstrate the efficacy of the drug. With suitable FDA agreement, a single Phase 3 clinical trial with other confirmatory evidence may be sufficient. In those instances, the study is usually a large multicenter trial demonstrating internal consistency and a statistically persuasive finding of an effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the United States. The NDA must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls. The cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee, and the manufacturer and sponsor under an approved new drug application are also subject to annual product and establishment user fees. These fees are typically increased annually.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of new drug applications. Priority review can be applied to drugs that the FDA determines offer major advances in treatment, or provide a treatment where no adequate therapy exists. For certain drugs, priority review is further limited only for drugs intended to treat a serious or life-threatening disease relative to the currently approved products. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission.

The FDA may also refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with current good manufacturing practice ("cGMP") is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy ("REMS") to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals and elements to assure safe use ("ETASU"). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

The Hatch-Waxman Act

Orange Book Listing

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent whose claims cover the applicant's product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an abbreviated new drug application ("ANDA"). An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, preclinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that: (1) the required patent information has not been filed; (2) the listed patent has expired; (3) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patent is invalid or will not be infringed by the new product. The ANDA applicant may also elect to submit a section viii statement certifying that its proposed ANDA label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the applicant does not challenge the listed patents, the ANDA will not be approved until all the listed patents claiming the referenced product have expired.

A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then commence a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced product has expired.

Exclusivity

Upon NDA approval of a new chemical entity ("NCE") which is a drug that contains no active moiety that has been approved by the FDA in any other NDA, that drug receives five years of marketing exclusivity during which the FDA cannot receive any ANDA seeking approval of a generic version of that drug. Certain changes to a drug, such as the addition of a new indication to the package insert, are associated with a three-year period of exclusivity during which the FDA cannot approve an ANDA for a generic drug that includes the change.

An ANDA may be submitted one year before NCE exclusivity expires if a Paragraph IV certification is filed. If there is no listed patent in the Orange Book, there may not be a Paragraph IV certification and, thus, no ANDA may be filed before the expiration of the exclusivity period.

REMS

The FDA has the authority to require a REMS to ensure the safe use of the drug. In determining whether a REMS is necessary, the FDA must consider the size of the population likely to use the drug, the seriousness of the disease or condition to be treated, the expected benefit of the drug, the duration of treatment, the seriousness of known or potential adverse events, and whether the drug is a new molecular entity. If the FDA determines a REMS is necessary, the drug sponsor must agree to the REMS plan at the time of approval. A REMS may be required to include various elements, such as a medication guide or patient package insert, a communication plan to educate healthcare providers of the drug's risks, limitations on who may prescribe or dispense the drug, or other measures that the FDA deems necessary to assure the safe use of the drug. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use ("ETASU"). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. In addition, the REMS must include a timetable to periodically assess the strategy. The FDA may also impose a REMS requirement on a drug already on the market if the FDA determines, based on new safety information, that a REMS is necessary to ensure that the drug's benefits outweigh its risks. The requirement for a REMS can materially affect the potential market and profitability of a drug.

Patent Term Extension

After NDA approval, owners of relevant drug patents may apply for up to a five-year patent extension. The allowable patent term extension is calculated as half of the drug's testing phase, the time between IND application and NDA submission, and all of the review phase, the time between NDA submission and approval, up to a maximum of five years. The time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed 14 years.

For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the USPTO must determine that approval of the drug covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug for which an NDA has not been submitted.

Post-Approval Requirements

Once an NDA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling.

Adverse event reporting and submission of periodic reports is required following FDA approval of an NDA. The FDA also may require post-marketing testing, known as Phase 4 testing, REMS, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality-control, drug manufacture, packaging and labeling procedures must continue to conform to cGMPs after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

Pediatric Information

Under the Pediatric Research Equity Act, NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data.

The Best Pharmaceuticals for Children Act ("BPCA") provides NDA holders a six-month extension of any exclusivity, patent or non-patent, for a drug if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric studies and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

The Orphan Drug Act of 1983

The Orphan Drug Act of 1983 was designed to provide financial incentives for, and to reduce the costs associated with, developing drugs for rare diseases and disorders. A "rare disease or disorder" is defined by the Orphan Drug Act of 1983 as affecting fewer than 200,000 Americans at the time of designation or one for which "there is no reasonable expectation that the cost of developing and making available in the United States…will be recovered from sales in the United States." A sponsor must request that the FDA designate a drug currently under development for a "rare disease or condition" as an orphan drug, and if the FDA agrees that the drug and indication meet the criteria set forth in the Orphan Drug Act of 1983, certain financial and marketing incentives become available.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved. Competitors may use this publicly-available information to gain knowledge regarding the progress of development programs.

Regulation Outside of the United States

In addition to regulations in the United States, we will be subject to regulations of other countries governing any clinical trials and commercial sales and distribution of our product candidates. Whether or not we obtain FDA approval for a product, we must obtain approval by the comparable regulatory authorities of countries outside of the United States before we can commence clinical trials in such countries and approval of the regulators of such countries or economic areas, such as the European Union, before we may market products in those countries or areas. Certain countries outside of the United States have a process similar to the FDA's that requires the submission of a clinical trial application ("CTA") much like the IND prior to the commencement of human clinical trials. In the European Union, for example, a CTA must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval.

Under European Union regulatory systems, a company may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure, which is compulsory for medicines produced by biotechnology or those medicines intended to treat AIDS, cancer, neurodegenerative disorders or diabetes and is optional for those medicines which are highly innovative, provides for the grant of a single marketing authorization that is valid for all European Union member states. The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and assessments report, each member state must decide whether to recognize approval. If a member state does not recognize the marketing authorization, the disputed points are eventually referred to the European Commission, whose decision is binding on all member states.

Anti-Kickback and False Claims Laws

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical industry. These laws include, among others, anti-kickback statutes, false claims statutes and other statutes pertaining to healthcare fraud and abuse. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "Affordable Care Act"), amended the intent element of the federal anti-kickback statute so that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor.

Federal false claims laws prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. This includes claims made to programs where the federal government reimburses, such as Medicaid, as well as programs where the federal government is a direct purchaser, such as when it purchases off the Federal Supply Schedule. Pharmaceutical and other healthcare companies have been prosecuted under these laws for, among other things, allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate federal false claims laws. Additionally, Affordable Care Act amended the federal healthcare program anti-kickback statute such that a violation of that statute can serve as a basis for liability under certain federal false claims laws.

The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Other federal statutes pertaining to healthcare fraud and abuse include the civil monetary penalties statute, which prohibits, among other things, the offer or payment of remuneration to a Medicaid or Medicare beneficiary that the offerer or payor knows or should know is likely to influence the beneficiary to order or receive a reimbursable item or service from a particular supplier, and the healthcare fraud and false statements statutes, which prohibit, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program or obtain by means of false or fraudulent pretenses, representations, or promises any money or property owned by or under the control of any healthcare benefit program in connection with the delivery of or payment for healthcare benefits, items, or services.

Violations of these federal healthcare fraud and abuse laws are punishable by imprisonment, criminal fines, civil monetary penalties and exclusion from participation in federal healthcare programs.

Other Federal and State Regulatory Requirements

The Centers for Medicare & Medicaid Services (CMS) has issued a final rule pursuant to Affordable Care Act that requires certain manufacturers of prescription drugs to annually collect and report information on payments or transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Manufacturers were required to begin collecting information on August 1, 2013, with the first reports due March 31, 2014. The reported data is posted in searchable form on a public website. Failure to submit required information may result in civil monetary penalties.

In addition, several states now require prescription drug companies to report expenses relating to the marketing and promotion of drug products and to report gifts and payments to individual healthcare practitioners and entities in these states. Other states prohibit various other marketing-related activities. Still other states require the posting of information relating to clinical studies and their outcomes. In addition, California, Connecticut, Nevada and Massachusetts require pharmaceutical companies to implement compliance programs and marketing codes. Several additional states are considering similar proposals. Some of the state laws are broader in scope than federal laws. Compliance with these laws is difficult and time consuming, and companies that do not comply with these state laws face civil penalties.

Reimbursement

Sales of any of our product candidates that are approved will depend, in part, on the extent to which the costs of our approved products will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly challenging the prices charged for medical products and services. Additionally, the containment of healthcare costs has become a priority of federal and state governments and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. If any of our products are approved and these third-party payors do not consider our approved products to be cost-effective compared to other therapies, they may not cover our approved products as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our approved products on a profitable basis.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (“MMA”), imposed new requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities which will provide coverage of outpatient prescription drugs. Part D plans include both stand-alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans. Unlike Medicare Part A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for our products for which we receive marketing approval. However, any negotiated prices for our approved products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

The ARRA provides funding for the federal government to compare the effectiveness of different treatments for the same illness. A plan for the research will be developed by the Department of Health and Human Services, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures will be made to the U.S. Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, it is not clear what effect, if any, the research will have on the sales of any approved product, if any such product or the condition that it is intended to treat is the subject of a study. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's product could adversely affect the sales of our product candidates. If third-party payors do not consider our approved products to be cost-effective compared to other available therapies, they may not cover our approved products as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our approved products on a profitable basis.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010, collectively referred to as the ACA, was enacted in March 2010, which includes measures to significantly change the way healthcare is financed by both governmental and private insurers. Among the provisions of the Affordable Care Act of importance to the pharmaceutical and biotechnology industry are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, that began in 2011;

- an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for branded and generic drugs, respectively;

- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts to negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;

- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;

- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing manufacturers' Medicaid rebate liability;

- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;

- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;

- a licensure framework for follow-on biologic products;

- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;

- new requirements under the federal Open Payments program for drug manufacturers to report information related to payments and other transfers of value made to physicians and other healthcare providers as well as ownership or investment interests held by physicians and their immediate family members;

- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians, effective April 1, 2012;

- creation of the Independent Payment Advisory Board which, beginning in 2014, will have authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs and those recommendations could have the effect of law even if Congress does not act on the recommendations; and

- establishment of a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending that began on January 1, 2011.

In addition, in some non-U.S. jurisdictions, the proposed pricing for a product candidate must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, product candidates launched in the European Union do not follow price structures of the United States and generally tend to be significantly lower.

Manufacturing and Supply

We do not have any facilities suitable for manufacturing on a commercial scale any of our product candidates nor do we have any experience in volume manufacturing. We currently use third-party cGMP contract manufacturing organizations (“CMOs”) to manufacture our product candidates for our preclinical studies and clinical trials and intend to continue doing so in the future in accordance with FDA and other appropriate regulations. We anticipate that these CMOs will have capacity to support commercial scale, but we do not have any formal agreements at this time with any of these CMOs to cover commercial production. We also may elect to pursue other CMOs for manufacturing supplies for later-stage trials and for commercialization. We currently have no plans to establish a manufacturing capability, but rather plan to continue to rely on third-party cGMP manufacturers for any future trials and commercialization of our product candidates for which we retain manufacturing responsibility.

Sales and Marketing

We currently have no sales and marketing personnel to sell any of our product candidates on a commercial basis if and when our product candidates received required regulatory approvals. If and when we are ready to commercially launch a product, we will either contract with or hire qualified sales and marketing personnel or seek a joint marketing partner or licensee to assist us with this function.

Employees

Prior to the completion of the Merger, as of December 31, 2015, RestorGenex had five employees, including one in product development and four in management or administrative positions. RestorGenex also retained independent consultants to support the organization. After the merger, none of RestorGenex's employees and consultants remained employees of Diffusion. As of December 31, 2015, Diffusion LLC had 8 employees, including 3 in product development and 5 in management or administrative positions and had 5 independent consultants supporting our organization.

Directors and Executive Officers

The table below sets forth, as of March 15, 2016, certain information concerning our current directors and executive officers. No family relationships exist among any of our directors or executive officers.

Name	Age	Position with Diffusion
David G. Kalergis	67	Chairman and Chief Executive Officer
John L. Gainer, Ph.D.	77	Director and Chief Scientific Officer
David R. Jones, M.D.	52	Chief Medical Officer
Ben Shealy	57	Senior Vice President – Finance and Treasurer
Robert Adams	65	Director
Thomas Byrne	58	Director
Mark T. Giles	61	Director
Alan Levin	53	Director

The following is a biographical summary of the experience of our directors and executive officers:

David G. Kalergis – Mr. Kalergis serves as our Chairman and Chief Executive Officer and as one of our directors. Mr. Kalergis was appointed as Chairman and Chief Executive Officer in connection with the completion of the Merger. Mr. Kalergis, along with Dr. Gainer, is a co-founder of Diffusion LLC and served as a director of Diffusion LLC from its inception in 2001 until January 2016, and has served as Diffusion LLC's Chief Executive Officer since 2004. Prior to joining Diffusion LLC, Mr. Kalergis held positions with the University of Virginia, as the general counsel and director of business development for Pharmaceutical Research Associates, Inc., a pharmaceutical contract research organization, as an intelligence analyst for the U.S. Government and with the law firm Dewey, Ballantine, Bushby, Palmer & Wood, practicing in the areas of corporate finance, public offerings and mergers and acquisitions. In addition, from July 1998 until May 2012, Mr. Kalergis served on the board of directors and audit committee of Virginia National Bank. Mr. Kalergis received a B.A. in psychology, as well as an M.B.A. and J.D., from the University of Virginia, and is a graduate of the Harvard Business School's Leadership and Strategy in the Pharmaceutical and Biotechnology Industry program.

John L. Gainer, Ph.D. – Dr. Gainer serves as our Chief Scientific Officer and as one of our directors. Dr. Gainer was appointed as Chief Scientific Officer in connection with the completion of the Merger. Dr. Gainer, along with Mr. Kalergis, is a co-founder of Diffusion LLC as well as its Chief Scientific Officer, a position he has held since 2001, and served as one of its directors from its inception in 2001 until January 2016. From 1966 until his retirement in 2005, Dr. Gainer was a professor of chemical engineering at the University of Virginia. During his career, Dr. Gainer authored more than 100 scientific journal articles, including more than 30 published in medical journals, and spent two sabbaticals investigating drug actions and related research at Karolinska Institute in Stockholm and the laboratory of a major pharmaceutical company. He has been a member of the International Society for Oxygen Transport in Tissues since its inception in 1973. Dr. Gainer received a BSChE from West Virginia University and a Ph.D. in chemical engineering from the University of Delaware.

David R. Jones, M.D. – Dr. Jones serves as our Chief Medical Officer. Dr. Jones was appointed Chief Medical Officer in connection with the completion of the Merger, and has served as Diffusion LLC's Chief Medical Officer since September 2012. In addition to serving as Diffusion's Chief Medical Officer, Dr. Jones is also the Fiona and Stanley Druckenmiller Endowed Professor for Lung Cancer Research and Chief of Thoracic Surgery at Memorial Sloan-Kettering Cancer Center in New York, NY, a position he has held since 2013. From 2007 to 2013, Dr. Jones was Professor of Surgery and Division Chief of Thoracic & Cardiovascular Surgery at the University of Virginia. In addition to his clinical practice, Dr. Jones has published more than 220 scientific articles, authored or co-authored over 35 book chapters, and served as Principal Investigator or Co-Investigator of over 30 clinical trials. Dr. Jones received an undergraduate degree in chemistry and an M.D. from West Virginia University, and completed his thoracic surgery residency and postdoctoral research fellowship in molecular oncology at the University of North Carolina - Chapel Hill.

Ben Shealy – Mr. Shealy serves as our Senior Vice President – Finance and Treasurer. Mr. Shealy was appointed Senior Vice President – Finance and Treasurer in connection with the completion of the Merger. Mr. Shealy has served as Diffusion LLC's Senior Vice President – Finance and Treasurer, since December 2015, and prior to that had served as Diffusion LLC's Chief Financial Officer since 2004. Prior to joining Diffusion LLC, Mr. Shealy spent more than 20 years in the financial management industry focusing on private and public corporate financings, including serving as the Vice President of REBAR Inc. and positions with Donaldson, Lufkin & Jenrette, Prudential-Bache Capital Funding and the John Hancock Derivatives Group. Mr. Shealy received a B.S. in accounting from San Jose State University, an M.B.A. in finance from Columbia University and is a CFA Charter holder.

Robert Adams – Mr. Adams serves as one of our directors. Mr. Adams was appointed a director in connection with the completion of the Merger after serving as a director of Diffusion LLC from 2002 to January 2016. Prior to his retirement in 2015, Mr. Adams was a partner in the intellectual property law firm of Nixon & Vanderhye P.C, where he had practiced for over 25 years, focusing on patent litigation and international patent licensing and negotiations. During that time period, Mr. Adams was lead litigation counsel in more than 50 major intellectual property lawsuits, where he directly handled, for example, all intellectual property valuations and settlements on behalf of his U.S. and foreign clients. Moreover, Mr. Adams served as the head negotiator for a well-known Japanese consumer products company for 15 years in various complicated licensing situations. Those negotiations typically involved the cross-licensing of up to hundreds of U.S. and foreign patent rights. His lead licensing activities on behalf of that client included, among other things, multi-year negotiations with Texas Instruments, Advanced Micro Devices and Freescale. Mr. Adams received a B.A. from the University of Maryland and a J.D. from George Washington University (with honors), and is a member of the Virginia State Bar.

Thomas Byrne – Mr. Byrne serves as one of our directors. Mr. Byrne was appointed a director in connection with the completion of the Merger. Mr. Byrne served as a director of Diffusion LLC from 2001 to January 2016, and has served as its Secretary and Director of Patent Strategy since 2007. Prior to joining Diffusion LLC, Mr. Byrne served in in-house counsel positions at both Genentech Inc. and Amgen Inc., where he co-invented the erythropoiesis stimulating agent darbepoietin alpha (Aranesp®). From 1992 to 2000, he was a partner in the intellectual property law firm of Nixon and Vanderhye P.C. Mr. Byrne also currently acts as a consultant for start-up biotechnology companies on intellectual property, contract and business issues. He received a B.S. in chemical engineering and nuclear engineering, as well as a J.D., from the University of Virginia, and an M.S. in biochemical engineering from Yale University.

Mark T. Giles – Mr. Giles serves as one of our directors. Mr. Giles was appointed a director in connection with the completion of the Merger after serving as a director of Diffusion LLC from 2008 to January 2016. Since July 2007, Mr. Giles has been the sole managing member of Panda Holdings, LLC, which engages in the investment and management of private capital. Prior to joining Panda Holdings, Mr. Giles served as the Chief Executive Officer and Chairman of Virginia National Bank from July 1998 until December 2011. Prior to joining Virginia National Bank, Mr. Giles also served as the president of two publicly traded bank holding companies and subsidiary banks in Texas, practiced law with the banking group of a Houston law firm and served as the Chairman of VNBTrust. He is a founding director of Walk2Campus Properties, LLC, and chairs the boards of Relay Foods, Inc. and Expedition Trust Company. He also serves on the boards of The Paramount Theater Foundation and The Paramount Theater Operating Company, the Thomas Jefferson Area United Way and the Computers4Kids Program. He also serves on the Medical Affairs Board and Finance Committee of Martha Jefferson Hospital. Mr. Giles received a B.S. from the McIntire School of Commerce at the University of Virginia and a J.D. from the University of Virginia School of Law.

Alan Levin – Mr. Levin serves as one of our directors. Mr. Levin was appointed a director in connection with the completion of the merger. Mr. Levin served as a director of Diffusion LLC from June 2015 to January 2016. He previously served as Executive Vice President and Chief Financial Officer of Endo Health Solutions Inc. (“Endo”), a global specialty healthcare company, from June 2009 until his retirement in September 2013. Prior to joining Endo, Mr. Levin worked with Texas Pacific Group, a leading private equity firm, and one of their start-up investments. Before that, he was Senior Vice President and Chief Financial Officer of Pfizer, Inc. where he worked for 20 years in a variety of executive positions of increasing responsibility, including Treasurer and Senior Vice President of Finance & Strategic Management for the company’s research and development organization. Mr. Levin received a bachelor’s degree from Princeton University and a master’s degree from New York University’s Stern School of Business. Mr. Levin is a certified public accountant. He is a member of the Board of Directors of Aceto Corp, a NASDAQ-traded company specialized in generics and pharmaceutical intermediate products. He is also a member of the Advisory Board of Auven Therapeutics, a private equity fund; and the Critical Path Institute, a nonprofit collaboration between the Food and Drug Administration and pharmaceutical industry participants focused on streamlining and accelerating the development and regulatory pathways for innovative medicines.

Corporate Information and History

We are a Delaware corporation that was originally incorporated in the State of Nevada on January 10, 1995. We reincorporated into the State of Delaware on June 18, 2015. In 2013, as part of an effort to reposition our company at that time as a specialty biopharmaceutical company, our Board of Directors authorized management to pursue acquisition opportunities in the life sciences sector. In November 2013, we completed the acquisition of Canterbury Laboratories, LLC (“Canterbury”) and Hygeia Therapeutics, Inc. On March 7, 2014, we effected a reverse stock split of one-for-100 of our common stock. All share and per share amounts in this report have been adjusted to reflect the one-for-100 reverse split of outstanding common stock. On March 28, 2014, we completed the acquisition of Paloma Pharmaceuticals, Inc. (“Paloma”) and VasculoMedics, Inc. These acquisitions are described in more detail in the notes to our consolidated financial statements. On January 8, 2016, we acquired Diffusion LLC in connection with the Merger to create a clinical-stage biotechnology company focused on developing therapeutics primarily for the treatment of certain cancers.

Our corporate headquarters are located at 2020 Avon Court, #4, Charlottesville, Virginia 22902, our telephone number is (434) 220-0718, and our Internet web site address is www.diffusionpharma.com. The information contained on our web site or connected to our web site is not incorporated by reference into and should not be considered part of this annual report on Form 10-K.

Available Information

We make available, free of charge and through our Internet web site, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any amendments to any such reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. We also make available, free of charge and through our Internet web site, to any shareholder who requests, the charters of our board committees, our Corporate Governance Guidelines and our Code of Business Conduct and Ethics. Requests for copies can be directed to Investor Relations at (434) 220-0718.

Cautionary Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K (this "Annual Report") includes forward-looking statements. We may, in some cases, use terms such as "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Forward-looking statements appear in a number of places throughout this Annual Report and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned preclinical development and clinical trials, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our product candidates, our intellectual property position, the degree of clinical utility of our products, particularly in specific patient populations, our ability to develop commercial functions, expectations regarding clinical trial data, our results of operations, cash needs, financial condition, liquidity, prospects, growth and strategies, the industry in which we operate and the trends that may affect the industry or us.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics and industry change, and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Annual Report, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Annual Report. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this Annual Report, they may not be predictive of results or developments in future periods.

Actual results could differ materially from our forward-looking statements due to a number of factors, including risks related to:

- our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- the success and timing of our preclinical studies and clinical trials;
- the difficulties in obtaining and maintaining regulatory approval of our products and product candidates, and the labeling under any approval we may obtain;
- our plans and ability to develop and commercialize our product candidates;

- our failure to recruit or retain key scientific or management personnel or to retain our executive officers;
- the accuracy of our estimates of the size and characteristics of the potential markets for our product candidates and our ability to serve those markets;
- regulatory developments in the United States and foreign countries;
- the rate and degree of market acceptance of any of our product candidates;
- our ability to obtain additional financing;
- obtaining and maintaining intellectual property protection for our product candidates and our proprietary technology;
- our ability to operate our business without infringing the intellectual property rights of others;
- recently enacted and future legislation regarding the healthcare system;
- the success of competing products that are or become available; and
- the performance of third parties, including contract research organizations and manufacturers.

You should also read carefully the factors described in the "Risk Factors" section of this Annual Report and elsewhere to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified timeframe, or at all.

Any forward-looking statements that we make in this Annual Report speak only as of the date of such statement, and, except as required by applicable law, we undertake no obligation to update such statements to reflect events or circumstances after the date of this Annual Report or to reflect the occurrence of unanticipated events. Comparisons of results for current and any prior periods are not intended to express any future trends or indications of future performance, unless expressed as such, and should only be viewed as historical data.

ITEM 1A. RISK FACTORS

The following are significant factors known to us that could materially harm our business, operating results or financial condition or could cause our actual results to differ materially from our anticipated results or other expectations, including those expressed in any forward-looking statement made in this report:

Risks Related to Our Financial Needs

We have incurred significant losses since our inception and have a history of net losses and negative cash flow from operations.

We are a clinical-stage biotechnology company and, as a result, we have a limited operating history and there is little historical basis upon which to assess how we will respond to competitive or economic challenges or other challenges to our business. Our business and prospects must be considered in light of the risks and uncertainties frequently encountered by similarly situated companies.

We have generated substantial net losses and negative cash flow from operations since our inception, and we continue to incur significant research, development and other expenses related to our ongoing operations for other product candidates. We expect to incur losses and negative cash flow for the foreseeable future. Our ability to generate sufficient revenues from our other product candidates, if approved, will depend on numerous factors described in the following risk factors. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses and expected future have had and will continue to have an adverse effect on our stockholders' equity.

We currently generate no revenue from the sale of products and may never become profitable.

To date, we have not generated any revenues from our product candidates. Even if we are able to successfully achieve regulatory approval for our product candidates, we do not know when any of these products will generate revenue for us, if at all. Our ability to generate revenue from our current products or future product candidates also depends on a number of additional factors, including our ability to:

• successfully complete development activities, including the necessary clinical trials;

• complete and submit NDAs to the FDA and obtain regulatory approval for indications for which there is a commercial market;

• complete and submit applications to, and obtain regulatory approval from, foreign regulatory authorities;

• develop a commercial organization capable of sales, marketing and distribution for the products we intend to sell ourselves in the markets in which we have retained commercialization rights; and

• find suitable distribution partners to help us market, sell and distribute our approved products in other markets.

In addition, because of the numerous risks and uncertainties associated with product development, including that our product candidates may not advance through development or achieve the endpoints of applicable clinical trials, we are unable to predict the timing or amount of increased expenses, or when or if we will be able to achieve or maintain profitability. Even if we are able to complete the process described above, we anticipate incurring significant costs associated with commercializing these products.

If we require additional capital to fund our operations and we fail to obtain necessary financing, we may be unable to complete the development and commercialization of our product candidates.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to advance the clinical development of our product candidates and to commercialize any product candidates for which we receive regulatory approval. We believe that our existing cash will be sufficient to fund our projected operating requirements into the third quarter of 2016. However, we may require additional capital for the further development and commercialization of our product candidates and may also need to raise additional funds sooner in order to accelerate development of our product candidates.

We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates or one or more of our other research and development initiatives. We also could be required to:

• seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available; or

• relinquish or license on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this "Risk Factors" section. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

• the initiation, progress, timing, costs and results of clinical trials for our product candidates and any future product candidates we may in-license;

• the clinical development plans we establish for these product candidates;

• the number and characteristics of product candidates that we in-license and develop;

• the outcome, timing and cost of regulatory approvals by the FDA and comparable foreign regulatory authorities, including the potential for the FDA or comparable foreign regulatory authorities to require that we perform more studies than those that we currently expect;

• the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;

• the effect of competing technological and market developments; and

• the cost and timing of completion of becoming a commercial organization.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We may seek additional capital through a combination of private and public equity offerings, debt financings, receivables or royalty financings, strategic partnerships and alliances and licensing arrangements. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of existing stockholders. Debt, receivables and royalty financings may be coupled with an equity component, such as warrants to purchase stock, which could also result in dilution of our existing stockholders' ownership. The incurrence of indebtedness would result in increased fixed payment obligations and could also result in certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business and may result in liens being placed on our assets and intellectual property. If we were to default on such indebtedness, we could lose such assets and intellectual property. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, or grant licenses on terms that are not favorable to us.

Our auditors have expressed substantial doubt as to our ability to continue as a going concern in their report.

In its report on our consolidated financial statements for the year ended December 31, 2015, our independent registered public accounting firm included an explanatory paragraph expressing substantial doubt regarding our ability to continue as a going concern. A "going concern" opinion means, in general, that our independent registered public accounting firm has substantial doubt about our ability to continue our operations without continuing infusions of capital from external sources. This opinion could impair our ability to finance our operations through the sale of debt or equity securities or commercial bank loans.

We currently have no sources of revenue and our ability to continue as a going concern is dependent on our ability to raise capital to fund our future business plans. Additionally, volatility in the capital markets and general economic conditions in the United States may be a significant obstacle to raising the required funds. These factors raise substantial doubt about our ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might be necessary should the Company be unable to continue as a going concern. If the going concern basis were not appropriate for these financial statements, adjustments would be necessary in the carrying value of assets and liabilities, the reported expenses and the balance sheet classifications used.

Risks Related to Development, Regulatory Approval and Commercialization

Our business is dependent on the successful development, regulatory approval and commercialization of our product candidates, which include products primarily for the treatment of glioblastoma multiforme, pancreatic cancer and brain metastases.

Our portfolio of product candidates includes trans sodium crocetinate (TSC), which is a novel small molecule that re-oxygenates hypoxic tissue, enhancing the efficacy of radiation and chemotherapy without harmful side effects poised to enter Phase III clinical development for glioblastoma multiforme. In addition, our TSC may have potential applications in pancreatic cancer and brain metastases. The success of our business, including our ability to finance our company and generate any revenue in the future, primarily will depend on the successful development, regulatory approval and commercialization of our product candidates. In the future, we may also become dependent on one or more of other product candidates or any future product candidates that we may in-license, acquire or develop.

The clinical and commercial success of our product candidates will depend on a number of factors, including the following:

- timely completion of our clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- whether we are required by the FDA or similar foreign regulatory agencies to conduct additional clinical trials beyond those planned to support the approval and commercialization of our product candidates or any future product candidates;
- acceptance of our proposed indications and primary endpoint assessments relating to the proposed indications of our product candidates by the FDA and similar foreign regulatory authorities;
- our ability to demonstrate to the satisfaction of the FDA and similar foreign regulatory authorities, the safety and efficacy of our product candidates or any future product candidates;
- the prevalence, duration and severity of potential side effects experienced with our product candidates or future approved products, if any;
- the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;

- achieving and maintaining, and, where applicable, ensuring that our third-party contractors achieve and maintain, compliance with our contractual obligations and with all regulatory requirements applicable to our product candidates or any future product candidates or approved products, if any;

- the ability of third parties with whom we contract to manufacture clinical trial and commercial supplies of our product candidates or any future product candidates, remain in good standing with regulatory agencies and develop, validate and maintain commercially viable manufacturing processes that are compliant with cGMP;

- a continued acceptable safety profile during clinical development and following approval of our product candidates or any future product candidates;

- our ability to successfully commercialize our product candidates or any future product candidates in the United States and internationally, if approved for marketing, sale and distribution in such countries and territories, whether alone or in collaboration with others;

- acceptance by physicians and patients of the benefits, safety and efficacy of our product candidates or any future product candidates, if approved, including relative to alternative and competing treatments;

- our and our partners' ability to establish and enforce intellectual property rights in and to our product candidates or any future product candidates;

- our and our partners' ability to avoid third-party patent interference or intellectual property infringement claims; and

- our ability to in-license or acquire additional product candidates or commercial-stage products that we believe can be successfully developed and commercialized.

If we do not achieve one or more of these factors, many of which are beyond our control, in a timely manner or at all, we could experience significant delays or an inability to obtain regulatory approvals or commercialize our product candidates. Even if regulatory approvals are obtained, we may never be able to successfully commercialize any of our product candidates. Accordingly, we cannot assure you that we will be able to generate sufficient revenue through the sale of our product candidates or any future product candidates to continue our business.

Clinical drug development for our product candidates is very expensive, time-consuming and uncertain. Our clinical trials may fail to adequately demonstrate the safety and efficacy of our product candidates, which could prevent or delay regulatory approval and commercialization.

Clinical drug development for our product candidates is very expensive, time-consuming, difficult to design and implement and its outcome is inherently uncertain. Before obtaining regulatory approval for the commercial sale of a product candidate, we must demonstrate through clinical trials that a product candidate is both safe and effective for use in the target indication. Most product candidates that commence clinical trials are never approved by regulatory authorities for commercialization. Our product candidates are in early stages of development. We expect that clinical trials for these product candidates will take several years, but may take significantly longer than expected to complete. In addition, we, any partner with which we may in the future collaborate, the FDA, an IRB or other regulatory authorities, including state and local agencies and counterpart agencies in foreign countries, may suspend, delay, require modifications to or terminate our clinical trials at any time, for various reasons, including:

- discovery of serious or unexpected toxicities or side effects experienced by study participants or other safety issues;
- lack of effectiveness of any product candidate during clinical trials or the failure of our product candidates to meet specified endpoints;
- slower than expected rates of subject recruitment and enrollment rates in clinical trials resulting from numerous factors, including the prevalence of other companies' clinical trials for their product candidates for the same indication, or clinical trials for indications for which patients do not as commonly seek treatment;
- difficulty in retaining subjects who have initiated a clinical trial but may withdraw at any time due to adverse side effects from the therapy, insufficient efficacy, fatigue with the clinical trial process or for any other reason;
- difficulty in obtaining IRB approval for studies to be conducted at each site;
- delays in manufacturing or obtaining, or inability to manufacture or obtain, sufficient quantities of materials for use in clinical trials;
- inadequacy of or changes in our manufacturing process or the product formulation or method of delivery;
- changes in applicable laws, regulations and regulatory policies;
- delays or failure in reaching agreement on acceptable terms in clinical trial contracts or protocols with prospective clinical regulatory organizations ("CROs") clinical trial sites and other third-party contractors;
- inability to add a sufficient number of clinical trial sites;
- uncertainty regarding proper dosing;
- failure of our CROs or other third-party contractors to comply with contractual and regulatory requirements or to perform their services in a timely or acceptable manner;
- failure by us, our employees, our CROs or their employees or any partner with which we may collaborate or their employees to comply with applicable FDA or other regulatory requirements relating to the conduct of clinical trials or the handling, storage, security and recordkeeping for drug products;
- scheduling conflicts with participating clinicians and clinical institutions;
- failure to design appropriate clinical trial protocols;
- insufficient data to support regulatory approval;
- inability or unwillingness of medical investigators to follow our clinical protocols; or
- difficulty in maintaining contact with subjects during or after treatment, which may result in incomplete data.

We or any partner with which we may collaborate may suffer significant setbacks in our clinical trials similar to the experience of a number of other companies in the pharmaceutical and biotechnology industries, even after receiving promising results in earlier trials. In the event that we or our potential partners abandon or are delayed in the clinical development efforts related to our product candidates, we may not be able to execute on our business plan effectively and our business, financial condition, operating results and prospects would be harmed.

We may be unable to obtain regulatory approval for TSC for the indications of which we are seeking or our other future product candidates under applicable regulatory requirements. The FDA and foreign regulatory bodies have substantial discretion in the approval process, including the ability to delay, limit or deny approval of product candidates. The delay, limitation or denial of any regulatory approval would adversely impact commercialization, our potential to generate revenue, our business and our operating results.

We currently have no products approved for sale, and we may never obtain regulatory approval to commercialize any of our current or future product candidates. The research, testing, manufacturing, safety surveillance, efficacy, quality control, recordkeeping, labeling, packaging, storage, approval, sale, marketing, distribution, import, export, and reporting of safety and other post-market information related to our drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and in foreign countries, and such regulations differ from country to country. We are not permitted to market any of our current product candidates in the United States until we receive approval of an NDA or other applicable regulatory filing from the FDA. We are also not permitted to market any of our current product candidates in any foreign countries until we receive the requisite approval from the applicable regulatory authorities of such countries.

To gain approval to market a new drug, such as TSC, the FDA and foreign regulatory authorities must receive preclinical and clinical data that adequately demonstrate the safety, purity, potency, efficacy and compliant manufacturing of the product for the intended indication applied for in an NDA or other applicable regulatory filing. The development and approval of new drug products involves a long, expensive and uncertain process, and delay or failure can occur at any stage. A number of companies in the pharmaceutical and biopharmaceutical industry have suffered significant setbacks in clinical trials, including in Phase 3 clinical development, even after promising results in earlier preclinical studies or clinical trials. These setbacks have been caused by, among other things, findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and the results of clinical trials by other parties may not be indicative of the results in trials we or our partners may conduct.

The FDA and foreign regulatory bodies have substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of product candidates for many reasons, including:

- the FDA or the applicable foreign regulatory body may disagree with the design or implementation of one or more clinical trials;
- the FDA or the applicable foreign regulatory body may not deem a product candidate safe and effective for its proposed indication, or may deem a product candidate’s safety or other perceived risks to outweigh its clinical or other benefits;
- the FDA or the applicable foreign regulatory body may not find the data from preclinical studies and clinical trials sufficient to support approval, or the results of clinical trials may not meet the level of statistical or clinical significance required by the FDA or the applicable foreign regulatory body for approval;

- the FDA or the applicable foreign regulatory body may disagree with our interpretation of data from preclinical studies or clinical trials performed by us or third parties, or with the interpretation of any partner with which we may collaborate;

- the data collected from clinical trials may not be sufficient to support the submission of an NDA or other applicable regulatory filing;

- the FDA or the applicable foreign regulatory body may require additional preclinical studies or clinical trials;

- the FDA or the applicable foreign regulatory agency may identify deficiencies in the formulation, quality control, labeling or specifications of our current or future product candidates;

- the FDA or the applicable foreign regulatory agency may require clinical trials in pediatric patients in order to establish pharmacokinetics or safety for this more drug-sensitive population;

- the FDA or the applicable foreign regulatory agency may grant approval contingent on the performance of costly additional post-approval clinical trials;

- the FDA or the applicable foreign regulatory agency also may approve our current or any future product candidates for a more limited indication or a narrower patient population than we originally requested;

- the FDA or applicable foreign regulatory agency may not approve the labeling that we believe is necessary or desirable for the successful commercialization of our product candidates;

- the FDA or the applicable foreign regulatory body may not approve of the manufacturing processes, controls or facilities of third-party manufacturers or testing labs with which we contract; or

- the FDA or the applicable foreign regulatory body may change its approval policies or adopt new regulations in a manner rendering our clinical data or regulatory filings insufficient for approval.

Of the large number of drugs in development, only a small percentage successfully complete the FDA or other regulatory approval processes and are commercialized. Our product candidates may not be approved by the FDA or applicable foreign regulatory agencies even if they meet specified endpoints in our clinical trials. The FDA or applicable foreign regulatory agencies may ask us to conduct additional costly and time-consuming clinical trials in order to obtain marketing approval or approval to enter into an advanced phase of development, or may change the requirements for approval even after such agency has reviewed and commented on the design for the clinical trials.

Any delay in obtaining, or inability to obtain, applicable regulatory approval for any of our product candidates would delay or prevent commercialization of our product candidates and would harm our business, financial condition, operating results and prospects.

Even if our product candidates obtain regulatory approval, they may fail to achieve the broad degree of physician and patient adoption and use necessary for commercial success.

The commercial success of any of our current or future product candidates, if approved, will depend significantly on the broad adoption and use of the resulting product by physicians and patients for approved indications, and may not be commercially successful. The degree and rate of physician and patient adoption of our current or future product candidates, if approved, will depend on a number of factors, including:

- the clinical indications for which the product is approved and patient demand for approved products that treat those indications;
- the effectiveness of our product as compared to other available therapies;
- the availability of coverage and adequate reimbursement from managed care plans and other healthcare payors for any of our product candidates that may be approved;
- the cost of treatment with our product candidates in relation to alternative treatments and willingness to pay for the product, if approved, on the part of patients;
- acceptance by physicians, major operators of clinics and patients of the product as a safe and effective treatment;
- physician and patient willingness to adopt a new therapy over other available therapies to treat approved indications;
- overcoming any biases physicians or patients may have toward particular therapies for the treatment of approved indications;
- proper training and administration of our product candidates by physicians and medical staff;
- patient satisfaction with the results and administration of our product candidates and overall treatment experience;
- the willingness of patients to pay for certain of our product candidates relative to other discretionary items, especially during economically challenging times;
- the revenue and profitability that our product candidate may offer a physician as compared to alternative therapies;
- the prevalence and severity of side effects;
- limitations or warnings contained in the FDA-approved labeling for our product candidates;
- any FDA requirement to undertake a REMS;
- the effectiveness of our sales, marketing and distribution efforts;
- adverse publicity about our product candidates or favorable publicity about competitive products; and
- potential product liability claims.

Our product candidates, if approved, will face significant competition and our failure to effectively compete may prevent us from achieving significant market penetration.

The pharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on developing proprietary therapeutics. Numerous companies are engaged in the development, patenting, manufacturing and marketing of health care products competitive with those that we are developing. We face competition from a number of sources, such as pharmaceutical companies, generic drug companies, biotechnology companies and academic and research institutions, many of which have greater financial resources, marketing capabilities, sales forces, manufacturing capabilities, research and development capabilities, clinical trial expertise, intellectual property portfolios, experience in obtaining patents and regulatory approvals for product candidates and other resources than us. Some of the companies that offer competing products also have a broad range of other product offerings, large direct sales forces and long-term customer relationships with our target physicians, which could inhibit our market penetration efforts.

Many pharmaceutical companies currently offer products, and continue to develop additional alternative product candidates and technologies, for indications similar to those targeted by our product candidates. We anticipate that, if we obtain regulatory approval of our product candidates, we will face significant competition from other approved therapies. If approved, our product candidates may also compete with unregulated, unapproved and off-label treatments. Certain of our product candidates, if approved, will present novel therapeutic approaches for the approved indications and will have to compete with existing therapies, some of which are widely known and accepted by physicians and patients. To compete successfully in this market, we will have to demonstrate that the relative cost, safety and efficacy of our approved products, if any, provide an attractive alternative to existing and other new therapies. Such competition could lead to reduced market share for our product candidates and contribute to downward pressure on the pricing of our product candidates, which could harm our business, financial condition, operating results and prospects. For more information about the competition we face, see "*Business—Competition*."

Due to less stringent regulatory requirements in certain foreign countries, there are many more products and procedures available for use in those international markets than are approved for use in the United States. In certain international markets, there are also fewer limitations on the claims that our competitors can make about the effectiveness of their products and the manner in which they can market them. As a result, we expect to face more competition in these markets than in the United States.

Any product candidates that we commercialize, or that any partner with which we may collaborate commercializes, will be subject to ongoing and continued regulatory review.

Even after we or our partners achieve U.S. regulatory approval for a product candidate, if any, we or our partners will be subject to continued regulatory review and compliance obligations. For example, with respect to our product candidates, the FDA may impose significant restrictions on the approved indicated uses for which the product may be marketed or on the conditions of approval. A product candidate's approval may contain requirements for potentially costly post-approval studies and surveillance, including Phase 4 clinical trials or a REMS, to monitor the safety and efficacy of the product. We will also be subject to ongoing FDA obligations and continued regulatory review with respect to, among other things, the manufacturing, processing, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for our product candidates. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP requirements and with the FDA's GCP requirements and good laboratory practice ("GLP") requirements, which are regulations and guidelines enforced by the FDA for all of our product candidates in clinical and preclinical development, and for any clinical trials that we conduct post-approval. To the extent that a product candidate is approved for sale in other countries, we may be subject to similar restrictions and requirements imposed by laws and government regulators in those countries.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations. If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where, or processes by which, the product is manufactured, a regulatory agency may impose restrictions on that product or us, including requesting that we initiate a product recall, or requiring notice to physicians, withdrawal of the product from the market or suspension of manufacturing.

If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- impose restrictions on the marketing or manufacturing of the product, suspend or withdraw product approvals or revoke necessary licenses;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require us or our partners to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- issue warning letters, show cause notices or untitled letters describing alleged violations, which may be publicly available;
- commence criminal investigations and prosecutions;
- impose injunctions, suspensions or revocations of necessary approvals or other licenses;
- impose other civil or criminal penalties;
- suspend any ongoing clinical trials;
- delay or refuse to approve pending applications or supplements to approved applications filed by us or our potential partners;
- refuse to permit drugs or precursor chemicals to be imported or exported to or from the United States;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products or require us or our partners to initiate a product recall.

The regulations, policies or guidance of the FDA and other applicable government agencies may change and new or additional statutes or government regulations may be enacted that could prevent or delay regulatory approval of our product candidates or further restrict or regulate post-approval activities. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to achieve and maintain regulatory compliance, we may not be permitted to market our product candidates, which would adversely affect our ability to generate revenue and achieve or maintain profitability.

We have conducted and may in the future conduct clinical trials for our product candidates outside the United States and the FDA and applicable foreign regulatory authorities may not accept data from such trials.

We have conducted and may in the future choose to conduct one or more of our clinical trials outside the United States. Although the FDA or applicable foreign regulatory authority may accept data from clinical trials conducted outside the United States or the applicable jurisdiction, acceptance of such study data by the FDA or applicable foreign regulatory authority may be subject to certain conditions. Where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will not approve the application on the basis of foreign data alone unless those data are applicable to the U.S. population and U.S. medical practice; the studies were performed by clinical investigators of recognized competence; and the data are considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Many foreign regulatory bodies have similar requirements. In addition, such foreign studies would be subject to the applicable local laws of the foreign jurisdictions where the studies are conducted. There can be no assurance the FDA or applicable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or applicable foreign regulatory authority does not accept such data, it would likely result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan.

Our product candidates may cause undesirable side effects or have other unexpected properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in post-approval regulatory action.

Unforeseen side effects from any of our product candidates could arise either during clinical development or, if approved, after the approved product has been marketed. Undesirable side effects caused by product candidates could cause us, any partners with which we may collaborate or regulatory authorities to interrupt, modify, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign authorities. In such an event, trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us, or our potential partners, to cease further development of or deny approval of product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in product liability claims. Any of these occurrences may harm our business, financial condition, operating results and prospects.

Additionally, if we or others identify undesirable side effects, or other previously unknown problems, caused by our product candidates after obtaining U.S. or foreign regulatory approval or other products with the same or related active ingredients, a number of potentially negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product;
- regulatory authorities may require a recall of the product or we or our potential partners may voluntarily recall a product;
- regulatory authorities may require the addition of warnings or contraindications in the product labeling, narrowing of the indication in the product label or field alerts to physicians and pharmacies;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients or institute a REMS;
- we may have limitations on how we promote the product;
- we may be required to change the way the product is administered or modify the product in some other way;
- the FDA or applicable foreign regulatory authority may require additional clinical trials or costly post-marketing testing and surveillance to monitor the safety or efficacy of the product;
- sales of the product may decrease significantly;
- we could be sued and held liable for harm caused to patients; and
- our brand and reputation may suffer.

Any of the above events resulting from undesirable side effects or other previously unknown problems could prevent us or our potential partners from achieving or maintaining market acceptance of the affected product candidate and could substantially increase the costs of commercializing our product candidates.

Because the results of preclinical studies and early-stage clinical trials are not necessarily predictive of future results, any product candidate we advance into additional clinical trials may not continue to have favorable results or receive regulatory approval.

Success in preclinical studies and early clinical trials does not ensure that later clinical trials will generate adequate data to demonstrate the efficacy and safety of an investigational drug. Many companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience, have suffered significant setbacks in clinical trials, even after reporting promising results in earlier clinical trials. We do not know whether the clinical trials we may conduct will demonstrate adequate efficacy and safety or otherwise provide adequate information to result in regulatory approval to market any of our product candidates in any particular jurisdiction. If later-stage clinical trials do not produce favorable results, our ability to achieve regulatory approval for any of our product candidates may be compromised.

We may face product liability exposure, and if successful claims are brought against us, we may incur substantial liability if our insurance coverage for those claims is inadequate.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. This risk exists even if a product is approved for commercial sale by the FDA and manufactured in facilities licensed and regulated by the FDA or an applicable foreign regulatory authority. Our products and product candidates are designed to affect important bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with our product candidates could result in injury to a patient or even death. We cannot offer any assurance that we will not face product liability suits in the future, nor can we assure you that our insurance coverage will be sufficient to cover our liability under any such cases.

In addition, a liability claim may be brought against us even if our product candidates merely appear to have caused an injury. Product liability claims may be brought against us by consumers, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with our product candidates, among others. If we cannot successfully defend ourselves against product liability claims we will incur substantial liabilities and reputational harm. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- the inability to commercialize our product candidates;
- decreased demand for our product candidates;
- impairment of our business reputation;
- product recall or withdrawal from the market or labeling, marketing or promotional restrictions;
- substantial costs of any related litigation or similar disputes;
- distraction of management’s attention and other resources from our primary business;
- substantial monetary awards to patients or other claimants against us that may not be covered by insurance; or
- loss of revenue.

We intend to obtain product liability insurance coverage for our clinical trials. Large judgments have been awarded in class action or individual lawsuits based on drugs that had unanticipated side effects. Our insurance coverage may not be sufficient to cover all of our product liability related expenses or losses and may not cover us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost, in sufficient amounts or upon adequate terms to protect us against losses due to product liability. We will need to increase our product liability coverage if any of our product candidates receive regulatory approval, which will be costly, and we may be unable to obtain this increased product liability insurance on commercially reasonable terms, or at all. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could decrease our cash and could harm our business, financial condition, operating results and prospects.

If any of our product candidates are approved for marketing and we are found to have improperly promoted off-label uses, or if physicians misuse our products or use our products off-label, we may become subject to prohibitions on the sale or marketing of our products, product liability claims and significant fines, penalties and sanctions, and our brand and reputation could be harmed.

The FDA and other regulatory agencies strictly regulate the marketing and promotional claims that are made about drug products. In particular, a product may not be promoted for uses or indications that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling and comparative safety or efficacy claims cannot be made without direct comparative clinical data. If we are found to have promoted off-label uses of any of our product candidates, we may receive warning or untitled letters and become subject to significant liability, which would materially harm our business. Both federal and state governments have levied large civil and criminal fines against companies for alleged improper promotion and have enjoined several companies from engaging in off-label promotion. If we become the target of such an investigation or prosecution based on our marketing and promotional practices, we could face similar sanctions, which would materially harm our business. In addition, management's attention could be diverted from our business operations, significant legal expenses could be incurred and our brand and reputation could be damaged. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we are deemed by the FDA to have engaged in the promotion of our products for off-label use, we could be subject to FDA regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our business activities constitute promotion of an off-label use, which could result in significant penalties, including criminal, civil or administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment or restructuring of our operations.

We cannot, however, prevent a physician from using our product candidates outside of those indications for use when in the physician's independent professional medical judgment he or she deems appropriate. Physicians may also misuse our product candidates or use improper techniques, potentially leading to adverse results, side effects or injury, which may lead to product liability claims. If our product candidates are misused or used with improper technique, we may become subject to costly litigation by physicians or their patients. Furthermore, the use of our product candidates for indications other than those cleared by the FDA may not effectively treat such conditions, which could harm our reputation among physicians and patients.

We may choose not to continue developing or commercializing any of our product candidates at any time during development or after approval, which would reduce or eliminate our potential return on investment for those product candidates.

At any time, we may decide to discontinue the development of any of our product candidates or not to continue commercializing one or more of our approved product candidates for a variety of reasons, including changes in our internal product, technology or indication focus, the appearance of new technologies that make our product obsolete, competition from a competing product or changes in or failure to comply with applicable regulatory requirements. If we terminate a program in which we have invested significant resources, we will not receive any return on our investment and we will have missed the opportunity to have allocated those resources to potentially more productive uses.

We or our prospective partners may be subject to product recalls in the future that could harm our brand and reputation and could negatively affect our business.

We or our prospective partners may be subject to product recalls, withdrawals or seizures if any of our product candidates, if approved for marketing, fail to meet specifications or are believed to cause injury or illness or if we are alleged to have violated governmental regulations including those related to the manufacture, labeling, promotion, sale or distribution. Any recall, withdrawal or seizure in the future could materially and adversely affect consumer confidence in our brands and lead to decreased demand for our approved products. In addition, a recall, withdrawal or seizure of any of our approved products would require significant management attention, would likely result in substantial and unexpected expenditures and would harm our business, financial condition and operating results.

If we or any partners with which we may collaborate are unable to achieve and maintain coverage and adequate levels of reimbursement for any of our product candidates for which we receive regulatory approval, or any future products we may seek to commercialize, their commercial success may be severely hindered.

For any of our product candidates that become available only by prescription, successful sales by us or by any partners with which we may collaborate depend on the availability of coverage and adequate reimbursement from third-party payors. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. The availability of coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and private third-party payors is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. If any of our product candidates do not demonstrate attractive efficacy profiles, they may not qualify for coverage and reimbursement. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

In addition, the market for our product candidates will depend significantly on access to third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, although private third-party payors tend to follow Medicare, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions both in the United States and in international markets. Third-party coverage and reimbursement for any of our product candidates for which we may receive regulatory approval may not be available or adequate in either the United States or international markets, which could harm our business, financial condition, operating results and prospects.

Healthcare reform measures could hinder or prevent the commercial success of our products and product candidates.

In the United States, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system that could affect our future revenue and profitability and the future revenue and profitability of any partner with which we may collaborate. Federal and state lawmakers regularly propose and, at times, enact legislation that results in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. For example, in March 2010, President Obama signed one of the most significant healthcare reform measures in decades, the Affordable Care Act. It contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which are expected to impact existing government healthcare programs and result in the development of new programs. The Affordable Care Act, among other things, (1) increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to certain individuals enrolled in Medicaid managed care organizations, (2) established annual fees on manufacturers of certain branded prescription drugs and (3) enacted a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect on April 1, 2013. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals and imaging centers.

More recently, the Protecting Access to Medicare Act of 2014, signed into law in April 2014, provides for a 0.5% change from 2013 federal payment rates under the Medicare Physician Fee Schedule through 2014 and a 0% update from January 1 until April 1, 2015. Congressional failure to intervene to prevent these changes in payment rates may adversely affect our future revenue and operating results.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products once approved or additional pricing pressures.

We may also be subject to healthcare laws, regulation and enforcement and our failure to comply with those laws could adversely affect our business, operations and financial condition.

Certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We are subject to regulation by both the federal government and the states in which we or our partners conduct our business. The laws and regulations that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, any person or entity from knowingly and willfully offering, soliciting, receiving or providing any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce either the referral of an individual or in return for the purchase, lease, or order of any good, facility item or service, for which payment may be made, in whole or in part, under federal healthcare programs such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws and civil monetary penalty laws, including, for example, the federal civil False Claims Act, which impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations, which impose obligations on covered entities, including healthcare providers, health plans, and healthcare clearinghouses, as well as their respective business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal physician sunshine requirements under the Affordable Care Act, which require manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value provided to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments that may be provided to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Recent health care reform legislation has strengthened these laws. For example, the recently enacted Affordable Care Act, among other things, amended the intent requirement of the federal Anti-Kickback Statute and certain criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. In addition, the Affordable Care Act provided that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

Achieving and sustaining compliance with these laws may prove costly. In addition, any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the laws described above or any other governmental laws or regulations that apply to us, we may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, individual imprisonment or the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results.

Our business involves the use of hazardous materials and we and our third-party suppliers and manufacturers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

The manufacturing activities of our third-party suppliers and manufacturers involve the controlled storage, use and disposal of hazardous materials owned by us, including the components of our product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our suppliers' or manufacturers' facilities pending use and disposal. We and our suppliers and manufacturers cannot completely eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, injury to our service providers and others and environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party suppliers and manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources. We do not currently carry biological or hazardous waste insurance coverage.

Our employees, independent contractors, principal investigators, consultants, vendors, CROs and any partners with which we may collaborate may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, principal investigators, consultants, vendors, CROs and any partners with which we may collaborate may engage in fraudulent or other illegal activity. Misconduct by these persons could include intentional, reckless or negligent conduct or unauthorized activity that violates: laws or regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA or foreign regulatory authorities; manufacturing standards; federal, state and foreign healthcare fraud and abuse laws and data privacy; or laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and other business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of business activities, including research, manufacturing, distribution, pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations, and serious harm to our reputation. In addition, federal procurement laws impose substantial penalties for misconduct in connection with government contracts and require certain contractors to maintain a code of business ethics and conduct. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our operating results.

Risks Related to Our Dependence on Third Parties

We expect to rely on third-party CROs and other third parties to conduct and oversee our clinical trials and other aspects of product development. If these third parties do not meet our requirements or otherwise conduct the trials as required, we may not be able to satisfy our contractual obligations or obtain regulatory approval for, or commercialize, our product candidates when expected or at all.

We expect to rely on third-party CROs to conduct and oversee our clinical trials and other aspects of product development. We also rely upon various medical institutions, clinical investigators and contract laboratories to conduct our trials in accordance with our clinical protocols and all applicable regulatory requirements, including the FDA's regulations and GCPs, which are an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors, and state regulations governing the handling, storage, security and recordkeeping for drug products. These CROs and other third parties play a significant role in the conduct of these trials and the subsequent collection and analysis of data from the clinical trials. We rely heavily on these parties for the execution of our clinical trials and preclinical studies, and control only certain aspects of their activities. We and our CROs and other third-party contractors are required to comply with GCP and GLP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for products in clinical development. Regulatory authorities enforce these GCP and GLP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP and GLP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or other regulatory authority may require us to perform additional clinical trials before approving our or our partners' marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical or preclinical trials complies with applicable GCP and GLP requirements. In addition, our clinical trials must generally be conducted with product produced under cGMP regulations. Our failure to comply with these regulations and policies may require us to repeat clinical trials, which would delay the regulatory approval process.

If any of our CROs or clinical trial sites terminate their involvement in one of our clinical trials for any reason, we may not be able to enter into arrangements with alternative CROs or clinical trial sites, or do so on commercially reasonable terms. In addition, if our relationship with clinical trial sites is terminated, we may experience the loss of follow-up information on patients enrolled in our ongoing clinical trials unless we are able to transfer the care of those patients to another qualified clinical trial site. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and could receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, the integrity of the data generated at the applicable clinical trial site may be questioned by the FDA.

We rely completely on third-party contractors to supply, manufacture and distribute clinical drug supplies for our product candidates, including certain sole-source suppliers and manufacturers, we intend to rely on third parties for commercial supply, manufacturing and distribution if any of our product candidates receive regulatory approval and we expect to rely on third parties for supply, manufacturing and distribution of preclinical, clinical and commercial supplies of any future product candidates. We do not currently have, nor do we plan to acquire, the infrastructure or capability to supply, manufacture or distribute preclinical, clinical or commercial quantities of drug substances or products.

Our ability to develop our product candidates depends and our ability to commercially supply our products will depend, in part, on our ability to successfully obtain the APIs and other substances and materials used in our product candidates from third parties and to have finished products manufactured by third parties in accordance with regulatory requirements and in sufficient quantities for preclinical and clinical testing and commercialization. If we fail to develop and maintain supply relationships with these third parties, we may be unable to continue to develop or commercialize our product candidates.

We do not have direct control over the ability of our contract suppliers and manufacturers to maintain adequate capacity and capabilities to serve our needs, including quality control, quality assurance and qualified personnel. Although we are ultimately responsible for ensuring compliance with regulatory requirements such as cGMPs, we are dependent on our contract suppliers and manufacturers for day-to-day compliance with cGMPs for production of both APIs and finished products. Facilities used by our contract suppliers and manufacturers to produce the APIs and other substances and materials or finished products for commercial sale must pass inspection and be approved by the FDA and other relevant regulatory authorities. Our contract suppliers and manufacturers must comply with cGMP requirements enforced by the FDA through its facilities inspection program and review of submitted technical information. If the safety of any product or product candidate or component is compromised due to a failure to adhere to applicable laws or for other reasons, we may not be able to successfully commercialize or obtain regulatory approval for the affected product or product candidate, and we may be held liable for injuries sustained as a result. Any of these factors could cause a delay or termination of preclinical studies, clinical trials or regulatory submissions or approvals of our product candidates, and could entail higher costs or result in our being unable to effectively commercialize our approved products on a timely basis, or at all.

We also rely and will continue to rely on certain third parties as the sole source of the materials they supply or the finished products they manufacture. In the event an existing supplier fails to supply product on a timely basis or in the requested amount, supplies product that fails to meet regulatory requirements, becomes unavailable through business interruption or financial insolvency or loses its regulatory status as an approved source or if we or our manufacturers are unable to renew current supply agreements when such agreements expire and we do not have a second supplier, we likely would incur added costs and delays in identifying or qualifying replacement manufacturers and materials and there can be no assurance that replacements would be available to us on a timely basis, on acceptable terms or at all. In certain cases we may be required to get regulatory approval to use alternative suppliers, and this process of approval could delay production of our products or development of product candidates indefinitely. We and our manufacturers do not currently maintain inventory of these APIs and other substances and materials. Any interruption in the supply of an API or other substance or material or in the manufacture of a finished product could have a material adverse effect on our business, financial condition, operating results and prospects.

In addition, these contract manufacturers are engaged with other companies to supply and manufacture materials or products for such companies, which also exposes our suppliers and manufacturers to regulatory risks for the production of such materials and products. As a result, failure to meet the regulatory requirements for the production of those materials and products may also affect the regulatory clearance of a contract supplier’s or manufacturer’s facility. If the FDA or a comparable foreign regulatory agency does not approve these facilities for the supply or manufacture of our product candidates, or if it withdraws its approval in the future, we may need to find alternative supply or manufacturing facilities, which would negatively impact our ability to develop, obtain regulatory approval of or market our product candidates, if approved.

To date, our drug substances and product candidates have been manufactured in small quantities for preclinical studies and early-stage clinical trials. As we prepare for later-stage clinical trials and potential commercialization, we will need to take steps to increase the scale of production of our drug substances and product candidates, which may include transferring production to new third-party suppliers or manufacturers. In order to conduct larger or late-stage scale clinical trials for our product candidates and supply sufficient commercial quantities of the resulting drug product and its components, if that product candidate is approved for sale, our contract manufacturers and suppliers will need to produce our drug substances and product candidates in larger quantities, more cost effectively and, in certain cases, at higher yields than they currently achieve. These third-party contractors may not be able to successfully increase the manufacturing capacity for any of such drug substance and product candidates in a timely or cost-effective manner or at all. Significant scale up of manufacturing may require additional processes, technologies and validation studies, which are costly, may not be successful and which the FDA and foreign regulatory authorities must review and approve. In addition, quality issues may arise during those scale-up activities because of the inherent properties of a product candidate itself or of a product candidate in combination with other components added during the manufacturing and packaging process, or during shipping and storage of the APIs or the finished product. If our third-party contractors are unable to successfully scale up the manufacture of any of our product candidates in sufficient quality and quantity and at commercially reasonable prices, and we are unable to find one or more replacement suppliers or manufacturers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality, and we are unable to successfully transfer the processes on a timely basis, the development of that product candidate and regulatory approval or commercial launch for any resulting products may be delayed, or there may be a shortage in supply, either of which could significantly harm our business, financial condition, operating results and prospects.

We expect to continue to depend on third-party contract suppliers and manufacturers for the foreseeable future. Our supply and manufacturing agreements, if any, do not guarantee that a contract supplier or manufacturer will provide services adequate for our needs. We and our contract suppliers and manufacturers continue to improve production processes, certain aspects of which are complex and unique, and we may encounter difficulties with new or existing processes. While we attempt to build in certain contractual obligations on such third-party suppliers and manufacturers, we may not be able to ensure that such third parties comply with these obligations. Depending on the extent of any difficulties encountered, we could experience an interruption in clinical or commercial supply, with the result that the development, regulatory approval or commercialization of our product candidates may be delayed or interrupted. In addition, third-party suppliers and manufacturers may have the ability to increase the price payable by us for the supply of the APIs and other substances and materials used in our product candidates, in some cases without our consent.

Additionally, any damage to or destruction of our third-party manufacturers' or suppliers' facilities or equipment may significantly impair our ability to have our product candidates manufactured on a timely basis. Furthermore, if a contract manufacturer or supplier becomes financially distressed or insolvent, or discontinues our relationship beyond the term of any existing agreement for any other reason, this could result in substantial management time and expense to identify, qualify and transfer processes to alternative manufacturers or suppliers, and could lead to an interruption in clinical or commercial supply.

Our reliance on contract manufacturers and suppliers further exposes us to the possibility that they, or third parties with access to their facilities, will have access to and may misappropriate our trade secrets or other proprietary information. In addition, the manufacturing facilities of certain of our suppliers are located outside of the United States. This may give rise to difficulties in importing our products or product candidates or their components into the United States or other countries as a result of, among other things, regulatory agency approval requirements or import inspections, incomplete or inaccurate import documentation or defective packaging.

Because we currently rely on a sole supplier to manufacture the active pharmaceutical ingredients of certain of our product candidates, any production problems with our supplier could adversely affect us.

We have relied upon supply agreements with third parties for the manufacture and supply of the bulk active pharmaceutical ingredients used in certain of our product candidates for purposes of preclinical testing and clinical trials. We presently depend upon a single source as the sole manufacturer of our supply of APIs for certain of our product candidates Although we have identified alternate sources for these supplies, it would be time-consuming and costly to qualify these sources. Since we currently obtain our API from our manufacturers on a purchase-order basis, either we or our suppliers may terminate our arrangements, without cause, at any time without notice. If our suppliers were to terminate our arrangements or fail to meet our supply needs we might be forced to delay our development .

Manufacturing and supply of the APIs and other substances and materials used in our product candidates and finished drug products is a complex and technically challenging undertaking, and there is potential for failure at many points in the manufacturing, testing, quality assurance and distribution supply chain, as well as the potential for latent defects after products have been manufactured and distributed.

Manufacturing and supply of APIs, other substances and materials and finished drug products is technically challenging. Changes beyond our direct control can impact the quality, volume, price and successful delivery of our product candidates and can impede, delay, limit or prevent the successful development and commercialization of our product candidates. Mistakes and mishandling are not uncommon and can affect successful production and supply. Some of these risks include:

- failure of our manufacturers to follow cGMP requirements or mishandling of product while in production or in preparation for transit;
- inability of our contract suppliers and manufacturers to efficiently and cost-effectively increase and maintain high yields and batch quality, consistency and stability;
- difficulty in establishing optimal drug delivery substances and techniques, production and storage methods and packaging and shipment processes;
- transportation and import/export risk, particularly given the global nature of our supply chain;
- delays in analytical results or failure of analytical techniques that we depend on for quality control and release of product;
- natural disasters, labor disputes, financial distress, lack of raw material supply, issues with facilities and equipment or other forms of disruption to business operations of our contract manufacturers and suppliers; and
- latent defects that may become apparent after product has been released and which may result in recall and destruction of product.

Any of these factors could result in delays or higher costs in connection with our clinical trials, regulatory submissions, required approvals or commercialization of our products, which could harm our business, financial condition, operating results and prospects.

If we are not able to establish and maintain collaborations, we may have to alter our development and commercialization plans.

The development and potential commercialization of our product candidates will require substantial additional cash to fund expenses. In order to fund further development of our product candidates, we may collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates. We face significant competition in seeking appropriate partners. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the partner's resources and experience, the terms and conditions of the proposed collaboration and the proposed partner's evaluation of a number of factors. Those factors may include the design or results of clinical trials; the likelihood of approval by the FDA or other regulatory authorities; the potential market for the subject product candidate; the costs and complexities of manufacturing and delivering such product candidate to patients; the potential of competing products; any uncertainty with respect to our ownership of our intellectual property; and industry and market conditions generally. The partner may also consider alternative product candidates or technologies for similar indications that may be available for collaboration and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under future license agreements from entering into agreements on certain terms with potential partners. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future partners. Collaborations typically impose detailed obligations on each party. If we were to breach our obligations, we may face substantial consequences, including potential termination of the collaboration, and our rights to our partners' product candidates, in which we have invested substantial time and money, would be lost.

We may not be successful in our efforts to implement collaborations or other alternative arrangements for the development of our product candidates. When we partner with a third party for development and commercialization of a product candidate, we can expect to relinquish to the third party some or all of the control over the future success of that product candidate. Our collaboration partner may not devote sufficient resources to the commercialization of our product candidates or may otherwise fail in their commercialization. The terms of any collaboration or other arrangement that we establish may not be favorable to us. In addition, any collaboration that we enter into may be unsuccessful in the development and commercialization of our product candidates. In some cases, we may be responsible for continuing preclinical and initial clinical development of a partnered product candidate or research program, and the payment we receive from our collaboration partner may be insufficient to cover the cost of this development.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms or at all. If we are unable to do so, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Risks Related to Our Business and Financial Operations

We will need to further increase the size and complexity of our organization in the future, and we may experience difficulties in executing our growth strategy and managing any growth.

Our management, personnel, systems and facilities currently in place are not adequate to support our business plan and future growth. We will need to further expand our scientific, clinical, managerial, operational, financial and other resources to support our planned research, development and commercialization activities.

Our need to manage our operations, growth and various projects effectively requires that we:

- continue to improve our operational, clinical, financial, management and regulatory compliance controls and reporting systems and procedures;
- attract and retain sufficient numbers of talented employees;
- manage our preclinical and clinical trials effectively;

- manage our third-party supply and manufacturing operations effectively and in a cost-effective manner, while increasing production capabilities for our current product candidates to commercial levels;

- manage our development efforts effectively while carrying out our contractual obligations to partners and other third parties;

- manage our commercialization activities for our product candidates effectively and in a cost-effective manner; and

- establish and maintain relationships with development and commercialization partners.

In addition, historically, we have utilized and continue to utilize the services of part-time outside consultants to perform a number of tasks for us, including tasks related to preclinical and clinical testing. Our growth strategy may also entail expanding our use of consultants to implement these and other tasks going forward. We rely on consultants for certain functions of our business and will need to effectively manage these consultants to ensure that they successfully carry out their contractual obligations and meet expected deadlines. There can be no assurance that we will be able to manage our existing consultants or find other competent outside consultants, as needed, on economically reasonable terms, or at all. If we are not able to effectively manage our growth and expand our organization by hiring new employees and expanding our use of consultants, we might be unable to implement successfully the tasks necessary to execute effectively on our planned research, development and commercialization activities and, accordingly, might not achieve our research, development and commercialization goals.

If we fail to attract and retain management and other key personnel, we may be unable to continue to successfully develop or commercialize our product candidates or otherwise implement our business plan.

Our ability to compete in the highly competitive pharmaceuticals industry depends upon our ability to attract and retain highly qualified managerial, clinical, scientific, medical, sales and marketing and other personnel. We are highly dependent on our management and scientific personnel, including our Chief Executive Officer, Chief Scientific Officer and our Senior Vice President – Finance and Treasurer, certain consultants and members of our Board of Directors who are well known and respected in our industry. The loss of the services of any of these individuals could impede, delay or prevent the successful development of our product pipeline, completion of our planned clinical trials, commercialization of our product candidates or in-licensing or acquisition of new assets and could negatively impact our ability to successfully implement our business plan. If we lose the services of any of these individuals, we might not be able to find suitable replacements on a timely basis or at all, and our business could be harmed as a result. We do not maintain “key man” insurance policies on the lives of these individuals or the lives of any of our other employees. We employ all of our executive officers and key personnel on an at-will basis and their employment can be terminated by us or them at any time, for any reason and without notice. In order to retain valuable employees at our company, in addition to salary and cash incentives, we provide stock options that vest over time. The value to employees of stock options that vest over time will be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract offers from other companies.

We might not be able to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly in the Charlottesville, Virginia area where we are headquartered. We could have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts. Many of the other pharmaceutical companies with whom we compete for qualified personnel have greater financial and other resources, different risk profiles and longer histories in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will harm our ability to implement our business strategy and achieve our business objectives.

We currently have no sales and marketing personnel or capabilities. If we are unable to establish sales and marketing capabilities on our own or through third parties when we are ready to commercialize our product candidates, we will be unable to successfully commercialize our product candidates, if approved, or generate product revenue.

We currently have no sales and marketing personnel or capabilities. To commercialize our product candidates, if approved, in the United States, Canada, the European Union and other jurisdictions we may seek to enter, we must build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. We as a company have no prior experience in the marketing, sale and distribution of pharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may choose to collaborate with additional third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize our product candidates. The inability to successfully commercialize our product candidates, either on our own or through collaborations with one or more third parties, would harm our business, financial condition, operating results and prospects.

Our failure to successfully in-license, acquire, develop and market additional product candidates or approved products would impair our ability to grow our business.

We are considering activities to in-license, acquire, develop and market additional products and product candidates. If we implement these activities, we may be dependent upon pharmaceutical companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify and select promising pharmaceutical product candidates and products, negotiate licensing or acquisition agreements with their current owners and finance these arrangements.

The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing, sales and other resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all.

Further, any product candidate that we acquire may require additional development efforts prior to commercial sale, including preclinical or clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot provide assurance that any approved products that we acquire will be manufactured or sold profitably or achieve market acceptance.

If we implement activities to in-license and acquire product candidates and we in-license and acquire commercial-stage products or engage in other strategic transactions, we could impact our liquidity, increase our expenses and present significant distractions to our management.

If we implement a strategy to in-license and acquire product candidates, we may in-license and acquire commercial-stage products or engage in other strategic transactions. Additional potential transactions that we may consider include a variety of different business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near- and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example, these transactions entail numerous potential operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention in order to develop acquired products, product candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions;
- substantial acquisition and integration costs;
- write-downs of assets or impairment charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers, partners or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain our key employees or those of any acquired businesses.

Accordingly, there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, and any transaction that we do complete could harm our business, financial condition, operating results and prospects. We have no current plan, commitment or obligation to enter into any other transaction described above.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations.

Our operations will be limited primarily to researching and developing our product candidates and undertaking preclinical studies and clinical trials of our product candidates. We have not yet obtained regulatory approvals for any of our product candidates. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or approved products on the market. From time to time, we may enter into collaboration agreements and license agreements with other companies that include development funding and significant upfront and milestone expenditures and payments, and we expect that amounts earned from or paid pursuant to these agreements will be a significant source of our capital expenditures and an important source of our revenue. Accordingly, our revenue and profitability may depend on development funding and the achievement of development and clinical milestones under potential future collaboration and license agreements and sales of our products, if approved. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next. In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award as determined by our Board of Directors, and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, including our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly. Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

- delays in the commencement, enrollment and the timing of clinical testing for our product candidates;
- the timing and success or failure of clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- any delays in regulatory review and approval of product candidates in clinical development;
- the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time;
- the cost of manufacturing our product candidates, which may vary depending on FDA guidelines and requirements, and the quantity of production;
- our ability to obtain additional funding to develop our product candidates;
- expenditures that we will or may incur to acquire or develop additional product candidates and technologies;
- the level of demand for our product candidates, should they receive approval, which may vary significantly;
- potential side effects of our product candidates that could delay or prevent commercialization or cause an approved drug to be taken off the market;
- the ability of patients or healthcare providers to obtain coverage of or sufficient reimbursement for our product candidates, if approved;
- our dependency on third-party manufacturers to supply or manufacture our product candidates;
- our ability to establish an effective sales, marketing and distribution infrastructure in a timely manner;
- market acceptance of our product candidates, if approved, and our ability to forecast demand for those product candidates;
- our ability to receive approval and commercialize our product candidates outside of the United States;

- our ability to establish and maintain collaborations, licensing or other arrangements;
- our ability and third parties' abilities to protect intellectual property rights;
- costs related to and outcomes of potential litigation or other disputes;
- our ability to adequately support future growth;
- our ability to attract and retain key personnel to manage our business effectively;
- our ability to maintain adequate insurance policies; and
- future accounting pronouncements or changes in our accounting policies.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur significant costs.

In connection with our research and development activities and our manufacture of materials and product candidates, we are subject to federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials, biological specimens and wastes. Although we believe that we have complied with the applicable laws, regulations and policies in all material respects and have not been required to correct any material noncompliance, we may be required to incur significant costs to comply with environmental and health and safety regulations in the future. Current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Our operating results and liquidity needs could be negatively affected by market fluctuations and economic downturn.

Our operating results and liquidity could be negatively affected by economic conditions generally, both in the United States and elsewhere around the world. Domestic and international equity and debt markets have experienced and may continue to experience heightened volatility and turmoil based on domestic and international economic conditions and concerns. In the event these economic conditions and concerns continue or worsen and the markets continue to remain volatile, our operating results and liquidity could be adversely affected by those factors in many ways, including weakening demand for certain of our products and making it more difficult for us to raise funds if necessary, and our stock price may decline. Additionally, although we plan to market our products primarily in the United States, our partners may have extensive global operations, indirectly exposing us to risk.

Our ability to utilize our net operating loss ("NOL") carryforwards and research and development income tax credit carryforwards may be limited.

As of December 31, 2015, RestorGenex had NOL carryforwards available to reduce future taxable income, if any, for income tax purposes of $63.0 million. If not utilized, the federal and California NOL carryforwards will begin expiring during the year ended December 31, 2021. Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited. We believe that our recent merger, as well as the acquisitions RestorGenex effected at the end of 2013 and beginning of 2014 and other transactions that have occurred over the past three years, may have triggered an "ownership change" limitation. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, if we earn net taxable income, our ability to use our pre-change NOL carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOL carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

We may be adversely affected by natural disasters and other catastrophic events, and by man-made problems such as terrorism, that could disrupt our business operations and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our corporate headquarters are located in Charlottesville, Virginia. If a disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as enterprise financial systems, manufacturing resource planning or enterprise quality systems, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. Our contract manufacturers' and suppliers' facilities are located in multiple locations, where other natural disasters or similar events, such as blizzards, tornadoes, earthquakes, fires, explosions or large-scale accidents or power outages, could severely disrupt our operations and have a material adverse effect on our business, financial condition, operating results and prospects. In addition, acts of terrorism and other geo-political unrest could cause disruptions in our business or the businesses of our partners, manufacturers or the economy as a whole. All of the aforementioned risks may be further increased if we do not implement a disaster recovery plan or our partners' or manufacturers' disaster recovery plans prove to be inadequate. To the extent that any of the above should result in delays in the regulatory approval, manufacture, distribution or commercialization of our product candidates, our business, financial condition, operating results and prospects would suffer.

Our business and operations would suffer in the event of failures in our internal computer systems.

Despite the implementation of security measures, our internal computer systems and those of our current and any future partners, contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our manufacturing activities, development programs and our business operations. For example, the loss of manufacturing records or clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further commercialization and development of our products and product candidates could be delayed.

Risks Related to Our Intellectual Property

We may not be able to obtain or enforce patent rights or other intellectual property rights that cover our product candidates and technologies that are of sufficient breadth to prevent third parties from competing against us.

Our success with respect to our product candidates and technologies will depend in part on our ability to obtain and maintain patent protection in both the United States and other countries, to preserve our trade secrets and to prevent third parties from infringing upon our proprietary rights. Our ability to protect any of our product candidates from unauthorized or infringing use by third parties depends in substantial part on our ability to obtain and maintain valid and enforceable patents.

Our patent portfolio includes patents and patent applications in the United States and foreign jurisdictions where we believe there is a market opportunity for our products. The covered technology and the scope of coverage vary from country to country. For those countries where we do not have granted patents, we may not have any ability to prevent the unauthorized use of our technologies. Any patents that we may obtain may be narrow in scope and thus easily circumvented by competitors. Further, in countries where we do not have granted patents, third parties may be able to make, use or sell products identical to or substantially similar to, our product candidates.

The patent application process, also known as patent prosecution, is expensive and time-consuming, and we and our current or future licensors and licensees may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our current licensors, or any future licensors or licensees, will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, these and any of our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, such as with respect to proper priority claims, inventorship, claim scope or patent term adjustments. If our current licensors, or any future licensors or licensees, are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised and we might not be able to prevent third parties from making, using and selling competing products. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business, financial condition and operating results.

Due to legal standards relating to patentability, validity, enforceability and claim scope of patents covering pharmaceutical inventions, our ability to obtain, maintain and enforce patents is uncertain and involves complex legal and factual questions. Accordingly, rights under any existing patents or any patents we might obtain or license may not cover our product candidates, or may not provide us with sufficient protection for our product candidates to afford a commercial advantage against competitive products or processes, including those from branded and generic pharmaceutical companies. In addition, we cannot guarantee that any patents will issue from any pending or future patent applications owned by or licensed to us. Even if patents have issued or will issue, we cannot guarantee that the claims of these patents are or will be held valid or enforceable by the courts or will provide us with any significant protection against competitive products or otherwise be commercially valuable to us.

Competitors in the fields of oncology have created a substantial amount of prior art, including scientific publications, patents and patent applications. Our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Although we believe that our technology includes certain inventions that are unique and not duplicative of any prior art, we do not have outstanding issued patents covering all of the recent developments in our technology and we are unsure of the patent protection that we will be successful in obtaining, if any. Even if the patents do successfully issue, third parties may design around or challenge the validity, enforceability or scope of such issued patents or any other issued patents we own or license, which may result in such patents being narrowed, invalidated or held unenforceable. If the breadth or strength of protection provided by the patents we hold or pursue with respect to our product candidates is challenged, it could dissuade companies from collaborating with us to develop, or threaten our ability to commercialize, our product candidates.

The laws of some foreign jurisdictions do not provide intellectual property rights to the same extent as in the United States and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. If we encounter such difficulties in protecting or are otherwise precluded from effectively protecting our intellectual property in foreign jurisdictions, our business prospects could be substantially harmed. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents.

The degree of future protection of our proprietary rights is uncertain. Patent protection may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- we might not have been the first to invent or the first to file the inventions covered by each of our pending patent applications and issued patents;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- the patents of others may have an adverse effect on our business;
- any patents we obtain or our licensors' issued patents may not encompass commercially viable products, may not provide us with any competitive advantages or may be challenged by third parties;
- any patents we obtain or our in-licensed issued patents may not be valid or enforceable; and
- we may not develop additional proprietary technologies that are patentable.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however the life of a patent, and the protection it affords, is limited. Without patent protection for our product candidates, we may be open to competition from generic versions of our product candidates. Further, the extensive period of time between patent filing and regulatory approval for a product candidate limits the time during which we can market a product candidate under patent protection, which may particularly affect the profitability of our early-stage product candidates.

Proprietary trade secrets and unpatented know-how are also very important to our business. Although we have taken steps to protect our trade secrets and unpatented know-how by entering into confidentiality agreements with third parties, and intellectual property protection agreements with certain employees, consultants and advisors, third parties may still obtain this information or we may be unable to protect our rights. We also have limited control over the protection of trade secrets used by our suppliers, manufacturers and other third parties. There can be no assurance that binding agreements will not be breached, that we would have adequate remedies for any breach or that our trade secrets and unpatented know-how will not otherwise become known or be independently discovered by our competitors. If trade secrets are independently discovered, we would not be able to prevent their use. Enforcing a claim that a third party illegally obtained and is using our trade secrets or unpatented know-how is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secret information.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

The United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Further, recent U.S. Supreme Court rulings have either narrowed the scope of patent protection available in certain circumstances or weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the scope and value of patents, once obtained.

For our U.S. patent applications containing a priority claim after March 16, 2013, there is a greater level of uncertainty in the patent law. In September 2011, the Leahy-Smith America Invents Act, also known as the America Invents Act ("AIA") was signed into law. The AIA includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The U.S. Patent and Trademark Office ("USPTO") is currently developing regulations and procedures to govern administration of the AIA, and many of the substantive changes to patent law associated with the AIA. It is not clear what other, if any, impact the AIA will have on the operation of our business. Moreover, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have an adverse effect on our business. An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO after that date but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal court necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that may weaken our and our licensors' ability to obtain new patents or to enforce existing patents we and our licensors or partners may obtain in the future.

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

Filing, prosecuting and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly developing countries. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement on infringing activities is inadequate. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, certain countries in Europe and certain developing countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we may have limited remedies if our patents are infringed or if we are compelled to grant a license to our patents to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license. Finally, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws.

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

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market, which would have an adverse effect on our business.

If we are sued for infringing intellectual property rights of third parties, it will be costly and time-consuming, and an unfavorable outcome in that litigation could have a material adverse effect on our business.

Our commercial success depends upon our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. We cannot assure you that marketing and selling such candidates and using such technologies will not infringe existing or future patents. Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields relating to our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that others may assert that our product candidates, technologies or methods of delivery or use infringe their patent rights. Moreover, it is not always clear to industry participants, including us, which patents cover various drugs, biologics, drug delivery systems or their methods of use, and which of these patents may be valid and enforceable. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods.

In addition, there may be issued patents of third parties that are infringed or are alleged to be infringed by our product candidates or proprietary technologies. Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our own and in-licensed issued patents or our pending applications. Our competitors may have filed, and may in the future file, patent applications covering our product candidates or technology similar to ours. Any such patent application may have priority over our own and in-licensed patent applications or patents, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to those owned or in-licensed to us, we or, in the case of in-licensed technology, the licensor may have to participate, in the United States, in an interference proceeding to determine priority of invention.

We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates or proprietary technologies infringe such third parties' intellectual property rights, including litigation resulting from filing under Paragraph IV of the Hatch-Waxman Act. These lawsuits could claim that there are existing patent rights for such drug and this type of litigation can be costly and could adversely affect our operating results and divert the attention of managerial and technical personnel, even if we do not infringe such patents or the patents asserted against us are ultimately established as invalid. There is a risk that a court would decide that we are infringing the third party's patents and would order us to stop the activities covered by the patents. In addition, there is a risk that a court will order us to pay the other party damages for having violated the other party's patents.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries generally. To date, no litigation asserting infringement claims has been brought against us. If a third party claims that we infringe its intellectual property rights, we may face a number of issues, including:

- infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;

- substantial damages for infringement, which we may have to pay if a court decides that the product or technology at issue infringes or violates the third party's rights, and if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;

- a court prohibiting us from selling or licensing the product or using the technology unless the third party licenses its intellectual property rights to us, which it is not required to do;

- if a license is available from a third party, we may have to pay substantial royalties or upfront fees or grant cross-licenses to intellectual property rights for our products or technologies; and

- redesigning our products or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could harm our ability to raise additional funds or otherwise adversely affect our business, financial condition, operating results and prospects.

Because we may in the future rely on certain third-party licensors and partners, if one of those licensors or partners is sued for infringing a third party's intellectual property rights, our business, financial condition, operating results and prospects could suffer in the same manner as if we were sued directly. In addition to facing litigation risks, we may agree in the future to indemnify certain third-party licensors and partners against claims of infringement caused by our proprietary technologies, and we may enter into cost-sharing agreements with some our licensors and partners that could require us to pay some of the costs of patent litigation brought against those third parties whether or not the alleged infringement is caused by our proprietary technologies. In certain instances, these cost-sharing agreements could also require us to assume greater responsibility for infringement damages than would be assumed just on the basis of our technology.

The occurrence of any of the foregoing could adversely affect our business, financial condition or operating results.

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

Competitors may infringe our intellectual property, including our patents. As a result, we may be required to file infringement claims to stop third-party infringement or unauthorized use. This can be expensive, particularly for a company of our size, and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patent claims do not cover its technology or that the factors necessary to grant an injunction against an infringer are not satisfied. An adverse determination of any litigation or other proceedings could put one or more of our patents at risk of being invalidated, interpreted narrowly or amended such that they do not cover our product candidates. Moreover, such adverse determinations could put our patent applications at risk of not issuing, or issuing with limited and potentially inadequate scope to cover our product candidates or to prevent others from marketing similar products.

Interference, derivation or other proceedings brought at the USPTO may be necessary to determine the priority or patentability of inventions with respect to our patent applications or those of our licensors or potential partners. Litigation or USPTO proceedings brought by us may fail or may be invoked against us by third parties. Even if we are successful, domestic or foreign litigation or USPTO or foreign patent office proceedings may result in substantial costs and distraction to our management. We may not be able, alone or with our licensors or potential partners, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other proceedings, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings. In addition, during the course of this kind of litigation or proceedings, there could be public announcements of the results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed to us alleged trade secrets of their former employers or their former or current customers.

As is common in the biotechnology and pharmaceutical industries, certain of our employees were formerly employed by other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Moreover, we engage the services of consultants to assist us in the development of our product candidates, many of whom were previously employed at or may have previously been or are currently providing consulting services to, other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees and consultants or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or their former or current customers. Although we have no knowledge of any such claims being alleged to date, if such claims were to arise, litigation may be necessary to defend against any such claims. Even if we are successful in defending against any such claims, any such litigation could be protracted, expensive, a distraction to our management team, not viewed favorably by investors and other third parties and may potentially result in an unfavorable outcome.

Risks Related to Ownership of Our Common Stock

The trading volume and price of our common stock has been and may continue to be volatile and you may not be able to resell your shares at or above the price at which you purchased them.

The trading volume and prices of our common stock have been and may continue to be volatile and could fluctuate widely due to factors beyond our control. During 2015, the sale price of RestorGenex common stock ranged from $0.40 per share to $3.75 per share, as reported by the OTCQX. Since the completion of the merger and through March 21, 2016, the sale price of our common stock has ranged from $1.70 per share to $0.85 per share, as reported by the OTCQX. Such volatility may be the result of broad market and industry factors. In addition to market and industry factors, the price and trading volume for our common stock may be highly volatile for factors specific to our own operations, many of which are beyond our control, including:

- the results of our clinical trials and preclinical studies;
- the clinical results of our competitors or potential competitors;
- the development status of our product candidates, including whether any of our product candidates receive regulatory approval;
- the success of, and fluctuations in, the commercial sales of products approved for commercialization, if any;
- regulatory or legal developments in the United States and foreign countries;
- the execution of our partnering and manufacturing arrangements;
- our execution of any collaboration, co-promotion, licensing or other arrangements, and the timing of payments we may make or receive under these arrangements;
- variations in the level of expenses related to our preclinical and clinical development programs, including relating to the timing of invoices from, and other billing practices of, our CROs and clinical trial sites;
- variations in the level of expenses related to our commercialization activities, if any product candidates are approved;
- the performance of third parties on whom we rely for clinical trials, manufacturing, marketing, sales and distribution, including their ability to comply with regulatory requirements;
- overall performance of the equity markets;
- changes in operating performance and stock market valuations of other pharmaceutical companies;
- market conditions or trends in our industry or the economy as a whole;
- the public’s response to press releases or other public announcements by us or third parties, including our filings with the SEC and announcements relating to acquisitions, strategic transactions, licenses, joint ventures, capital commitments, intellectual property, litigation or other disputes impacting us or our business;
- developments with respect to intellectual property rights;
- our commencement of, or involvement in, litigation;
- FDA or foreign regulatory actions affecting us or our industry;
- changes in the structure of healthcare payment systems;
- financial or other forward-looking guidance we may provide to the public, any changes in these projections or our failure to meet these projections;

- changes in financial estimates by any securities analysts who follow our common stock, our failure to meet these estimates or failure of those analysts to initiate or maintain coverage of our common stock;
- ratings downgrades by any securities analysts who follow our common stock;
- the listing or lack of listing of our common stock on a national securities exchange;
- the development and sustainability of an active trading market for our common stock;
- the size of our market float;
- the expiration of market standoff or contractual lock-up agreements and future sales of our common stock by our officers, directors and significant stockholders;
- recruitment or departure of key personnel;
- changes in accounting principles;
- other events or factors, including those resulting from war, incidents of terrorism, natural disasters or responses to these events; and
- any other factors discussed in this report.

In addition, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many pharmaceutical companies. Stock prices of many pharmaceutical companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies. In the past, stockholders have instituted securities class action litigation following periods of market volatility. If we were involved in securities litigation, we could incur substantial costs and our resources and the attention of management could be diverted from our business.

Our common stock trades on the OTCQX and may be considered a "penny stock," which may result in difficulty for our stockholders to sell shares of our common stock.

Our common stock may be subject to the "penny stock" rules adopted under Section 15(g) of the Exchange Act. The penny stock rules generally apply to companies whose common stock is not listed on The NASDAQ Stock Market or other national securities exchange and trades at less than $5.00 per share, other than companies that have had average revenue of at least $6,000,000 for the last three years or that have tangible net worth of at least $5,000,000 ($2,000,000 if the company has been operating for three or more years). The penny stock rules require, among other things, that brokers who trade penny stock to persons other than "established customers" complete certain documentation, make suitability inquiries of investors and provide investors with certain information concerning trading in the security, including a risk disclosure document and quote information under certain circumstances. Many brokers have decided not to trade penny stocks because of the requirements of the penny stock rules and, as a result, the number of broker-dealers willing to act as market makers in such securities is limited. If we remain subject to the penny stock rules for any significant period, it could have an adverse effect on the market, if any, for our securities. If our common stock is subject to the penny stock rules, our stockholder will find it more difficult to sell our shares.

We are the result of a "reverse merger" with a shell entity in 2008, resulting in certain limitations on the ability of our stockholders to use the Rule 144 safe harbor under the Securities Act of 1933, as amended, for resales of our common stock.

As we were party to a "reverse merger" with a shell entity in 2008, resale of shares of our common stock under Rule 144 may be limited. The use of Rule 144 is one of the most common methods of selling restricted shares. Rule 144(i) pertains to shares issued by a former shell company . Under Rule 144(i), sales of shares may only be made under certain conditions, including that we are current with respect to certain filings required under the federal securities laws. As a result, permission to remove a restrictive legend on shares of our common stock may be granted under more limited circumstances compared to an issuer that is not a former shell company.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. Ineffective internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock. In addition, any future testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act of 2002, as amended ("Sarbanes-Oxley Act"), or any required subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement.

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting as of December 31, 2015. However, our independent registered public accounting firm is not required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404. Under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, our management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control—Integrated Framework (1992) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on that evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2015. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

In addition, as the Merger was completed after the date of this report on January 8, 2016, we were not required to and have not yet evaluated our internal control systems on a consolidated basis following our business combination with Diffusion LLC. We are currently integrating our business processes and information systems, including internal controls, with those of Diffusion LLC. This work began immediately upon completion of the Merger and will continue throughout calendar year 2016. Under current law, we will be required to complete such evaluation and include the report of management in our annual report for the fiscal year ending December 31, 2016.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision- making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

We incur significant costs as a result of our public company status and devote substantial management time to operating as a public company.

As a public company, we incur significant legal, accounting and other expenses to comply with the reporting requirements of the Exchange Act and applicable requirements of the Sarbanes-Oxley Act and the Dodd-Frank Wall Street Reform and Consumer Protection Act, as well as rules and regulations subsequently implemented by the SEC, including the establishment and maintenance of effective disclosure and financial controls, changes in corporate governance practices and required filing of annual, quarterly and current reports with respect to our business and operating results. These requirements increase our legal and financial compliance costs and make some activities more time-consuming and costly. In addition, our management and other personnel devote significant time and attention to these public company requirements, which diverts their time attention from operational and other business matters.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. We do not currently have and may never obtain research coverage by securities and industry analysts. If no securities or industry analysts commence coverage of our company, the trading price for our common stock would be negatively impacted. If we obtain securities or industry analyst coverage and if one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our common stock could decrease, which could cause our stock price and trading volume to decline.

Future sales of our common stock or securities convertible into our common stock may depress our stock price.

Sales of a substantial number of shares of our common stock or securities convertible into our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. If a large number of shares of our common stock or securities convertible into our common stock are sold in the public market, the sales could reduce the trading price of our common stock and impede our ability to raise future capital.

Our directors, executive officers and principal stockholders exert significant influence over us and could impede a change of corporate control.

Our directors, executive officers and holders of more than five percent of our common stock, together with their affiliates, beneficially own, in the aggregate, 30.1 percent of our outstanding common stock. As a result, these stockholders, acting together, would have the ability to exert significant influence on matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these stockholders, acting together, would have the ability to significantly influence the management and affairs of our company. Accordingly, this concentration of ownership could harm the market price of our common stock by:

- delaying, deferring or preventing a change of control of us;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquiror from making a tender offer or otherwise attempting to obtain control of us.

Delaware law and provisions in our restated articles of incorporation and restated bylaws could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock.

The anti-takeover provisions under Delaware corporate law may discourage, delay or prevent a change of control by prohibiting us from engaging in a business combination with stockholders owning in excess of 15 percent of our outstanding voting stock for a period of three years after the person becomes an interested stockholder, even if a change of control would be beneficial to our existing stockholders. In addition, our restated articles of incorporation and restated bylaws contain provisions that may make the acquisition of our company more difficult, including the following:

- provide that only our Board of Directors will have the right to fill a vacancy created by the expansion of our Board of Directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our Board of Directors;
- provide that only our Chairman of the Board, our Chief Executive Officer or a majority of our Board of Directors will be authorized to call a special meeting of stockholders;
- authorize the issuance of undesignated preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval, and which may include rights superior to the rights of the holders of common stock;
- provide that our Board of Directors is expressly authorized to make, alter or repeal our bylaws; and
- establish advance notice requirements for nominations for elections to our Board of Directors or for proposing matters that can be acted upon by stockholders at stockholder meetings.

These provisions could also discourage proxy contests and make it more difficult for our stockholders to elect directors of their choosing so as to cause us to take certain corporate actions our stockholders may desire to take.

We have never paid dividends on our capital stock, and we do not anticipate paying any cash dividends in the foreseeable future.

We have never declared nor paid cash dividends on our capital stock. We currently intend to retain any future earnings to finance the operation and expansion of our business, and we do not expect to declare or pay any dividends in the foreseeable future. Consequently, stockholders must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investment.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our principal executive office is located in a leased facility in Charlottesville, Virginia, where we lease approximately 5,000 square feet of office space for approximately $5,500 per month. We lease this space on a month-to-month basis. In addition, as a result of the Merger, we have additional executive office space located in a leased facility in Buffalo Grove, Illinois, where we lease approximately 2,900 square feet of office space for approximately $6,000 per month. The lease for this space expires in February 2018; however, we are currently marketing this space in order to terminate our lease obligation beginning April 1, 2016. We consider our leased properties suitable and adequate for our current and immediately foreseeable needs.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we are subject to various pending or threatened legal actions and proceedings, including those that arise in the ordinary course of our business, which may include employment matters, breach of contract disputes and stockholder litigation. Such matters are subject to many uncertainties and to outcomes that are not predictable with assurance and that may not be known for extended periods of time. We record a liability in our consolidated financial statements for costs related to claims, including future legal costs, settlements and judgments, where we have assessed that a loss is probable and an amount can be reasonably estimated. If the reasonable estimate of a probable loss is a range, we record the most probable estimate of the loss or the minimum amount when no amount within the range is a better estimate than any other amount. We disclose a contingent liability even if the liability is not probable or the amount is not estimable, or both, if there is a reasonable possibility that a material loss may have been incurred.

On August 7, 2014, a complaint was filed in the Superior Court of Los Angeles County, California by Paul Feller, our former Chief Executive Officer under the caption *Paul Feller v. RestorGenex Corporation, Pro Sports & Entertainment, Inc., ProElite, Inc. and Stratus Media Group, GmbH* (Case No. BC553996). The complaint asserts various causes of action, including, among other things, promissory fraud, negligent misrepresentation, breach of contract, breach of employment agreement, breach of the covenant of good faith and fair dealing, violations of the California Labor Code and common counts. The plaintiff is seeking, among other things, compensatory damages in an undetermined amount, punitive damages, accrued interest and an award of attorneys' fees and costs. On December 30, 2014, we filed a petition to compel arbitration and a motion to stay the action. On April 1, 2015, the plaintiff filed a petition in opposition to our petition to compel arbitration and a motion to stay the action. After a hearing for the petition and motion on April 14, 2015, the Court granted our petition to compel arbitration and a motion to stay the action. On January 8, 2016, the plaintiff filed an arbitration demand with the American Arbitration Association. No arbitration hearing has yet been scheduled. We believe this matter is without merit and intend to defend the arbitration vigorously. Because this matter is in an early stage, we are unable to predict its outcome and the possible loss or range of loss, if any, associated with its resolution or any potential effect the matter may have on our operations. Depending on the outcome or resolution of this matter, it could have a material effect on our financial statements.

On September 21, 2015, David Schmidt, a member of Diffusion, filed suit (the "Complaint") in the Circuit Court for Albemarle County (Virginia), which is proceeding as *Case. No. CL15-791, David G. Schmidt v. Diffusion Pharmaceuticals, LLC*. The primary claim asserted in the Complaint is a claim for breach of contract, with Mr. Schmidt asserting that Diffusion breached the terms of a $1.5 million convertible promissory note, dated December 15, 2009, which he elected to fully convert into membership units on the same day at the contractual per-unit conversion price of $3.50. Mr. Schmidt alleges that the anti-dilution provisions of the convertible promissory note and certain terms of the operating agreement entitle him to convert his note at the conversion price of $1 per unit, which was the conversion price that Diffusion subsequently renegotiated in 2012 with other noteholders who had not converted their notes. Mr. Schmidt contends that if he had converted his note at $1 per unit instead of $3.50 per unit, he would have received an additional 1,071,432.50 units. His claim for relief is an award of specific performance requiring Diffusion to issue him an additional 1,071,432.50 units or to pay damages equal to the value of such units. Mr. Schmidt also asserts tort claims for breach of fiduciary duty and conversion, together with a claim for unjust enrichment. These claims are all based on the alleged breaches of contract underpinning his claim for breach of contract.

Diffusion filed a Demurrer asking the court to dismiss the Complaint for failing to state a viable cause of action. Diffusion maintains that neither the convertible promissory note nor the operating agreement entitle Mr. Schmidt to receive a lower conversion price that was negotiated with other noteholders after he elected to convert his notes. Diffusion also seeks dismissal of the other claims on various grounds, including the economic loss rule (which generally prohibits tort claims arising out of a breach of contract) and the statute of limitations. A hearing on Diffusion's Demurrer was held on March 14, 2016, at which hearing the claim was dismissed for failing to state a viable cause of action. Mr. Schmidt has up to 21 days to file an amended, restated complaint. Management and legal counsel for Diffusion are of the opinion that the plaintiff's claim is without merit and Diffusion will prevail in defending the suit. Diffusion is unable to estimate the possible loss or range of loss should Diffusion not prevail in defending the suit.

ITEM 4. MINE SAFETY DISCLOSURES

None.

PART II

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

Market Price

Prior to the Merger, our common stock was quoted on the OTCQX marketplace of the OTC Market Groups, under the symbol "RESX." Effective January 25, 2016, our trading symbol changed to "DFFN." The following table sets forth the high and low daily sale prices for RestorGenex common stock, as quoted by the OTCQX, for each calendar quarter during 2015 and 2014. The over-the-counter market quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

2015	High	Low
First Quarter	$ 3.75	$ 2.35
Second Quarter	3.05	1.65
Third Quarter	1.75	0.80
Fourth Quarter	2.60	0.40

2014	High	Low
First Quarter	$ 10.20	$ 2.00
Second Quarter	6.20	3.82
Third Quarter	4.18	3.01
Fourth Quarter	4.50	2.88

Number of Record Holders

As of March 21, 2016, there were 1,140 record holders of our common stock.

Dividends

To date, we have not declared or paid any cash dividends on our common stock and do not intend to do so in the near future.

Securities Authorized for Issuance Under Equity Compensation Plans

For certain information concerning securities authorized for issuance under our equity compensation plan, see Item 12 — Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Recent Sales of Unregistered Equity Securities

During the fourth quarter ended December 31, 2015, we did not issue or sell any RestorGenex equity securities without registration under the Securities Act of 1933, as amended.

Issuer Purchases of Equity Securities

During the fourth quarter of 2015, we did not purchase any shares of RestorGenex common stock or other RestorGenex equity securities.

Our Board of Directors has not authorized any repurchase plan or program for the purchase of shares of our common stock or other securities on the open market or otherwise.

ITEM 6. SELECTED FINANCIAL DATA

Item 6 is not applicable to us as a smaller reporting company and has been omitted.

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

Introduction

This Management's Discussion and Analysis provides material historical and prospective disclosures intended to enable investors and other users to assess our financial condition and results of operations. Statements that are not historical are forward-looking and involve risks and uncertainties discussed under the headings "*Part I. Item 1. Business—Cautionary Note Regarding Forward-Looking Statements*" and "*Part I. Item 1A. Risk Factors*" of this report. The following discussion of our results of operations and financial condition should be read in conjunction with our financial statements and the related notes thereto included elsewhere in this report. These risks could cause our actual results to differ materially from any future performance suggested below.

For accounting purposes, the Merger is treated as a "reverse acquisition" under generally acceptable accounting practices in the United States ("U.S. GAAP") and Diffusion LLC is considered the accounting acquirer. Accordingly, Diffusion LLC's historical results of operations will replace the Company's historical results of operations for all periods prior to the Merger and, for all periods following the Merger, the results of operations of the combined company will be included in the Company's financial statements. However, because the Merger was not completed until January 8, 2016, after the period of this report, unless the context otherwise requires, this Management's Discussion and Analysis is with respect to the legacy RestorGenex business and does not include a discussion and analysis of the business of Diffusion LLC for the year ended December 31, 2015. The first periodic report that will includes results of operations for Diffusion LLC will be our quarterly report on Form 10-Q for the quarter ending March 31, 2016.

We are a clinical stage biotechnology company focused on extending the life expectancy of cancer patients by improving the effectiveness of current standard-of-care treatments, including radiation therapy and chemotherapy. We are developing our lead product candidate, *transcrocetinate sodium*, also known as *trans sodium crocetinate* ("TSC"), for use in the many cancer types in which tumor oxygen deprivation ("hypoxia") is known to diminish the effectiveness of current treatments. TSC is designed to target the cancer's hypoxic micro-environment, re-oxygenating treatment-resistant tissue and making the cancer cells more susceptible to the therapeutic effects of standard-of-care radiation therapy and chemotherapy. Our lead development programs target TSC against cancers known to be inherently treatment-resistant, including brain cancers and pancreatic cancer. A Phase 1/2 clinical trial of TSC combined with first-line radiation and chemotherapy in patients newly diagnosed with primary brain cancer ("glioblastoma" or "GBM") was completed in 2015. This trial provided evidence of efficacy and safety in extending overall survival without the addition of toxicity. Based on these results, an End-of-Phase 2 meeting was held with the U.S. Food and Drug Administration ("FDA") in August 2015, resulting in agreement on the design of a single 400 patient pivotal Phase 3 registration study which, if successful, would be sufficient to support approval. Discussions with the FDA regarding extension of the TSC development program from first line GBM into first-line pancreatic cancer treatment are currently underway. TSC has been granted Orphan Drug designation for the treatment of GBM.

Recent Development -- Diffusion/RestorGenex Merger

On January 8, 2016, we completed the Merger. In connection with the Merger, the Company issued to the holders of outstanding units of Diffusion LLC an aggregate of approximately 82.9 million shares of Common Stock and, as a result, immediately following the completion of the Merger, the former equity holders of Diffusion LLC owned approximately 84.1% of our Common Stock and the stockholders of RestorGenex immediately prior to the Merger owned approximately 15.9% of the Common Stock, in each case, on a fully-diluted basis (subject to certain exceptions and adjustments). Also in connection with the Merger, the pre-Merger directors and officers of the Company tendered their resignations and the pre-Merger directors and officers of Diffusion LLC were appointed as the new directors and officers of the Company, and our corporate headquarters moved from Buffalo Grove, Illinois to Charlottesville, Virginia. Following the completion of the Merger, the Company changed its corporate name from "RestorGenex Corporation" to "Diffusion Pharmaceuticals Inc." and changed the trading symbol of the Company's common stock from "RESX" to "DFFN."

At the effective time of the Merger, each outstanding unit of membership interest of Diffusion LLC (collectively, "Diffusion units") was converted into the right to receive 3.652658 shares of RestorGenex common stock, as determined pursuant to the terms of the merger agreement ("exchange ratio"). Also at the effective time of the Merger, $1,125,000 of Diffusion convertible notes were outstanding and the rights of the holders of each outstanding convertible promissory note convertible into Diffusion units ("Diffusion convertible notes") was converted into the right to convert such securities into a number of shares of RestorGenex common stock equal to the number of Diffusion units such Diffusion convertible note would be convertible into pursuant to its terms multiplied by the exchange ratio. In addition, at the effective time of the Merger and as a result of the Merger, all outstanding options to purchase Diffusion units were converted into and became options to purchase RestorGenex common stock on terms substantially identical to those in effect prior to the effective time, except for adjustments to the underlying number of shares and the exercise price based on the exchange ratio.

2015 Financial Summary

Our total working capital as of December 31, 2015 totaled $10,971,423, including $12,006,075 in cash and cash equivalents, compared to total working capital of $21,832,217, including $21,883,887 in cash and cash equivalents, as of December 31, 2014.

We recognized no revenues and our operating expenses were $23,827,032 during 2015 compared to operating expenses of $14,613,818 during 2014. The primary reason for the increase in our 2015 operating expenses over the prior year period was an $11,070,991 non-cash impairment of goodwill during 2015.

We expect to continue to recognize net losses for the foreseeable future. We intend to use our existing cash and cash equivalents for working capital and to fund the research and development of our lead product candidate, trans sodium crocetinate, for use in the treatment of glioblastoma multiforme, pancreatic cancer and brain metastases.

Results of Operations for Year Ended December 31, 2015 Compared to the Year Ended December 31, 2014

Revenues

We recognized no revenues during 2015 and 2014. In light of the fact that we are a clinical stage biotechnology company, we do not anticipate recognizing any revenues for the immediate foreseeable future.

Operating Expenses

Operating expenses were $23,827,032 during 2015, representing an increase of 63%, from operating expenses of $14,613,818 during 2014. This increase was due primarily to a non-cash $11,070,991 goodwill impairment. In addition, the increase was also due to an increase in research and development expenses, an increase in general and administrative expenses, the recognition of former employee severance expense and expenses of RestorGenex associated with the Merger.

We recognized $3,852,973 in research and development expenses during 2015 compared to $2,860,658 in research and development expenses recognized during 2014. These research and development expenses relate solely to research and development expenses incurred by RestorGenex on its RES-529 and RES-440 product candidates. The increase in research and development expenses was a result of increased research and development activity of our technologies and product candidates during 2015. We expect that our research and development expenses will increase significantly in future periods compared to 2015 and prior year periods due to our anticipated efforts to advance the research and development of our lead product candidate, trans sodium crocetinate, for use in the treatment of glioblastoma multiforme, pancreatic cancer and brain metastases.

General and administrative expenses were $7,912,116 during 2015, representing an increase of 66% from $4,760,145 during 2014. This increase in general and administrative expenses was primarily a result of employee and director non-cash stock-based compensation expenses, the recognition of former employee severance expense and expenses of RestorGenex associated with the Merger.

Non-cash stock-based compensation expense, which is included in research and development expenses and general and administrative expenses, was $2,095,086 during 2015, representing an increase of 30% over non-cash stock-based compensation expense of $1,606,947 recognized in 2014.

We recognized a non-cash goodwill impairment of $11,070,991 during the third quarter of 2015. We considered certain triggering events when evaluating whether an interim goodwill impairment analysis was warranted at that time. Among these was a then significant long-term decrease in our market capitalization based on events specific to our operations at that time. Our market capitalization had decreased significantly during 2015 as our per share price had declined from $2.80 as of April 30, 2015 to $0.90 as of September 30, 2015. As of September 30, 2015, our market capitalization was approximately $16.7 million, falling to an amount significantly less than our stockholders' equity at such time. In September 2015, management concluded that given the significant and sustained decrease in our share price to a level below our stockholders' equity, combined with information on our fair value derived from strategic discussions with third parties during the third quarter of 2015, a triggering event requiring an interim assessment of goodwill impairment had occurred during the third quarter of 2015. Management performed the interim goodwill impairment assessment using a market approach to estimating the fair value of our company, using multiple inputs, some weighted heavier than others. The inputs included our market capitalization and other more heavily weighted unobservable inputs as to our fair value derived from our strategic discussions with third parties. The initial step one assessment indicated that it was likely our goodwill was impaired, and we proceeded to perform step two of our goodwill impairment assessment resulting in the conclusion that an impairment loss had occurred. We performed our annual goodwill impairment analysis at the end of 2015 and determined no further impairment. As such, our goodwill as of December 31, 2015 remained $985,000. During 2014, we recorded an impairment of our intangible assets of $6,670,345 due to our strategic decision in the fourth quarter of 2014 to focus our development efforts on RES-529 and RES-440 (for dermatology). The impairment charge consisted of $3,035,000 of impairment of one of our in-process research and development intangible assets and $3,635,345 of impairment of finite lived intangible assets.

We did not recognize any gains or losses on settlements in 2015. Gain on settlement of property damage was $243,592 during 2014. In July 2013, we received notice that a complaint for property damage had been filed by the Truck Insurance Exchange against us for $393,592 related to water damage incurred by a printing company on the ground floor of our former office space in Los Angeles. This complaint was settled for $150,000 in December 2014.

Depreciation and amortization was $23,269 during 2015, consisting solely of depreciation, compared with $566,262 during 2014. This decrease was primarily related to amortization expense in 2014 attributed to intangible assets, which, as discussed previously, were ultimately deemed to be fully impaired in the fourth quarter of 2014.

Loss on Settlement of Notes Payable

Loss on settlement of notes payable – related parties was $1,907,772 during 2014. During the second quarter of 2014, we issued shares of RestorGenex common stock and warrants to purchase shares of RestorGenex common stock to a then member of our Board of Directors in exchange for notes payable in the aggregate principal amount of $1,050,000. These shares were valued at $3.55 per share, resulting in a charge of $1,650,378 during 2014. In addition, during the fourth quarter of 2014, we issued shares of RestorGenex common stock and warrants to purchase shares of RestorGenex common stock to a then member of our Board of Directors in exchange for a note payable in the principal amount of $200,000. These shares were valued at $3.50 per share, resulting in a charge of $257,394 during 2014. Since these notes were extinguished in 2014, there was no comparable gain or loss during 2015.

Loss on settlement of notes payable was $400,016 during 2014. During the second quarter of 2014, we issued shares of RestorGenex common stock to a creditor upon conversion of a promissory note in the principal amount of $500,000. Since these notes were extinguished in 2014, there was no comparable gain or loss during 2015.

Other (Income) Expenses

Other income was $6,357 during 2015 compared to other income of $25,401 during 2014. Other income for 2015 and 2014 related primarily to the recognition of interest income.

Interest Expense

Interest expense was $273,503 during 2014 due to interest expense on notes payable we assumed in connection with our acquisition of Paloma Pharmaceuticals, Inc. on March 28, 2014. These notes plus interest expense accrued were paid in cash in August 2014. Therefore, there was no comparable interest expense during 2015.

Benefit From Income Taxes

Benefit from income taxes was zero during 2015 compared to $2,816,884 during 2014, which related primarily to a reduction in deferred tax liabilities related to the amortization of intangible assets.

Net Loss

We recognized a net loss of $23,820,675 for 2015, or $1.28 per share, compared to a net loss of $14,352,824, or $1.00 per share for 2014. As previously discussed, we recognized an $11,070,991 non-cash impairment of goodwill during 2015, which represents the primary reason for the increase in our operating expenses and net loss over the respective prior year period. We expect to incur net losses in future periods for the foreseeable future as we plan to advance the research and development of our lead product candidate, trans sodium crocetinate, for use in the treatment of glioblastoma multiforme, pancreatic cancer and brain metastases.

Liquidity and Capital Resources

Working Capital

Our total working capital as of December 31, 2015 totaled $10,971,423, including $12,006,075 in cash and cash equivalents, compared to a total working capital $21,832,217, including $21,883,887 in cash and cash equivalents, as of December 31, 2014.

The following table summarizes our working capital as of December 31, 2015 and 2014:

Liquidity and Capital Resources	December 31, 2015	December 31, 2014
Cash and cash equivalents	$ 12,006,075	$ 21,883,887
Prepaid expenses, deposits and other assets	169,150	2,286,930
Total current liabilities	(1,203,802)	(2,338,600)
Working capital	$ 10,971,423	$ 21,832,217

We expect to continue to incur net losses for the foreseeable future. We intend to use our existing cash and cash equivalents for working capital and to fund the research and development of our lead product candidate, trans sodium crocetinate, for use in the treatment of glioblastoma multiforme, pancreatic cancer and brain metastases.

Cash Flows

The following table sets forth our cash flows for the years ended December 31, 2015 and 2014:

	Year Ended December 31,	
	2015	2014
Operating activities	$ (9,599,585)	$ (9,030,133)
Investing activities	(278,227)	(50,911)
Financing activities	0	30,709,967
Net (decrease) increase in cash and cash equivalents	$ (9,877,812)	$ 21,628,923

Operating Activities

Cash used in operating activities was primarily unchanged during 2015 compared to 2014. The increase in cash used for research and development and general and administrative activities during 2015 compared to 2014 approximated the additional cash used during 2014 to pay pre-2014 liabilities.

Investing Activities

Net cash used in investing activities was $278,227 during 2015 compared to $50,911 during 2014. The investment in Or-Genix Therapeutics, Inc. accounted for $250,000 and the purchase of fixed assets accounted for $28,227 of cash used in investing activities during 2015. The purchase of fixed assets accounted for the $50,911 of cash used in investing activities in 2014.

Financing Activities

Net cash provided by financing activities was $0 during 2015 compared to $30,709,967 during 2014. Net cash provided by financing activities during 2014 resulted primarily from proceeds from our 2014 private placement.

Capital Requirements

We expect to incur substantial expenses and generate significant operating losses as we intend to pursue to our new business strategy of developing of our lead product candidate, trans sodium crocetinate, for use in the treatment of glioblastoma multiforme, pancreatic cancer and brain metastases.

To date, we have used primarily equity and debt financings to fund ongoing business operations and short-term liquidity needs. We expect to continue this practice for the foreseeable future.

During 2014, RestorGenex completed a private placement pursuant to which we raised approximately $35.6 million in gross proceeds and $31.9 million in net proceeds, after paying placement agent fees and commission and offering expenses.

We believe our cash and cash equivalents as of December 31, 2015 will be sufficient to fund our planned operations into the third quarter of 2016. However, we may require additional funds earlier. Accordingly, there is no assurance that we will not need or seek additional funding prior to such time. We may elect to raise additional funds even before we need them if market conditions for raising additional capital are favorable.

As of December 31, 2015, we did not have any existing credit facilities under which we could borrow funds. We may seek to raise additional funds through various sources, such as equity and debt financings, or through strategic collaborations and license agreements. We can give no assurances that we will be able to secure additional sources of funds to support our operations, or if such funds are available to us, that such additional financing will be sufficient to meet our needs or on terms acceptable to us. This risk may increase if economic and market conditions deteriorate. If we are unable to obtain additional financing when needed, we may need to terminate, significantly modify or delay the development of our product candidates and our operations, or we may need to obtain funds through collaborators that may require us to relinquish rights to our technologies or product candidates that we might otherwise seek to develop or commercialize independently.

To the extent that we raise additional capital through the sale of our common stock, the interests of our current stockholders may be diluted. If we issue preferred stock or convertible debt securities, it could affect the rights of our common stockholders or reduce the value of our common stock. In particular, specific rights granted to future holders of preferred stock or convertible debt securities may include voting rights, preferences as to dividends and liquidation, conversion and redemption rights, sinking fund provisions, and restrictions on our ability to merge with or sell our assets to a third party. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

Contractual Obligations

Set forth below is information concerning our known contractual obligations as of December 31, 2015.

	Payments Due By Period				
Contractual Obligations	**Total**	**Less than 1 Year**	**1-3 Years**	**3-5 Years**	**More than 5 Years**
Rent obligations	$ 583,862	$ 497,075	$ 86,787	$ –	$ –
Total	$ 583,862	$ 497,075	$ 86,787	$ –	$ –

Subsequent to December 31, 2015, we assumed additional contractual obligations as a result of the Merger. We assumed $1,125,000 of principal amount of convertible notes of Diffusion LLC, with an aggregate of approximately $38,200 of interest accrued thereon as of January 8, 2016, of which $550,000, $325,000, $50,000 and $200,000 of principal amount were issued as Series B, Series C, Series E and Series F notes, respectively. The Series B notes were issued in March 2011, mature June 30, 2018 and, as a result of the Merger, are convertible into our common stock at a conversion price of $0.27464888 per share. The Series C notes were issued in September 2012, mature March 31, 2016 and, as a result of the Merger, are convertible into our common stock at a conversion price of $0.27464888 per share. The Series E notes were issued in May 2013, mature May 1, 2017 and, as a result of the Merger, are convertible into our common stock at a conversion price of $0.41197332 per share. The Series F notes were issued in December 2015, mature December 7, 2019 and, as a result of the merger, are convertible into our common stock at a conversion price of $0.54929776. All of the notes are convertible into an aggregate of 3,821,572 shares of our common stock as of the January 8, 2016 Merger transaction date. All of the notes bear interest at a rate of 1.0% per annum and, are convertible into shares of our common stock at the holder's discretion. In the event a holder does not convert prior a note's maturity date, the entire principal amount and all accrued interest are due and payable on such date. The notes are subject to acceleration in the case of certain customary events of default, including failure to make payments on the notes when due and certain bankruptcy events, and the conversion prices are subject to adjustment in the case of certain dilutive company events.

Effective upon the Merger, we assumed purchase obligations of approximately $467,000, the significant majority of which are due within one year. These purchase obligations are associated with the manufacture of Diffusion's TSC active pharmaceutical ingredient and TSC clinical product to be used in Diffusion's clinical trials.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements, as defined by the rules and regulations of the SEC that have or are reasonably likely to have a material effect on our financial condition, changes in financial condition, revenue or expenses, results of operations, liquidity, capital expenditures or capital resources. As a result, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these arrangements.

Critical Accounting Policies

Certain of our critical accounting estimates require the application of significant judgment by management in selecting the appropriate assumptions in determining the estimate. By their nature, these judgments are subject to an inherent degree of uncertainty. We develop these judgments based on our historical experience, terms of existing contracts, our observance of trends in the industry and information available from other outside sources, as appropriate. Actual results may differ from these judgments under different assumptions or conditions. Different, reasonable estimates could have been used for the current period. Additionally, changes in accounting estimates are reasonably likely to occur from period to period. Both of these factors could have a material impact on the presentation of our financial condition, changes in financial condition or results of operations. We believe the following accounting estimates are the most critical to aid in fully understanding and evaluating our financial statements as they require our most subjective or complex judgments:

Goodwill

Goodwill is the excess of the cost of an acquired entity over the net amounts assigned to tangible and intangible assets acquired and liabilities assumed. We apply Accounting Standards Codification (ASC) 350 "*Goodwill and Other Intangible Assets*," which requires testing goodwill for impairment on an annual basis. We assess goodwill for impairment as part of our annual reporting process in the fourth quarter of each year. In between valuations, we conduct additional tests if circumstances indicate a need for testing. We evaluate goodwill on a consolidated basis as we are organized as a single reporting unit.

We consider certain triggering events when evaluating whether an interim goodwill impairment analysis is warranted. Among these would be a significant long-term decrease in our market capitalization based on events specific to our operations. Our market capitalization decreased significantly during the second and third quarters of 2015. Our share price had declined from $2.80 per share as of April 30, 2015 to $0.90 per share as of September 30, 2015. As of September 30, 2015, our market capitalization was approximately $16.7 million, falling to an amount significantly less than our stockholders' equity at that time. In September 2015, management concluded that given the significant and sustained decrease in our share price to a level below our stockholders' equity, combined with information on our fair value derived from strategic discussions with third parties during the third quarter of 2015, a triggering event requiring an interim assessment of goodwill impairment had occurred during the third quarter of 2015. Management performed the goodwill impairment assessment using a market approach to estimating the fair value of our company, using multiple inputs, some weighted heavier than others. The inputs included our market capitalization, which, based on the inactive trading activity in our stock, is a lower level input on the fair value measurement hierarchy, and other more heavily weighted unobservable inputs as to our fair value derived from our strategic discussions with third parties. The initial step one assessment indicated that it was likely our goodwill was impaired, and we proceeded to perform step two of our goodwill impairment assessment. As a result of that assessment, we concluded that a goodwill impairment loss of $11,070,991 was necessary. Following the recording of the goodwill impairment loss, our goodwill as of September 30, 2015 was $985,000.

Subsequent to the impairment on September 30, 2015, we performed our December 31, 2015 annual goodwill impairment review and deemed there to be no further impairment of goodwill. As of the December 31, 2015 impairment review, there was no additional impairment loss associated with recorded goodwill as the estimated fair value exceeded the carrying amount. The fair value of the reporting unit as of December 31, 2015, for the purpose of assessing the impairment of goodwill, was determined based on a qualitative assessment, utilizing the most recent baseline valuation that occurred on September 30, 2015, the market capitalization trend since the baseline valuation, and the then recently announced merger with Diffusion Pharmaceuticals LLC. The Company determined that it was more likely than not that the fair value of its businesses for accounting purposes exceeded the carrying amount, and therefore, indicated no impairment of goodwill. Following the December 31, 2015 annual impairment review of the goodwill, the Company's goodwill as of December 31, 2015 was $985,000.

As of December 31, 2014, goodwill was $12,055,991. No impairment of goodwill was identified in our 2014 annual goodwill impairment assessment.

Intangible Assets

Our intangible assets as of December 31, 2015 consist of an in-process research and development (IPR&D) intangible asset acquired as part of our acquisition of Paloma Pharmaceuticals, Inc., RES-529. The fair value of the IPR&D asset was determined as of the acquisition date using the cost approach. The cost approach was chosen as we were not able to estimate an income stream attributable to the IPR&D asset given the fact that the related product has only completed Phase I clinical trials and the timeline to commercial viability, if the FDA approval process is successful, is somewhat uncertain and would take a number of years. As the product continues in its development efforts, based on the facts and circumstances at the time of a future valuation for the purposes of assessing impairment, it is possible that the values for the IPR&D intangible asset currently on our consolidated balance sheets could be substantially reduced or eliminated, which could result in a maximum charge to operations equal to the current carrying value of our intangible assets of $6,449,628 as of December 31, 2015. We tested the IPR&D intangible asset for impairment during the second quarter of 2015 which is our annual impairment date and deemed there to be no impairment to our intangible assets. Our assessment in the second quarter of 2015 was made using a Step 0 qualitative approach to assessing impairment, during which time we concluded that based on a qualitative analysis, it was more likely than not that the IPR&D intangible asset was not impaired. This conclusion was subsequently reaffirmed during our process of completing Step 2 of the goodwill impairment assessment conducted in the third quarter of 2015 discussed previously, when a valuation using a cost approach similar to that used upon the acquisition of the IPR&D asset in 2014 concluded that the fair value of the IPR&D asset as of September 30, 2015 exceeded its carrying value.

In the fourth quarter of 2014, we strategically decided that our initial focus would be our development efforts with respect to RES-529 for ophthalmology (specifically age-related macular degeneration) and oncology (specifically glioblastoma multiforme) and RES-440 for dermatology (specifically acne vulgaris). Based on our decision to abandon our development efforts on the cosmeceutical finite lived intangible assets and the IPR&D asset that we acquired in connection with our acquisition of Canterbury Laboratories, LLC, we determined that the carrying value of such assets was no longer recoverable. We recorded an impairment of our intangible assets of $6,670,345 on our consolidated statements of operations as of December 31, 2014. The impairment consisted of $3,035,000 of impairment of the IPR&D asset and $3,635,345 of impairment of the finite lived intangible assets.

Stock-Based Compensation

We account for stock-based compensation based on the grant date fair value of the award. We recognize this cost as an expense over the requisite service period, which is generally the vesting period of the respective award. Forfeitures rates are used in stock-based compensation to adjust the recognized stock-based compensation expense to reflect the expected attrition of employees prior to their full vesting in stock-based compensation awards. Due to the small number of employees at our company during 2015, we assumed a forfeiture rate of zero as the population of employees was not large enough for our potential forfeitures to be adequately represented by a single percentage measurement, and in granting the awards, we expected that the employee will remain at our company until the award vests. Should an employee leave our company, management will adjust stock-based compensation to reflect the expense related to the portion of those awards that were unvested at the time of the employee's departure. We use the Black-Scholes option-pricing model to determine the estimated fair value of stock options. Critical inputs into the Black-Scholes option-pricing model include: the estimated grant date fair value of our common stock; the option exercise price; the expected term of the option in years; the annualized volatility of the stock; the risk-free interest rate; and the annual rate of quarterly dividends on the stock. If any of the assumptions used in the Black-Scholes model changes significantly, stock-based compensation for future awards may differ materially compared with the awards granted previously. The inputs that create the most sensitivity in our option valuation are the volatility and expected term.

Given our repositioning as a specialty biopharmaceutical company in November 2013, we did not have sufficient trading data to calculate volatility based on our own common stock, and the expected volatility was calculated as of each grant date based on reported data for a peer group of publicly traded companies for which historical information was available. The expected term of the stock options was determined based upon the simplified approach, allowed under SEC Staff Accounting Bulletin No. 110, which assumes that the stock options will be exercised evenly from vesting to expiration, as we did not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. As data associated with future exercises is obtained, the expected term of future grants will be adjusted accordingly.

During 2015, we granted only a minimal number of stock options, and therefore substantially all of the stock-based compensation expense recorded in 2015 related to stock-based awards granted in prior periods with the total related stock-based compensation expense, which is being recognized over the service period, based on assumptions that existed at the date of the grant of such stock-based awards. The completion of the Merger constituted a "change in control" under the Company's non-plan option agreements thereby resulting in automatic acceleration of vesting of all options outstanding as of the effective time of the Merger and such options remaining exercisable for the remainder of their terms.

See Note 15, "*Stock-Based Compensation*," to our consolidated financial statements for the year ended December 31, 2015 included in this Annual Report on Form 10-K for additional information regarding the assumptions used in the Black-Scholes model.

Recent Accounting Pronouncements

We do not expect the adoption of any recent accounting pronouncements to have a material effect on our financial position, results of operations or cash flows. We describe such pronouncements in Note 2 to our consolidated financial statements under "Recently Issued Accounting Pronouncements."

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Item 7A is not applicable to us as a smaller reporting company and has been omitted.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Diffusion Pharmaceuticals Inc.
Charlottesville, Virginia

We have audited the accompanying consolidated balance sheets of Diffusion Pharmaceuticals Inc. (formerly known as RestorGenex Corporation) and subsidiaries (the “Company”) as of December 31, 2015 and 2014, and the related consolidated statements of operations, stockholders’ equity, and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of RestorGenex Corporation and subsidiaries as of December 31, 2015 and 2014, and the results of their operations and their cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements for the year ended December 31, 2015 have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company's recurring losses from operations and its present financial resources raise substantial doubt about its ability to continue as a going concern. Management's plans concerning these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

As discussed in Note 17 to the consolidated financial statements, on January 8, 2016, the Company via merger acquired Diffusion Pharmaceuticals LLC in exchange for 82,963,544 shares of common stock, which represented approximately 84.1% of the outstanding common stock of the Company immediately following the completion of the merger.

/s/ Deloitte & Touche LLP

Chicago, Illinois
March 25, 2016

Diffusion Pharmaceuticals Inc. (Formerly RestorGenex Corporation)
Consolidated Balance Sheets
December 31, 2015 and December 31, 2014

	December 31, 2015	December 31, 2014
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	**$ 12,006,075**	**$ 21,883,887**
Prepaid expenses, deposits and other assets	**169,150**	**2,286,930**
	12,175,225	**24,170,817**
PROPERTY AND EQUIPMENT, NET	**57,995**	**102,315**
OTHER ASSETS		
Intangible assets, net	**6,449,628**	**6,449,628**
Goodwill	**985,000**	**12,055,991**
Investment in Or-Genix	**250,000**	**-**
TOTAL ASSETS	**$ 19,917,848**	**$ 42,778,751**
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	**$ 36,110**	**$ 417,307**
Other accrued expenses and liabilities	**1,167,692**	**1,921,293**
	1,203,802	**2,338,600**
DEFERRED TAXES	**2,274,526**	**2,274,526**
TOTAL LIABILITIES	**3,478,328**	**4,613,126**
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY		
Common stock:		
Issued and outstanding; $0.001 par value; 1,000,000,000 shares authorized; 2015 - 18,614,968; 2014 - 18,614,968	**18,615**	**18,615**
Additional paid-in-capital	**115,531,954**	**113,437,384**
Accumulated deficit	**(99,111,049)**	**(75,290,374)**
Total stockholders' equity	**16,439,520**	**38,165,625**
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 19,917,848**	**$ 42,778,751**

See accompanying notes to the consolidated financial statements.

Diffusion Pharmaceuticals Inc. (Formerly RestorGenex Corporation)
Consolidated Statements of Operations
December 31, 2015 and December 31, 2014

	Year Ended December 31,	
	2015	**2014**
REVENUES	**$ -**	**$ -**
TOTAL REVENUES	**-**	**-**
EXPENSES		
Research and development	**3,852,973**	**2,860,658**
General and administrative	**7,912,116**	**4,760,145**
Impairment of goodwill	**11,070,991**	-
Impairment of other intangible assets	**-**	**6,670,345**
Gain on property damage settlement	-	**(243,592)**
Depreciation and amortization	**23,269**	**566,262**
Former employee severance expense	**967,683**	-
TOTAL EXPENSES	**23,827,032**	**14,613,818**
LOSS FROM OPERATIONS	**(23,827,032)**	**(14,613,818)**
OTHER (INCOME)/EXPENSES		
Loss on settlement of notes payable - related parties	**-**	**1,907,772**
Loss on settlement of notes payable	**-**	**400,016**
Other (income) expenses	**(6,357)**	**(25,401)**
Interest expense	**-**	**273,503**
TOTAL OTHER (INCOME)/EXPENSES	**(6,357)**	**2,555,890**
LOSS FROM CONTINUING OPERATIONS BEFORE INCOME TAXES	**(23,820,675)**	**(17,169,708)**
Benefit from income taxes	**-**	**2,816,884**
NET LOSS	**$ (23,820,675)**	**$ (14,352,824)**
TOTAL BASIC AND DILUTED LOSS PER SHARE	**$ (1.28)**	**$ (1.00)**
BASIC WEIGHTED AVERAGE SHARES OUTSTANDING	**18,614,968**	**14,299,473**
FULLY-DILUTED WEIGHTED AVERAGE SHARES OUTSTANDING	**18,614,968**	**14,299,473**

See accompanying notes to the consolidated financial statements.

Diffusion Pharmaceuticals Inc. (Formerly RestorGenex Corporation)
Consolidated Statements of Stockholders' Equity
Years Ended December 31, 2015 and 2014

	Common Stock		Additional Paid-In	Accumulated	Total
	Shares	Amount	Capital	Deficit	
Balance at January 1, 2014	**5,813,785**	**$ 5,814**	**$ 67,390,493**	**$ (60,937,550)**	**$ 6,458,757**
Issuance of common stock, net of offering costs	8,895,685	8,896	31,841,071	-	31,849,967
Employee and director stock-based compensation	-	-	1,606,947	-	1,606,947
Warrants issued to consultants	-	-	547,061	-	547,061
Common stock issued for Paloma acquisition	2,500,000	2,500	6,247,500	-	6,250,000
Common stock issued for VasculoMedics acquisition	220,000	220	549,780	-	550,000
Issuance of common stock to third party for assumption of liabilities	150,000	150	272,952	-	273,102
Retirement of common stock originally issued to a third party for assumption of liabilities	(99,332)	(99)	-	-	(99)
Issuance of common stock as settlement of accounts payable and accrued liabilities	160,056	160	587,441	-	587,601
Common stock issued as settlement of an outstanding liability to law firm	53,457	53	214,112	-	214,165
Common stock issued as payment of notes payable	274,764	275	979,796	-	980,071
Common stock issued as payment of notes payable - related party	646,553	646	3,200,231	-	3,200,877
Net loss	-	-	-	(14,352,824)	(14,352,824)
Balance at December 31, 2014	**18,614,968**	**$ 18,615**	**$ 113,437,384**	**$ (75,290,374)**	**$ 38,165,625**
Employee and director stock-based compensation	-	-	2,095,086	-	2,095,086
Adjustment to fair value of warrants issued to consultants			(516)		(516)
Net loss	-	-	-	(23,820,675)	(23,820,675)
Balance at December 31, 2015	**18,614,968**	**$ 18,615**	**$ 115,531,954**	**$ (99,111,049)**	**$ 16,439,520**

See accompanying notes to the consolidated financial statements.

Diffusion Pharmaceuticals Inc. (Formerly RestorGenex Corporation)
Consolidated Statements of Cash Flows
Years Ended December 31, 2015 and December 31, 2014

	Year Ended December 31,	
	2015	2014
CASH FLOWS (USED IN) OPERATING ACTIVITIES		
Net loss	$ (23,820,675)	$ (14,352,824)
Adjustments to reconcile net loss to net cash (used in) operating activities		
Depreciation and amortization	23,269	566,262
Loss on disposal of fixed assets	49,278	6,056
Employee and director stock-based compensation - non-cash	2,095,086	1,606,947
Stock warrant expense - noncash	499,003	47,542
Deferred income taxes	-	(2,816,884)
Gain on settlement of property damage	-	(243,592)
Impairment of goodwill	11,070,991	-
Impairment of other intangible assets	-	6,670,345
Loss on settlement of note payable - related parties	-	1,907,772
Loss on settlement of note payable	-	400,016
Changes in other assets and liabilities affecting cash flows from operating activities		
Prepaid expenses, deposits and other assets	1,618,261	979,551
Accounts payable and accrued liabilities	(1,134,798)	(3,801,324)
Net cash (used in) operating activities	(9,599,585)	(9,030,133)
CASH FLOWS (USED IN) INVESTING ACTIVITIES		
Investment in Or-Genix	(250,000)	
Purchase of fixed assets	(28,227)	(50,911)
Net cash (used in) investing activities	(278,227)	(50,911)
CASH FLOWS PROVIDED BY FINANCING ACTIVITIES		
Proceeds on notes payable - related party	-	400,000
Proceeds on notes payable	-	-
Payment of notes payable	-	(1,540,000)
Proceeds from issuance of common stock net of offering costs	-	31,849,967
Net cash provided by financing activities	-	30,709,967
NET (DECREASE) INCREASE CASH AND CASH EQUIVALENTS	(9,877,812)	21,628,923
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	21,883,887	254,964
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 12,006,075	$ 21,883,887
SUPPLEMENTAL SCHEDULE OF CASH FLOW INFORMATION		
Cash paid for interest	$ -	$ 677,250
NON-CASH INVESTING AND FINANCING ACTIVITIES		
Conversion of accounts payable to notes payable related to Company's outside law firm	$ -	$ 407,998
Issuance of shares of common stock and stock warrants as payment of accounts payable and accrued liabilities	$ -	$ 1,323,771
Issuance of shares of common stock as payment of notes payable	$ -	$ 580,055
Issuance of shares of common stock and stock warrants as payment of notes payable - related parties	$ -	$ 1,293,105
Issuance of warrants as payment for consulting services	$ -	$ 547,061
Acquisition of business in exchange for common stock	$ -	$ 6,800,000

See accompanying notes to the consolidated financial statements.

1. Description of Business and Corporate History

Diffusion Pharmaceuticals Inc. (f/k/a RestorGenex Corporation) ("Company") is a specialty biopharmaceutical company focused on developing products for ophthalmology, oncology and dermatology. Unless the context otherwise indicates, all information in these notes relates to the Company during the years ended December 31, 2015 and 2014 and does not reflect the completion of the Merger (as defined below).

RestorGenex's primary product is a novel PI3K/Akt/mTOR pathway inhibitor which has completed two Phase I clinical trials for age-related macular degeneration and is in pre-clinical development in oncology, specifically glioblastoma multiforme. The Company's current pipeline also includes a "soft" anti-androgen compound for the treatment of acne vulgaris. The Company's novel inhibition of the PI3K/Akt/mTOR pathway and unique targeting of the androgen receptor show promise in a number of additional diseases, which the Company is evaluating for the purpose of creating innovative therapies that are safe and effective treatments to satisfy unmet medical needs.

On January 8, 2016, the Company completed its previously announced merger ("Merger") with Diffusion Pharmaceuticals LLC ("Diffusion LLC"), and changed its name to Diffusion Pharmaceuticals, Inc. Diffusion LLC is a clinical-stage specialty pharmaceutical company developing new, small-molecule drugs that help regulate the movement of oxygen into tissue by a novel mechanism of action. The Company's lead product candidate, trans sodium crocetinate ("TSC"), uses this novel mechanism to re-oxygenate the microenvironment of solid cancerous tumors, thereby enhancing tumor cells' response to conventional treatment without additional side effects. See note 17 to the consolidated financial statements for additional information regarding the Merger.

On June 18, 2015, the Company changed its state of incorporation from the State of Nevada to the State of Delaware.

On March 7, 2014, the Company effected a one-for-100 reverse split of its outstanding common stock. All share data have been adjusted retroactively to reflect the one-for-100 reverse stock split effected on March 7, 2014.

On March 3, 2014, the Company entered into an agreement and plan of merger with Paloma Acquisition, Inc., Paloma Pharmaceuticals, Inc. ("Paloma") and David Sherris, Ph.D., as founding stockholder and holder representative, pursuant to which the Company agreed to acquire by virtue of a merger all of the outstanding capital stock of Paloma, with Paloma becoming a wholly owned subsidiary of the Company. On March 28, 2014, the merger with Paloma was effected and the Company issued an aggregate of 2,500,000 shares of common stock to the holders of Paloma's common stock and its derivative securities, which included the assumption of promissory notes of Paloma in the aggregate amount (including both principal amount and accrued interest) of approximately $1,151,725, to be paid on the first anniversary of the closing date of the Paloma merger. For accounting purposes, the acquisition date was deemed to be March 3, 2014, the date the Company assumed oversight and control of the activities of Paloma and VasculoMedics.

Also on March 3, 2014, the Company entered into an agreement and plan of merger with VasculoMedics Acquisition, Inc., VasculoMedics, Inc. ("VasculoMedics") and David Sherris, Ph.D. pursuant to which the Company agreed to acquire by merger all of the outstanding capital stock of VasculoMedics, with VasculoMedics becoming a wholly owned subsidiary of the Company. The VasculoMedics merger was concurrently closed with and as a condition to the closing of the Paloma merger on March 28, 2014 and the Company issued an aggregate of 220,000 shares of common stock to the VasculoMedics stockholders.

Effective September 30, 2013, the Company entered into an agreement and plan of merger with Canterbury Acquisition LLC, Hygeia Acquisition, Inc., Canterbury Laboratories, LLC ("Canterbury"), Hygeia Therapeutics, Inc. ("Hygeia") and Yael Schwartz, Ph.D., as holder representative, pursuant to which the Company agreed to acquire by virtue of two mergers all of the outstanding capital stock of Canterbury and Hygeia, with Canterbury and Hygeia becoming wholly owned subsidiaries of the Company. The consideration paid by the Company in connection with such mergers was the issuance by the Company of an aggregate of 1,150,116 shares of common stock issued to the stakeholders of Canterbury and Hygeia. The mergers were completed on November 18, 2013. For accounting purposes, the acquisition date was deemed to be September 30, 2013, the date the Company assumed oversight and control of the activities of the acquired companies.

Prior to the Company repositioning itself as a specialty biopharmaceutical company in 2013, the Company operated various entertainment and sports events which it acquired in a series of acquisitions beginning in March 2008 and operated under the name Stratus Media Group, Inc. until March 7, 2014 when the Company changed its name to RestorGenex Corporation.

2. Basis of Presentation

Basis of Presentation

These financial statements are expressed in U.S. dollars. The Company is organized into one operating and one reporting segment.

The financial statements were prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"), pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC").

Going Concern

As of December 31, 2015, the Company had $12,006,075 in cash and cash equivalents. Net cash used in operating activities was $9,599,585 for the year ended December 31, 2015. Net loss for the year ended December 31, 2015 was $23,820,675. As of December 31, 2015, the Company had working capital of $10,971,423. On January 8, 2016, in connection with the Merger described in Note 17, the Company paid $3,261,044 in severance payments to former executives and employees. The Company expects to incur losses for the next several years as it plans to develop its TSC product candidate. The Company is unable to predict the extent of any further losses or when the Company will become profitable, if at all.

These financial statements have been prepared under the assumption that the Company will continue as a going concern. Due to the Company's recurring and expected continuing losses from operations and its present financial resources, the Company has concluded that there is substantial doubt in the Company's ability to continue as a going concern within one year of issuance on these financial statements without additional capital becoming available to fund planned Phase 2/3 and Phase 3 clinical trials, attain further operating efficiencies and, ultimately, to generate revenue. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

The Company will be required to raise additional capital within the next year to develop its trans sodium crocetinate product candidate and to fund operations at current cash expenditure levels. The Company cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that the Company raises additional funds by issuing equity securities, its stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact the Company's ability to conduct its business. If the Company is unable to obtain additional financing when needed, (i) it may be required to delay, scale back or discontinue the development and/or commercialization of one or more product candidates; (ii) seek collaborators for product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available; or (iii) relinquish or otherwise dispose of rights to technologies, product candidates or products that we would otherwise seek to develop or commercialize itself on unfavorable terms.

3. Summary of Significant Accounting Policies

Consolidation

The consolidated balance sheet at December 31, 2015 and 2014 consolidates the accounts of Canterbury, Hygeia, Paloma, VasculoMedics and ProElite, Inc. The consolidated statements of operations for the year ended December 31, 2015 and 2014 consolidate the accounts of Paloma and VasculoMedics from March 28, 2014, their date of acquisition. All significant intercompany balances were eliminated in consolidation.

Use of Estimates

The preparation of the Company's consolidated financial statements in accordance with U.S. GAAP requires the Company to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in the Company's consolidated financial statements and accompanying notes. Although these estimates are based on the Company's knowledge of current events and actions that the Company may undertake in the future, actual results may differ from such estimates and assumptions.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with maturities of three months or less to be cash equivalents.

Fair Value of Financial Instruments

The carrying value of certain of the Company's financial instruments, including cash and cash equivalents and accounts payable, approximate fair value due to their short maturities. Other information about the Company's assets and liabilities recorded at fair value is included in note 4.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. The Company records depreciation using the straight-line method over the following estimated useful lives:

Equipment (years)	3 – 5
Furniture and fixtures (years)	5
Leasehold improvements	Lesser of lease term or life of improvements

Long-Lived Assets

Long-lived assets are reviewed for potential impairment whenever events indicate that the carrying amount of such assets may not be recoverable. The Company does this by comparing the carrying value of the long-lived assets with the estimated future undiscounted cash flows expected to result from the use of the assets, including cash flows from disposition. If it is determined an impairment exists, the asset is written down to its estimated fair value.

Business Combinations

For all business combinations, the Company records all assets and liabilities of the acquired business, including goodwill and other identified intangible assets, at their fair values starting in the period when the acquisition is completed. Acquisition-related transaction costs are expensed as incurred.

Intangible Assets

Intangible assets as of December 31, 2015 and 2014 consisted of an identifiable in-process research and development ("IPR&D") project intangible asset arising from the acquisition of Paloma. Purchased intangible assets subject to amortization, are reviewed for impairment whenever events or circumstances indicate that the carrying amount of an asset may not be recoverable. Such events or circumstances include, but are not limited to, a significant decrease in the fair value of the underlying business, a significant decrease in the benefit realized from an acquired business, difficulties or delays in integrating the business or a significant change in the operations of an acquired business. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted future cash flows expected to be generated by the asset. An impairment charge is recognized by the amount by which the carrying amount of the asset exceeds its fair value.

The fair value of IPR&D projects acquired in a business combination are capitalized and accounted for as indefinite-lived intangible assets until the underlying project receives regulatory approval, at which point the intangible asset will be accounted for as a definite-lived intangible asset, or discontinuation, at which point the intangible asset will be recognized as an impairment charge. Research and development costs incurred after the acquisition are expensed as incurred.

Goodwill

Goodwill is the excess of the cost of an acquired entity over the net amounts assigned to tangible and intangible assets acquired and liabilities assumed. Goodwill is not amortized, but is subject to an annual impairment test. The Company has a single reporting unit and all goodwill relates to that reporting unit.

The Company performs its annual goodwill impairment test during the fourth quarter of its fiscal year or more frequently if changes in circumstances or the occurrence of events suggest that an impairment exists. If the fair value of the reporting unit is less than its carrying value, an impairment loss is recorded to the extent that the implied fair value of the reporting unit's goodwill is less than the carrying value of the reporting unit's goodwill.

Research and Development

All research and development costs are expensed as incurred.

Income Taxes

The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events included in the financial statements or tax returns. Under this method, deferred income taxes are recognized for the tax consequences in future years of differences between the tax bases of assets and liabilities and their financial reporting amounts at each year-end based on enacted tax laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount expected to be realized. The provision for income taxes represents the tax payable for the period and the change during the period in deferred tax assets and liabilities.

Stock-Based Compensation

Compensation cost is measured and recognized at fair value for all stock-based payments, including stock options. For stock options, the Company estimates fair value using the Black-Scholes option-pricing model, which requires assumptions, such as expected volatility, risk-free interest rate, expected life, and dividends. Stock-based compensation expense is recognized net of estimated forfeitures on a straight-line basis over the related service period of the awards taking into account the effects of the employees' expected exercise and post-vesting employment termination behavior, and is included in general and administrative expenses in the Company's consolidated statements of operations. For 2015 and 2014, the Company estimated a forfeiture rate of nil when computing stock based compensation expense and reassesses its estimated forfeiture rate periodically based on new facts and circumstances. The Company accounts for equity instruments issued to non-employees in accordance with ASC Topic 718 and Emerging Issues Tax Force ("EITF") Issue No. 96-18. The fair value of each stock option and warrant granted is estimated as of the grant date using the Black-Scholes option pricing model.

Basic and Diluted Loss Per Share

Basic loss per share is computed by dividing the net loss attributable to the Company by the weighted average number of shares of common stock outstanding for the period. Diluted loss per share is computed similar to basic loss per share except that the denominator is increased to include the number of additional shares of common stock that would have been outstanding if all of the Company's potential shares, warrants and stock options had been issued and if the additional shares were dilutive. The computation of diluted loss per share does not include the Company's stock options or warrants as such securities have an antidilutive effect on loss per share.

Because of their anti-dilutive effect, 7,793,072 and 8,472,013 shares of the Company's common stock equivalents comprised of stock options and warrants for the years ended December 31, 2015 and 2014, respectively, have been excluded from the calculation of diluted earnings per share.

Comprehensive Income (Loss)

The Company does not have items of other comprehensive income (loss) for the years ended December 31, 2015 or 2014; and therefore, comprehensive loss equals net loss for those years.

Recently Issued Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update ("ASU") 2014-09, "*Revenue from Contracts with Customers"* (ASC Topic 606). The core principle of the guidance is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To achieve that core principle, an entity should apply the following steps:

Step 1: Identify the contract(s) with a customer.
Step 2: Identify the performance obligation in the contract.
Step 3: Determine the transaction price.
Step 4: Allocate the transaction price to the performance obligations in the contract.
Step 5: Recognize revenue when (or as) the entity satisfies a performance obligation.

In July 2015, the FASB delayed the effective date of this guidance. As a result, this ASU will be effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period. Earlier application is permitted only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period. Entities have the option of applying either a full retrospective approach or a modified approach to adopt the guidance in the ASU. Although the Company currently does not have any revenues, it is evaluating the impact that this guidance will have on its results of operations, financial position and cash flows.

In August 2014, the FASB issued ASU 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* ("ASU 2014-15"). This pronouncement provides additional guidance surrounding the disclosure of going concern uncertainties in the financial statements and implementing requirements for management to perform interim and annual assessments of an entity's ability to continue as a going concern within one year of the date the financial statements are issued. The Company will adopt this guidance as of December 31, 2016. The Company will begin performing the periodic assessments required by ASU 2014-15 on its effective date.

In February 2016, the FASB issued ASU 2016-02, *Leases*. This pronouncement provides a comprehensive model for the identification of lease arrangements and their treatment in the financial statements of both lessees and lessors. The most significant impact of this new pronouncement is the removal of the distinction between operating and capital leases with assets and liabilities recognized in respect of all leases, subject to limited exceptions for short-term leases and leases of low value assets. Management is still assessing the full impact of adopting ASU 2016-02, and cannot yet assess if the impact will be material to the Company's financial position, results of operations or cash flows. The new guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years.

4. Acquisitions

Paloma and VasculoMedics Acquisitions

On March 3, 2014, the Company entered into an agreement and plan of merger with Paloma Acquisition, Inc., Paloma Pharmaceuticals, Inc. and David Sherris, Ph.D., as founding stockholder and holder representative, pursuant to which the Company agreed to acquire by virtue of a merger all of the outstanding capital stock of Paloma, with Paloma becoming a wholly-owned subsidiary of the Company. On March 28, 2014, the merger with Paloma was effected and the Company issued an aggregate of 2,500,000 shares of common stock to the holders of Paloma's common stock and its derivative securities, which included the assumption of promissory notes of Paloma in the aggregate amount (including both principal amount and accrued interest) of approximately $1,151,725, to be paid on the first anniversary of the closing date of the Paloma merger. On August 5, 2014, the Company repaid in full the then-outstanding balance including accrued interest of the Paloma assumed promissory notes, totaling $1,331,007. The notes were terminated upon their prepayment and there were no early termination fees. Interest expense incurred after acquisition was $179,282.

Also on March 3, 2014, the Company entered into an agreement and plan of merger with VasculoMedics Acquisition, Inc., VasculoMedics, Inc. and David Sherris, Ph.D. pursuant to which the Company agreed to acquire by virtue of a merger all of the outstanding capital stock of VasculoMedics, with VasculoMedics becoming a wholly owned subsidiary of the Company. The VasculoMedics merger was concurrently closed with and as a condition to the closing of the Paloma merger on March 28, 2014 and the Company issued an aggregate of 220,000 shares of common stock to the VasculoMedics stockholders.

The acquisitions of Paloma and VasculoMedics were additional steps in the implementation of the Company's plan to position itself as a specialty biopharmaceutical company. The total purchase consideration for the Paloma and VasculoMedics acquisitions was $6,800,000.

The transaction has been accounted for using the acquisition method of accounting which requires that assets acquired and liabilities assumed be recognized at their fair values as of the acquisition date. The valuation technique utilized to value the intangible assets was the cost approach. The following table summarizes the assets acquired and liabilities assumed as of the acquisition date:

Intangibles assets	$	6,449,628
Prepaids and other current assets		23,642
Property, plant and equipment		58,123
Goodwill		3,829,858
Accrued liabilities		(135,000)
Notes payable and accrued interest		(1,151,725)
Deferred tax liability		(2,274,526)
Net assets acquired	$	6,800,000

For the year ended December 31, 2014, expenses associated with the Paloma and VasculoMedics acquisitions were $846,910 included in the consolidated net loss of $14,352,824 for the year ended December 31, 2014. Acquisition-related costs related to the Paloma and VasculoMedics acquisitions were nominal. Due to the timing of this acquisition, it did not have a material impact on the Company's financial statements. As such, the Company has not presented pro forma disclosures.

5. Property and Equipment, Net

Property and equipment, net of accumulated depreciation at December 31, 2015 and 2014 consists of the following:

	December 31,	
	2015	2014
Computing equipment and office machines	$ 38,785	$ 16,072
Furniture and fixtures	35,196	32,945
Leasehold improvements	5,157	60,017
Total	79,138	109,034
Less accumulated depreciation	(21,143)	(6,719)
Property and equipment, net	$ 57,995	$ 102,315

For the year ended December 31, 2015, depreciation expense was $23,269. For the year ended December 31, 2014, depreciation expense was $11,924. For the years ended December 31, 2015 and 2014, the Company disposed of certain property and equipment, resulting in a loss on disposal of $49,278 and $6,056, respectively, which is included within general and administrative expenses on the condensed consolidated statements of operations.

6. Intangible Assets, Net

Intangible assets were as follows:

	December 31, 2015			December 31, 2014		
	Gross Carrying Amount	Accumulated Amortization	Intangible Assets, net	Gross Carrying Amount	Accumulated Amortization	Intangible Assets, net
In-process research and development costs (IPR&D)	$ 6,449,628	$ —	$ 6,449,628	$ 6,449,628	$ —	$ 6,449,628

During the second quarter of 2015, the Company performed its annual review for impairment of IPR&D intangible asset as prescribed in ASC 350 and determined that there had been no impairment to this asset. In connection with an impairment of the Company's goodwill as discussed in note 7 below, the Company re-assessed the IPR&D asset for impairment and concluded there was no impairment of the IPR&D asset for the year ended December 31, 2015.

For the years ending December 31, 2015 and 2014, the Company recorded amortization expense on finite lived intangible assets of $0 and $554,338, respectively, within depreciation and amortization on the consolidated statements of operations. In the fourth quarter of 2014, the Company strategically decided that its initial focus would be its development efforts with respect to RES-529 on ophthalmology (specifically age-related macular degeneration) and oncology (specifically glioblastoma multiforme) and RES-440 on dermatology (specifically acne vulgaris). Based on the Company's decision to abandon its development efforts on the Canterbury cosmeceutical finite lived intangible assets and the Canterbury IPR&D asset, the Company determined that the carrying value of such assets was no longer recoverable. The Company recorded an impairment of its intangible assets of $6,670,345 on its consolidated statements of operations as of December 31, 2014. The impairment consisted of $3,035,000 of impairment of the IPR&D asset and $3,635,345 of impairment of finite lived intangible assets.

7. Goodwill

Goodwill is the excess of the cost of an acquired entity over the net amounts assigned to tangible and intangible assets acquired and liabilities assumed. The Company applies ASC 350 "*Goodwill and Other Intangible Assets*," which requires testing goodwill for impairment on an annual basis. The Company assesses goodwill for impairment as part of its annual reporting process in the fourth quarter. In between valuations, the Company conducts additional tests if circumstances indicate a need for testing. The Company evaluates goodwill on a consolidated basis as the Company is organized as a single reporting unit.

The Company considers certain triggering events when evaluating whether an interim goodwill impairment analysis is warranted. Among these would be a significant long-term decrease in the market capitalization of the Company based on events specific to the Company's operations. The Company's market capitalization decreased significantly during second and third quarters of 2015 as the Company's share price declined from $2.80 per share as of April 30, 2015 to $0.90 per share as of September 30, 2015. As of September 30, 2015, the Company's market capitalization was approximately $16.7 million, falling to an amount significantly less than the Company's stockholders' equity. In September 2015, management concluded that given the significant and sustained decrease in the Company's share price to a level below its stockholders' equity at that time, combined with information on the Company's fair value derived from strategic discussions with third parties during the third quarter of 2015, a triggering event requiring an interim assessment of goodwill impairment had occurred during the third quarter of 2015. Management performed the goodwill impairment assessment using a market approach to estimating the fair value of the Company, using multiple inputs, some weighted heavier than others. The inputs included the Company's market capitalization at that time, which, based on the inactive trading activity in the Company's stock, was a lower level input on the fair value measurement hierarchy, and other more heavily weighted unobservable inputs as to the Company's fair value derived from strategic discussions with third parties. The initial step one assessment indicated that it was likely the Company's goodwill was impaired, and the Company proceeded to perform step two of its goodwill impairment assessment. As a result of that assessment, the Company concluded that a goodwill impairment loss of $11,070,991 was necessary. Following the recording of the goodwill impairment loss, the Company's goodwill as of September 30, 2015 was $985,000.

An annual impairment review was most recently completed on December 31, 2015. As of the December 31, 2015 impairment review, there was no additional impairment loss associated with recorded goodwill as the estimated fair value exceeded the carrying amount. The fair value of the reporting unit as of December 31, 2015, for the purpose of assessing the impairment of goodwill, was determined based on a qualitative assessment, utilizing the most recent baseline valuation that occurred on September 30, 2015, the market capitalization trend since the baseline valuation, and the then recently announced merger with Diffusion Pharmaceuticals LLC (See note 17 to the consolidated financial statements). The Company determined that it was more likely than not that the fair value of its businesses for accounting purposes exceeded the carrying amount, and therefore, indicated no impairment of goodwill. Following the December 31, 2015 annual impairment review of the goodwill, the Company's goodwill as of December 31, 2015 was $985,000.

8. Other Accrued Expenses and Liabilities

Other accrued expenses and liabilities consisted of the following:

	December 31,	
	2015	2014
Payroll related	$ 91,302	$ 741,032
Professional fees	101,151	217,663
Board fees	55,938	55,000
Rent liability for facilities no longer occupied	424,155	808,418
Severance	221,183	0
Franchise taxes	97,644	0
Other	176,319	99,180
	$ 1,167,692	$ 1,921,293

9. Stockholder's Equity

Preferred Stock

The Company has 5,000,000 shares of authorized, but unissued shares of preferred stock with a par value of $0.001 per share.

Common Stock

The Company has 1,000,000,000 shares of authorized common stock with a par value of $0.001 per share, of which 18,614,968 shares are issued and outstanding as of December 31, 2015.

Private Placements

On April 29, 2014, the Company issued to various institutional and individual accredited investors an aggregate of 2,776,500 shares of common stock and four-year warrants to purchase an aggregate of 832,950 shares of common stock. The price of each unit, which consisted of one share of common stock plus a warrant to purchase 0.3 share of common stock was $4.00. The exercise price of the warrant is $4.80 per share. In addition, on April 29, 2014, the Company issued to its placement agent as part of its compensation warrants to purchase 277,650 shares of common stock, on substantially the same terms as the warrants issued to investors. Also, on April 29, 2014, the Company issued a warrant to purchase 35,000 shares of common stock to its placement agent as compensation for a debt conversion transaction. The exercise price of the warrant is $4.80 per share.

On May 6, 2014, the Company issued to various institutional and individual accredited investors an aggregate of 3,418,125 shares of common stock and four-year warrants to purchase an aggregate of 1,025,438 shares of common stock. The price of each unit, which consisted of one share of common stock plus a warrant to purchase 0.3 share of common stock was $4.00. The exercise price of the warrant is $4.80 per share. In addition, on May 6, 2014, the Company issued to its placement agent as part of its compensation warrants to purchase 341,813 shares of common stock, on substantially the same terms as the warrants issued to investors.

On May 21, 2014, the Company issued to various institutional and individual accredited investors an aggregate of 872,310 shares of common stock and four-year warrants to purchase an aggregate of 261,693 shares of common stock. The price of each unit, which consisted of one share of common stock plus a warrant to purchase 0.3 share of common stock was $4.00. The exercise price of the warrant is $4.80 per share. In addition, on May 21, 2014, the Company issued to its placement agent as part of its compensation warrants to purchase 89,731 shares of common stock, on substantially the same terms as the warrants issued to investors.

On June 13, 2014, the Company issued to various institutional and individual accredited investors an aggregate of 1,778,750 shares of common stock and four-year warrants to purchase an aggregate of 533,625 shares of common stock. The price of each unit, which consisted of one share of common stock plus a warrant to purchase 0.3 share of common stock was $4.00. The exercise price of the warrant is $4.80 per share. In addition, on June 13, 2014, the Company issued to its placement agent as part of its compensation warrants to purchase 177,875 shares of common stock, on substantially the same terms as the warrants issued to investors.

On July 10, 2014, the Company issued to various institutional and individual accredited investors an aggregate of 50,000 shares of common stock and four-year warrants to purchase an aggregate of 15,000 shares of common stock. The price of each unit, which consisted of one share of common stock plus a warrant to purchase 0.3 share of common stock was $4.00. The exercise price of the warrant is $4.80 per share. In addition, on June 13, 2014, the Company issued to its placement agent as part of its compensation warrants to purchase 5,000 shares of common stock, on substantially the same terms as the warrants issued to investors.

Gross proceeds of the private placement to the Company were approximately $35.6 million and net proceeds were approximately $31.9 million, after paying $3.6 million of placement agent fees and $0.1 million of offering expenses. The Company filed a registration statement on Form S-1 with the SEC on July 14, 2014 registering the offering and resale of 11,633,885 shares of common stock, including the outstanding shares of common stock and shares of common stock issuable upon exercise of the warrants issued in the private placement. This registration statement was declared effective by the SEC on July 31, 2014.

Common Stock Issued in Settlement of Obligations

On April 29, 2014, the Company issued to its then Chairman of the Board 546,553 shares of common stock and a warrant to purchase 351,060 shares of common stock at an exercise price of $2.00 per share upon conversion of four convertible promissory notes in the aggregate principal amount of $1,050,000 issued by the Company. The Company recorded a loss on this conversion in the amount $1,650,378.

On May 21, 2014 the Company issued 259,236 shares of common stock to a creditor upon conversion of a promissory note in the principal amount of $500,000. On December 2, 2014, the Company issued 7,764 shares of common stock to two creditors upon conversion of promissory notes in the principal amount of $50,000. The Company recorded a loss on these settlements in the amount of $400,016.

The Company issued an aggregate of 160,056 shares of common stock to creditors, former directors and a former officer, pursuant to settlements of outstanding liabilities then owed to such individuals, and 53,457 shares of common stock and a warrant to purchase 16,037 shares of common stock as part of a settlement of outstanding amounts due to the law firm.

On October 21, 2014, the Company issued to a then member of the Company’s Board of Directors 100,000 shares of common stock and a warrant to purchase 75,000 shares of common stock at an exercise price of $4.80 per share upon conversion of a note payable in the principal amount of $200,000 issued by the Company. The Company recorded a loss on this conversion in the amount $257,394.

Stock Options

Options to purchase an aggregate of 3,011,498 shares of common stock were outstanding as of December 31, 2015, and options to purchase an aggregate of 1,861,952 shares of common stock were exercisable as of December 31, 2015.

During the year ended December 31, 2014, the Company issued options to purchase an aggregate of 438,131 shares, respectively, of common stock to non-employee members of the Company’s Board of Directors at a weighted average exercise price of $3.70 per share. These options have a ten-year term and vest in equal quarterly installments over three years. No such options were issued in 2015.

During the years ended December 31, 2015 and 2014, the Company issued options to purchase an aggregate of 6,650 and 2,849,050 shares of common stock to employees of the Company at a weighted average exercise price of $1.90 and $3.70 per share. These options have a ten-year term and vest in equal quarterly installments over three years.

Warrants

Warrants to purchase an aggregate of 4,781,574 shares of the Company's common stock were outstanding and exercisable as of December 31, 2015:

Issue Date	Number of Underlying Shares of Common Stock	Per Share Exercise Price	Expiration Date
February 2, 2011	2,000	100.00	February 2, 2016
February 23, 2011	1,500	100.00	February 23, 2016
March 15, 2011	1,200	100.00	March 15, 2016
April 6, 2011	2,000	100.00	April 6, 2016
April 15, 2011	1,200	100.00	April 15, 2016
April 26, 2011	2,500	100.00	April 26, 2016
April 29, 2011	3,000	100.00	April 29, 2016
June 26, 2011	104,057	65.00	June 26, 2016
June 26, 2011	52,028	100.00	June 26, 2016
July 1, 2011	5,300	65.00	July 1, 2016
May 23, 2012	30,000	30.00	May 23, 2017
July 1, 2012	10,000	75.00	July 1, 2017
August 20, 2012	90,000	38.00	August 20, 2017
March 27, 2013	173,917	3.00	March 27, 2018
March 17, 2014	15,000	4.90	March 17, 2019
April 29, 2014	832,950	4.80	April 29, 2018
April 29, 2014	277,650	4.80	April 29, 2018
April 29, 2014	35,000	4.80	April 29, 2018
April 29, 2014	351,060	2.00	April 29, 2018
May 6, 2014	1,025,438	4.80	May 6, 2018
May 6, 2014	341,813	4.80	May 6, 2018
May 21, 2014	261,693	4.80	May 21, 2018
May 21, 2014	89,731	4.80	May 21, 2018
June 13, 2014	533,625	4.80	June 13, 2018
June 13, 2014	177,875	4.80	June 13, 2018
June 13, 2014	16,037	4.80	June 13, 2018
July 10, 2014	15,000	4.80	July 10, 2018
July 10, 2014	5,000	4.80	July 10, 2018
October 21, 2014	75,000	4.80	October 21, 2018
December 8, 2014	250,000	3.75	December 8, 2019
	4,781,574		

During the year ended December 31, 2014, the Company issued to investors in its private placement warrants to purchase an aggregate of 2,668,706 shares of common stock at an exercise price of $4.80 per share and to the placement agent in the private placement as partial consideration for its services in connection with the private placement warrants to purchase an aggregate of 892,069 shares of common stock at an exercise price of $4.80 per share. The Company also issued the placement agent a warrant to purchase 35,000 shares of common stock at an exercise price of $4.80 per share as compensation for a debt conversion transaction. These warrants have a four-year term and were immediately vested and exercisable as of the date of grant.

In addition, during the year ended December 31, 2014, the Company issued to its then Chairman of the Board a warrant to purchase 351,060 shares of common stock at an exercise price of $2.00 per share in addition to 546,553 shares of common stock upon conversion of four convertible promissory notes of the Company in the aggregate principal amount of $1,050,000. See note 13 to the consolidated financial statements. This warrant has a four-year term and was immediately vested and exercisable as of the date of grant, resulting in Black-Scholes fair value of $803,221 included within "settlement loss on notes payable – related parties" on the consolidated statements of operations during the year ended December 31, 2014.

In addition, during the year ended December 31, 2014, the Company issued a warrant to purchase 75,000 shares of common stock at an exercise price of $4.80 per share in addition to 100,000 shares of common stock to a member of the Company's Board of Directors upon conversion of a non-interest bearing and unsecured note in the principal amount of $200,000. See note 13 to the consolidated financial statements. This warrant has a four-year term and was immediately vested and exercisable as of the date of grant, resulting in Black-Scholes fair value of $107,395 included within "settlement loss on notes payable – related parties" on the consolidated statements of operations during the year ended December 31, 2014.

In addition, during the year ended December 31, 2014, the Company issued to a law firm a four-year warrant to purchase 16,037 shares of common stock at an exercise price of $4.80 as part of a settlement of outstanding amounts due to the law firm. This warrant has a four-year term and was immediately vested and exercisable as of the date of grant, resulting in Black-Scholes fair value of $24,393 included within "general and administrative expenses" on the consolidated statements of operations during the year ended December 31, 2014.

In addition, during the year ended December 31, 2014, the Company issued to an independent consultant a warrant to purchase 15,000 shares of common stock at an exercise price of $4.90 in consideration for services. This warrant has a five-year term and vested in monthly installments over one year, resulting in 15,000 vested shares and a Black-Scholes warrant expense of $25,976 during the year ended December 31, 2014 and a mark to market adjustment of $516 during the year ended December 31, 2015. In addition, during the year ended December 31, 2014, the Company issued to its investor relations firm a warrant to purchase 250,000 shares of common stock at an exercise price of $3.75 in consideration for investor relations services for one year, which commenced on December 15, 2014 and ended in 2015. This warrant has a five-year term and was immediately vested and exercisable as of the date of grant, resulting in Black-Scholes warrant value of $517,576, of which $496,010and $21,566 was expensed in general and administrative expenses during the years ended December 31, 2015 and 2014.

The Company estimates the fair value of warrants using a Black-Scholes model that considers assumptions noted in the table below:

	2014
Risk-free interest rate	1.11 – 1.67%
Expected life in years	4.0 – 5.0
Expected volatility	64% - 66%
Expected dividend yield	—

10. Stock-Based Compensation

On March 5, 2015, the Company's Board of Directors approved the RestorGenex Corporation 2015 Equity Incentive Plan (the "2015 Equity Plan"), and on June 17, 2015, the Company's stockholders approved the 2015 Equity Plan. The 2015 Equity Plan allows for the issuance of up to a maximum of 2,500,000 shares of common stock in connection with the grant of stock-based awards, including stock options, restricted stock, restricted stock units, stock appreciation rights and other types of awards as deemed appropriate. In addition, the Company has granted several non-plan options.

As of December 31, 2015, a total of 3,004,848 and 2,500,000 were authorized under non-plan options and the 2015 Equity Plan, respectively, and the Company had 0 and 2,493,350 shares of common stock available under the non-plan options and 2015 Equity Plan. Options are granted with exercise prices equal to the fair value of the common stock on the date of grant.

The Company recognizes the fair value of stock-based awards granted in exchange for employee and non-employee services as a cost of those services. The Company recognizes stock-based compensation expense for option awards on a straight-line basis over the vesting period.

The following table summarizes the stock option compensation expense for employees and non-employees recognized in the Company's consolidated statements of operations for the period:

	December 31, 2015	December31, 2014
Research and development	$ 597,554	$ 526,331
General and administrative	1,497,532	1,080,616
Total stock-based compensation expense	$ 2,095,086	$ 1,606,947

The Company estimates the fair value of stock options using the Black-Scholes option pricing model. The Black-Scholes option pricing model requires the input of estimates, including the expected life of stock options, expected stock price volatility, the risk-free interest rate and the expected dividend yield. The Company calculates the expected life of stock options using the "simplified method" described in Staff Accounting Bulletin ("SAB") Topic 14, *Share-Based Payment*, where the expected term of awards granted is based on the midpoint between the vesting date and the end of the contractual term, as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate expected term. The expected stock price volatility assumption was estimated based upon historical volatility of the common stock of a group of the Company's peers that are publicly traded. The use of this assumption was based upon the Company repositioning itself as a specialty biopharmaceutical company in the fourth quarter of 2013. The risk-free interest rate was determined using U.S. Treasury rates with terms consistent with the expected life of the stock options. Expected dividend yield is not considered, as the Company has never paid dividends and currently has no plans of doing so during the term of the options. The Company estimates forfeitures at the time of grant and revises those estimates in subsequent periods if actual forfeitures differ from those estimates.

The Company uses historical data when available to estimate pre-vesting option forfeitures, and records stock-based compensation expense only for those awards that are expected to vest. The weighted-average fair value of the Company's options granted to employees was $1.90 and $3.71 per share, in 2015 and 2014, respectively. The fair value of each option grant is estimated on the date of grant using the Black-Scholes option pricing model using the following weighted-average assumptions:

	2015	2014
Risk-free interest rate	1.84%	1.82% - 2.03%
Expected life in years	6.0	6.0
Expected volatility	68%	70% - 71%
Expected dividend yield	—	—

Stock options outstanding that have vested or are expected to vest as of December 31, 2015 were as follows:

	Shares of Common Stock	Weighted-Average Per Share Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Vested	1,861,953	$ 4.22	6.7	$ -
Expected to vest	1,149,545	3.69	8.5	-
Total	3,011,498	$ 4.01	7.4	$ -

The aggregate intrinsic value amounts represent the difference between the exercise price and $1.00, the fair value of our common stock on December 31, 2015, for in-the-money options.

A summary of the Company's employee stock option activity is as follows:

	Outstanding			Exercisable		
	Number of Shares	Weighted-Average Per Share Exercise Price	Weighted-Average Remaining Contractual life (in years)	Number of Shares	Weighted-Average Per Share Exercise Price	Weighted-Average Remaining Contractual life (in years)
Outstanding at January 1, 2014	389,436	$ 11.77	3.9	367,110	$ 11.10	3.9
Granted	3,287,181	3.71				
Exercised	—	—				
Forfeited or expired	(28,370)	33.99				
Outstanding at December 31, 2014	3,648,247	$ 5.44	8.8	1,072,111	$ 9.49	7.2
Granted	6,650	1.90				
Exercised	—	—				
Forfeited or expired	(643,399)	6.28				
Outstanding at December 31, 2015	3,011,498	$ 4.01	7.4	1,861,952	$ 4.22	6.7

The completion of the Merger on January 8, 2016, as discussed in note 17, constituted a "change in control" under the Company's non-plan option agreements thereby resulting in automatic acceleration of vesting of all options outstanding as of the effective time of the Merger and such options remaining exercisable for the remainder of their terms.

As of December 31, 2015, the Company had $2,675,669 of total unrecognized compensation cost related to unvested stock-based compensation arrangements granted to employees. That cost was recognized in January 2016 due to the acceleration of vesting triggered by the Merger as explained above. Per share exercise prices for options outstanding at December 31, 2015 and 2014, ranged from $1.90 to $54.00.

11. Commitments and Contingencies

Office Space Rental

On September 4, 2014, the Company entered into a lease agreement for office space totaling approximately 2,900 square feet in Buffalo Grove, Illinois and relocated its corporate headquarters to this facility in the third quarter of 2014. The term of the lease commenced on September 15, 2014 and will continue through February 28, 2018. The Company has an option to renew the lease for one renewal term of three years. Under the lease agreement, the first five months are rent free and then the base rent will be approximately $6,000 per month through February 28, 2016 for a total of approximately $72,000 per year. The base rent will increase to approximately $6,100 per month for the first year thereafter and $6,200 per month for the second year thereafter.

The Company's contractual obligations with respect to rental commitments as of December 31, 2015 were as follows:

	Rental Commitments
Payments due by period:	
One year	$ 72,920
Two years	74,355
Three years	12,432
Four years	—
Five years	—
Over five years	—
Total	$ 159,707

Purchase Obligations

As of December 31, 2015, the Company had no material future commitments in regards to the preclinical development of RES-440 and RES-529.

Litigation

From time to time, the Company is subject to various pending or threatened legal actions and proceedings, including those that arise in the ordinary course of its business, which may include employment matters, breach of contract disputes and stockholder litigation. Such actions and proceedings are subject to many uncertainties and to outcomes that are not predictable with assurance and that may not be known for extended periods of time. The Company records a liability in its condensed consolidated financial statements for costs related to claims, including future legal costs, settlements and judgments, where the Company has assessed that a loss is probable and an amount can be reasonably estimated. If the reasonable estimate of a probable loss is a range, the Company records the most probable estimate of the loss or the minimum amount when no amount within the range is a better estimate than any other amount. The Company discloses a contingent liability even if the liability is not probable or the amount is not estimable, or both, if there is a reasonable possibility that a material loss may have been incurred. In the opinion of management, as of December 31, 2015, the amount of liability, if any, with respect to these matters, individually or in the aggregate, will not materially affect the Company's consolidated results of operations, financial position or cash flows.

On August 7, 2014, a complaint was filed in the Superior Court of Los Angeles County, California by Paul Feller, the Company's former Chief Executive Officer under the caption *Paul Feller v. RestorGenex Corporation, Pro Sports & Entertainment, Inc., ProElite, Inc. and Stratus Media Group, GmbH* (Case No. BC553996). The complaint asserts various causes of action, including, among other things, promissory fraud, negligent misrepresentation, breach of contract, breach of employment agreement, breach of the covenant of good faith and fair dealing, violations of the California Labor Code and common counts. The plaintiff is seeking, among other things, compensatory damages in an undetermined amount, punitive damages, accrued interest and an award of attorneys' fees and costs. On December 30, 2014, the Company filed a petition to compel arbitration and a motion to stay the action. On April 1, 2015, the plaintiff filed a petition in opposition to the Company's petition to compel arbitration and a motion to stay the action. After a hearing for the petition and motion on April 14, 2015, the Court granted the Company's petition to compel arbitration and a motion to stay the action. On January 8, 2016, the plaintiff filed an arbitration demand with the American Arbitration Association. No arbitration hearing has yet been scheduled. The Company believes this matter is without merit and intends to defend the arbitration vigorously. Because this matter is in an early stage, the Company is unable to predict its outcome and the possible loss or range of loss, if any, associated with its resolution or any potential effect the matter may have on the Company's financial position. Depending on the outcome or resolution of this matter, it could have a material effect on the Company's financial position.

On September 21, 2015, David Schmidt, a member of Diffusion, filed suit (the "Complaint") in the Circuit Court for Albemarle County (Virginia), which is proceeding as *Case. No. CL15-791, David G. Schmidt v. Diffusion Pharmaceuticals, LLC*. The primary claim asserted in the Complaint is a claim for breach of contract, with Mr. Schmidt asserting that Diffusion breached the terms of a $1.5 million convertible promissory note, dated December 15, 2009, which he elected to fully convert into membership units on the same day at the contractual per-unit conversion price of $3.50. Mr. Schmidt alleges that the anti-dilution provisions of the convertible promissory note and certain terms of the operating agreement entitle him to convert his note at the conversion price of $1 per unit, which was the conversion price that Diffusion subsequently renegotiated in 2012 with other noteholders who had not converted their notes. Mr. Schmidt contends that if he had converted his note at $1 per unit instead of $3.50 per unit, he would have received an additional 1,071,432.50 units. His claim for relief is an award of specific performance requiring Diffusion to issue him an additional 1,071,432.50 units or to pay damages equal to the value of such units. Mr. Schmidt also asserts tort claims for breach of fiduciary duty and conversion, together with a claim for unjust enrichment. These claims are all based on the alleged breaches of contract underpinning his claim for breach of contract.

Diffusion filed a Demurrer asking the court to dismiss the Complaint for failing to state a viable cause of action. Diffusion maintains that neither the convertible promissory note nor the operating agreement entitle Mr. Schmidt to receive a lower conversion price that was negotiated with other noteholders after he elected to convert his notes. Diffusion also seeks dismissal of the other claims on various grounds, including the economic loss rule (which generally prohibits tort claims arising out of a breach of contract) and the statute of limitations. A hearing on Diffusion's Demurrer was held on March 14, 2016, at which hearing the claim was dismissed for failing to state a viable cause of action. Mr. Schmidt has up to 21 days to file an amended, restated complaint. Management and legal counsel for Diffusion are of the opinion that the plaintiff's claim is without merit and Diffusion will prevail in defending the suit. Diffusion is unable to estimate the possible loss or range of loss should Diffusion not prevail in defending the suit.

12. Income Taxes

Significant components of the Company's deferred tax assets for federal income taxes consisted of the following:

	December 31,	
Deferred Tax Assets	**2015**	**2014**
Net operating loss carryforwards	$ 25,165,014	$ 23,030,884
Stock option compensation	6,937,512	6,083,848
Other	—	26,783
Valuation allowance	(32,102,526)	(29,141,515)
Net deferred tax asset	$ —	$ —
Deferred Tax Liabilities		
Intangible assets	$ (2,274,526)	$ (2,274,526)

During the year ended December 31, 2014, in conjunction with the accounting associated with the Paloma acquisition described in note 4 to the consolidated financial statements, the Company recorded a deferred tax liability related to tax basis differences associated with the acquired indefinite lived IPR&D intangible asset. As the entire deferred tax liability as of December 31, 2015 and 2014 relates to an indefinite lived intangible asset, which due to its indefinite life will not serve as reversible temporary differences that give rise to future taxable income; the Company maintains a full valuation allowance on its deferred tax assets, resulting in a net deferred tax liability position equal to the deferred tax liability on the Company's indefinite lived intangible asset.

The Company has no current tax provision due to its current and accumulated losses, which result in net operating loss carryforwards. The Company recorded a deferred tax benefit of $2,816,884 in the consolidated statements of operations for the year ended December 31, 2014 due primarily to the reduction in the Company's intangible assets resulting from the impairment loss on such assets recorded in 2014 and the amortization recorded on a portion of those impaired intangible assets prior to the date of the impairment.

The Company had net operating loss carry-forwards ("NOL") for federal and state income tax purposes of approximately:

	December 31,	
	2015	2014
Combined NOL Carryforwards:		
Federal	$ 63,013,194	$ 57,521,560
State	54,131,507	50,440,965

The net operating loss carryforwards begin expiring in 2020 for Federal income tax purposes and 2016 for state income tax purposes. From December 31, 2012 to December 31, 2015, the number of outstanding shares of our common stock increased from 890,837 to 18,614,968. In January 2016, the number of outstanding shares of common stock further increased to 101,578,512 following completion of the Merger discussed in note 17. This increase in the number of shares outstanding constitutes a change of ownership, under the provisions of Internal Revenue Code Section 382 and similar state provisions, and is likely to significantly limit the Company's ability to utilize these net operating loss carryforwards to offset future income. Accordingly, the Company recorded a 100% valuation allowance of the deferred tax assets as of December 31, 2015 and December 31, 2014 because of the uncertainty of their realization.

A reconciliation of the income tax rate computed at the federal statutory rate to that recorded in the financial statements for 2015 and 2014 is as follows:

	2015		2014	
Rate reconciliation:				
Federal tax benefit at statutory rate	$ (8,337,236)	(35.0%)	$ (6,009,398)	(35.0%)
State tax, net of Federal benefit	(1,368,216)	(5.7%)	(986,051)	(5.7%)
Change in valuation allowance	2,961,011	12.4%	2,866,582	10.9%
Goodwill impairment	4,510,986	18.9%	—	—
Other	2,233,455	9.4%	1,311,983	13.4%
Total provision	$ —	0.0%	$ (2,816,884)	(16.4%)

13. Employee Benefit Plan

The Company sponsors a defined contribution 401(k) retirement savings plan (the "401(k) Plan") covering all of its employees. Employee contributions to the 401(k) Plan are voluntary. Participants' contributions are limited to their annual tax deferred contribution limit as allowed by the Internal Revenue Service. There were matching contributions of $22,950 and $0 for the years ended December 31, 2015 and 2014, respectively. The Company terminated the 401(k) Plan in connection with the Merger. See note 17 to the consolidated financial statements.

14. Basic and Diluted Net Loss Per Share

Basic net loss per share is computed by dividing the net loss by the weighted average number of shares of common stock outstanding for the period. Diluted net loss per share is computed similar to basic net loss per share except that the denominator is increased to include the number of additional shares of common stock that would have been outstanding if all of the Company's potential shares, warrants and stock options had been issued and if the additional shares are dilutive.

Because of their anti-dilutive effect, all stock options and warrants for the years ended December 31, 2015 and 2014, respectively, have been excluded from the calculation of diluted net loss per share.

	Years Ended December 31,	
	2015	2014
Basic and dilutive numerator:		
Net loss, as reported	$ (23,820,675)	$ (14,352,824)
Denominator:		
Weighted-average shares outstanding	18,614,968	14,299,473
Net loss per share - basic and diluted	$ (1.28)	$ (1.00)

15. Investment in Or-Genix Therapeutics, Inc.

In April 2015, the Company entered into several agreements with Or-Genix Therapeutics, Inc. ("Or-Genix"), pursuant to which the Company transferred certain of its non-focus technology rights to Or-Genix in exchange for a 19.9% ownership interest in Or-Genix, representing 2,484,395 shares of the common stock of Or-Genix, and purchased $250,000 in perpetual non-redeemable preferred stock which is included in other assets as of December 31, 2015. The rights the Company transferred include exclusive rights to a compound formerly known as "RES-102," which is a "soft" estrogen potentially to be developed for the treatment of aging skin fragility/thinning and vulvo-vaginal atrophy, and exclusive rights to a compound formerly known as "RES-214," a non-prescription cosmeceutical product under development by a sublicensee. The Company previously licensed these rights from Yale University and as part of this transaction assigned those license agreements to Or-Genix. The Company also assigned its rights under a sublicense agreement with Ferndale Pharma Group, Inc. for the formulation, manufacture, sale and marketing of RES-214. As the rights exchanged for the common stock investment had a recorded value of zero as of the transaction date, and as the common stock transaction was a non-monetary exchange, no value was assigned to the common stock portion of the Company's Or-Genix investment and no gain or loss was recognized as a result of the transaction. Or-Genix is founded and owned primarily by Yael Schwartz, Ph.D., a former member of the Company's Board of Directors and former Executive Vice President, Preclinical Development. The transfer of these technology rights to Or-Genix was executed since the Company is focusing its development efforts and resources on its other technologies. The Company does not control nor exercise significant influence over Or-Genix.

16. Former Employee Severance Expense

On April 30, 2015, the Company entered into resignation agreements with the Company's former Executive Vice President, Preclinical Development and former Vice President of Pharmaceutical Sciences. As part of these resignation agreements, the Company modified their stock option agreements to provide for continued vesting until June 30, 2015 and to extend the post-termination exercise period from 90 days to one year, resulting in a minimal amount of additional stock-based compensation expense. On June 19, 2015, the Company entered into a resignation agreement with the Company's former Chief Scientific Officer. Costs associated with the resignation agreements, consisting primarily of severance-related charges, are reflected in the former employee severance expense section in the condensed consolidated statement of operations for the year ended December 31, 2015. $221,183 related to these charges was included in other accrued liabilities as of December 31, 2015.

17. Subsequent Event

Merger with Diffusion LLC

On January 8, 2016, the Company, through a subsidiary, completed the Merger with and into Diffusion LLC pursuant to the Merger Agreement and, as a result, Diffusion LLC became a wholly-owned subsidiary of the Company creating a combined company that is a clinical stage biotechnology company focused on developing therapeutics for the treatment of certain cancers. In connection with the Merger, the Company issued to the holders of outstanding units of Diffusion LLC an aggregate of 82,963,544 shares of Common Stock and, as a result, immediately following the completion of the Merger, the former equity holders of Diffusion LLC owned approximately 84.1% of the Common Stock of the Company and the stockholders of RestorGenex immediately prior to the Merger owned approximately 15.9% of the Common Stock of the combined company, in each case, on a fully-diluted basis (subject to certain exceptions and adjustments). Also in connection with the Merger, the pre-Merger directors and officers of the Company tendered their resignations and the pre-Merger directors and officers of Diffusion LLC were appointed as the new directors and officers of the Company, and our corporate headquarters moved from Buffalo Grove, Illinois to Charlottesville, Virginia. Following the completion of the Merger, the Company changed its corporate name from "RestorGenex Corporation" to "Diffusion Pharmaceuticals Inc." and changed the trading symbol of the Company's common stock from "RESX" to "DFFN."

At the effective time of the Merger, each outstanding unit of membership interest of Diffusion ("Diffusion Units") was converted into the right to receive 3.652658 shares of the Company's common stock, as determined pursuant to the Merger Agreement ("Exchange Ratio"). Also at the effective time of the Merger, $1,125,000 of Diffusion convertible notes were outstanding and the rights of the holders of each outstanding convertible promissory note convertible into Diffusion Units ("Diffusion Convertible Notes") was converted into the right to convert such securities into a number of shares of the Company's common stock equal to the number of Diffusion Units such Diffusion Convertible Note would be convertible into pursuant to its terms multiplied by the Exchange Ratio. In addition, at the effective time of the Merger and as a result of the Merger, all outstanding options to purchase Diffusion Units were converted into and became options to purchase the Company's common stock on terms substantially identical to those in effect prior to the effective time of the Merger, except for adjustments to the underlying number of shares and the exercise price based on the Exchange Ratio. As a result of the Merger, and taking into account the adjustments to the number of shares and exercise price as a result of the Merger, we assumed options to purchase Diffusion Units which converted into options to purchase an aggregate of 14,952,101 shares of the Company's common stock with a weighted average exercise price of $0.40 per share. No fractional shares of the Company's common stock were issued in connection with the Merger, and holders of Diffusion Units received cash in lieu thereof.

For accounting purposes, the Merger is treated as a "reverse acquisition" under generally acceptable accounting principles in the United States ("U.S. GAAP") and Diffusion LLC is considered the accounting acquirer. Accordingly, Diffusion LLC's historical results of operations will replace the Company's historical results of operations for all periods prior to the Merger and, for all periods following the Merger, the results of operations of the combined company will be included in the Company's financial statements.

During 2015, the Company incurred transaction costs of $1,193,115 in connection with the Merger that were incurred and expensed within "general and administrative expenses" on the consolidated statements of operations during the year ended December 31, 2015.

The completion of the Merger constituted a "change in control" under the Company's non-plan option agreements thereby resulting in automatic acceleration of vesting of all options outstanding as of the effective time of the Merger and such options remaining exercisable for the remainder of their terms. In addition, because of the termination of employment of the Company's officers and employees in connection with the Merger, the Company incurred approximately $3,039,860 in severance costs during the first quarter of 2016, which amounts were paid to the affected employees in January 2016.

Contingent Value Rights Distribution

Prior to the effective time of the Merger, the Company's Board of Directors authorized, declared and effected a distribution of contingent value rights ("CVRs") to existing stockholders of the Company as of the close of business on January 7, 2016 (the "CVR Record Date") at a rate of one CVR for each share of the Company's common stock. The CVRs, which are not certificated and not attached to the shares of the Company's common stock, were payable immediately prior to the effective time. Each CVR represents a non-transferable right (subject to certain limited exceptions) to potentially receive certain cash payments in the event the Company receives net cash payments during the five-year period after the Merger as a result of the sale, transfer, license or similar transaction relating to the Company's product currently known as RES-440, which is a "soft" anti-androgen, upon the terms and subject to the conditions set forth in a contingent value rights agreement, dated January 8, 2016, between the Company and Computershare, Inc., as rights agent (the "CVR Agreement"). The aggregate cash payments to be distributed to the holders of the CVRs, if any, will be equal to the amount of net cash payments received by the Company as a result of the sale, transfer, license or similar transaction relating to RES-440, as determined pursuant to the CVR Agreement, but will not exceed $50 million in the aggregate. Any option or warrant holder of the Company as of the record date for the CVRs would, at the time of exercise, be entitled to receive one CVR for each share of the Company's common stock issued upon the future exercise of the option or warrant, which would entitle the holder to a pro rata portion of any CVR payments made after the date of exercise.

Voting and Lock-Up Agreements

On January 8, 2016, the Company entered into a voting and lock-up agreement with each of the pre-closing directors and executive officers of the Company and Diffusion, who collectively held approximately 16.6% of the outstanding common stock of the combined company after the Merger, pursuant to which such persons agreed, for six months after the Merger, to vote all of their respective shares of common stock owned after the Merger for such proposals that are reasonably presented by the Company's Board of Directors and to not sell, pledge, encumber or take certain other actions with respect to such shares.

Assumption of Diffusion Indebtedness

As a result of the Merger, all of the outstanding indebtedness of Diffusion became the obligation of the Company. As of the closing date of the Merger, there was $1,125,000 of principal amount of notes outstanding (the "Notes") with an aggregate of approximately $38,264 of interest accrued thereon, of which $550,000, $325,000, $50,000 and $200,000 of principal amount were issued as Series B, Series C, Series E and Series F Notes, respectively. The Series B Notes were issued in March 2011, mature June 2018 and, as a result of the completion of the Merger, are convertible into the Company's common stock at a conversion price of $0.273773236 per share. The Series C notes were issued in September 2012, mature March 2016 and, as a result of the completion of the Merger, are convertible into the Company's common stock at a conversion price of $0.273773236 per share. The Series E Notes were issued in June 2014, mature June 2018 and, as a result of the completion of the Merger, are convertible into the Company's common stock at a conversion price of $0.410659854 per share. The Series F Notes were issued in December 2015, mature December 2019 and, as a result of the completion of the Merger, are convertible into the Company's common stock at a conversion price of $0.547546472. Immediately following the Effective Time, the Notes were convertible into an aggregate of 3,821,571 shares of the Company's common stock.

All of the Notes bear interest at a rate of 1.0% per annum and are convertible into shares of Company's common stock at the holder's discretion. In the event a holder does not convert prior to a Note's maturity date, the entire principal amount and all accrued interest are due and payable on such date. The Notes are subject to acceleration in the case of certain customary events of default, including failure to make payments on the Notes when due and certain bankruptcy events, and the conversion prices are subject to adjustment in the case of certain dilutive company events.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

The term "disclosure controls and procedures" means our controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

We carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a – 15(e) and 15d – 15(e)). Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of the end of the period covered in this report, our disclosure controls and procedures were effective to ensure that information required to be disclosed in reports filed under the Exchange Act is recorded, processed, summarized and reported within the required time periods and is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Our principal executive officer and principal financial officer do not expect that our disclosure controls or internal controls will prevent all error and all fraud. Although our disclosure controls and procedures were designed to provide reasonable assurance of achieving their objectives, a control system, no matter how well conceived and operated, can provide only reasonable, not absolute assurance that the objectives of the system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented if there exists in an individual a desire to do so. There can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, our management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control—Integrated Framework (1992) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on that evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2015.

Attestation Report of the Independent Registered Public Accounting Firm

This report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our independent registered public accounting firm pursuant to Section 989G of the Dodd-Frank Wall Street Reform and Consumer Protection Act, which exempts smaller reporting companies from the auditor attestation requirement.

Change in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting that occurred during our fourth quarter ended December 31, 2015 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information with respect to this item will be set forth in the Proxy Statement for the 2015 Annual Meeting of Stockholders ("Proxy Statement") or an amendment to this Annual Report on Form 10-K ("Form 10-K/A") under the headings "Election of Directors," "Executive Officers," "Section 16(a) Beneficial Ownership Reporting Compliance" and "Corporate Governance" and is incorporated herein by reference. The Proxy Statement or Form 10-K/A will be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report.

Code of Conduct and Ethics

Our Code of Conduct and Ethics applies to all of our employees, officers and directors, including our principal executive officer and principal financial officer, and meets the requirements of the Securities and Exchange Commission. A copy of our Code of Conduct and Ethics is filed as an exhibit to this report. We intend to satisfy the disclosure requirements of Item 5.05 of Form 8-K regarding amendments to or waivers from any provision of our Code of Conduct and Ethics by posting such information on our corporate website located at www.diffusionpharma.com.

ITEM 11. EXECUTIVE COMPENSATION

Information with respect to this item will be set forth in the Proxy Statement or Form 10-K/A under the headings "Executive Compensation" and "Director Compensation," and is incorporated herein by reference. The Proxy Statement or Form 10-K/A will be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report.

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

Stock Ownership

Information with respect to this item will be set forth in the Proxy Statement or Form 10-K/A under the headings "Stock Ownership" and is incorporated herein by reference. The Proxy Statement or Form 10-K/A will be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table and notes provide information about shares of our common stock that may be issued under all of our equity compensation plans as of December 31, 2015.

Plan Category	(a) Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	(b) Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	(c) Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders (1)	6,650	$ 1.90	2,493,350
Equity compensation plans not approved by security holders (2)	3,004,848	$ 2.57	0
Total	3,011,498	$ 2.57	2,493,350

(1) Represents options to purchase shares of our common stock granted under the RestorGenex 2015 Equity Incentive Plan, which was approved by our stockholders on June 17, 2015. The exercise price of the options is equal to the fair market value of the common stock on the date of grant. The options vest quarterly over three years and expire on the ten-year anniversary of the date of grant.

(2) Represents non-plan options to purchase shares of our common stock granted to directors, officers and employees. The exercise price of the options is equal to the fair market value of the common stock on the date of grant. Most of the options vest quarterly over three years and expire on the ten-year anniversary of the date of grant.

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

Information with respect to this item will be set forth in the Proxy Statement or Form 10-K/A under the headings “Certain Relationships and Related Party Transactions” and “Corporate Governance” and is incorporated herein by reference. The Proxy Statement or Form 10-K/A will be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Information with respect to this item will be set forth in the Proxy Statement or Form 10-K/A under the heading “Ratification of the Selection of Independent Registered Public Accounting Firm,” and is incorporated herein by reference. The Proxy Statement or Form 10-K/A will be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

Our financial statements are included in Item 8 of Part II of this report.

The exhibits to this report are listed on the Exhibit Index to this report. A copy of any of the exhibits listed will be furnished at a reasonable cost, upon receipt from any person of a written request for any such exhibit. Such request should be sent to Diffusion Pharmaceuticals Inc., 2020 Avon Court, #4, Charlottesville, Virginia 22902, Attention: Stockholder Information. The Exhibit Index indicates each management contract or compensatory plan or arrangement required to be filed as an exhibit to this report.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: March 25, 2016

DIFFUSION PHARMACEUTICALS INC.

By: /s/ David G. Kalergis
David G. Kalergis
Chairman and Chief Executive Officer
(Principal Executive Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name and Signature	Title	Date
/s/ David G. Kalergis David G. Kalergis	Chairman of the Board and Chief Executive Officer (Principal Executive Officer)	March 25, 2016
/s/ Ben Shealy Ben Shealy	Senior Vice President, Finance (Principal Financial and Accounting Officer)	March 25, 2016
/s/ John L. Gainer, Ph.D. John L. Gainer, Ph.D.	Director	March 25, 2016
/s/ Thomas Byrne Thomas Byrne	Director	March 25, 2016
/s/ Robert Adams Robert Adams	Director	March 25, 2016
/s/ Mark T. Giles Mark T. Giles	Director	March 25, 2016
/s/ Alan Levin Alan Levin	Director	March 25, 2016

DIFFUSION PHARMACEUTICALS INC.
EXHIBIT INDEX TO ANNUAL REPORT ON FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2015

Exhibit No.	Description	Method of Filing
2.1	Agreement and Plan of Merger between Pro Sports & Entertainment, Inc. and the Company dated August 20, 2007	Incorporated by reference to Exhibit 10.1 to the registrant's current report on Form 8-K filed March 14, 2008 (SEC File No. 0-24477)
2.2	Amendment to Agreement and Plan of Merger between Pro Sports & Entertainment, Inc. and the Company dated March 10, 2008	Incorporated by reference to Exhibit 10.2 to the registrant's current report on Form 8-K filed March 14, 2008 (SEC File No. 0-24477)
2.3	Agreement and Plan of Merger dated as of September 2013 among the Company, Canterbury Acquisition, LLC, Hygeia Acquisition, Inc., Canterbury Laboratories, LLC, Hygeia Therapeutics, Inc., and Yael Schwartz, Ph.D.*	Incorporated by reference to Exhibit 10.1 to the registrant's current report on Form 8-K filed on October 2, 2013 (SEC File No. 0-24477)
2.4	Agreement and Plan of Merger dated as of February 25, 2014 among the Company, Paloma Acquisition, Inc., Paloma Pharmaceuticals, Inc. and David Sherris, Ph.D.*	Incorporated by reference to Exhibit 2.1 to registrant's current report on Form 8-K filed on March 7, 2014 (SEC File No. 0-24477)
2.5	Agreement and Plan of Merger dated as of February 25, 2013 among the Company, VasculoMedics Acquisition, Inc., VasculoMedics, Inc. and David Sherris, Ph.D.*	Incorporated by reference to Exhibit 2.2 to the registrant's current report on Form 8-K filed on March 7, 2014 (SEC File No. 0-24477)
2.6	Plan of Conversion, dated June 18, 2015	Incorporated by reference to Exhibit 2.1 to the registrant's current report on Form 8-K filed on June 18, 2015 (SEC File No. 0-24477)
2.7	Agreement and Plan of Merger dated as of December 15, 2015 among the Company, Arco Merger Sub, LLC and Diffusion Pharmaceuticals LLC *	Incorporated by reference to Exhibit 2.1 to the registrant's current report on Form 8-K filed on December 15, 2015 (SEC File No. 0-24477)
3.1	Articles of Conversion, as filed with the Secretary of State of the State of Nevada on June 18, 2015	Incorporated by reference to Exhibit 3.1 to the registrant's current report on Form 8-K filed on June 18, 2015 (SEC File No. 0-24477)

Exhibit No.	Description	Method of Filing
3.2	Certificate of Conversion, as filed with the Secretary of State of the State of Delaware on June 18, 2015	Incorporated by reference to Exhibit 3.2 to the registrant's current report on Form 8-K filed on June 18, 2015 (SEC File No. 0-24477)
3.3	Certificate of Incorporation of Diffusion Pharmaceuticals Inc., as amended	Filed herewith
3.4	Bylaws of Diffusion Pharmaceuticals Inc., as amended	Filed herewith
4.1	Form of Debt Conversion Agreement effective May 2, 2013 among the Company and two holders of the Company's Promissory Notes	Incorporated by reference to Exhibit 10.01 to the registrant's current report on Form 8-K filed on June 18, 2013 (SEC File No. 0-24477)
4.2	Form of Warrant issued to Investors in the 2014 Private Placement by the Company	Incorporated by reference to Exhibit 4.1 to the registrant's current report on Form 8-K filed on April 29, 2014 (SEC File No. 0-24477)
4.3	Form of Registration Rights Agreement entered into by and among the Company and Investors in the 2014 Private Placement	Incorporated by reference to Exhibit 10.2 to the registrant's current report on Form 8-K filed on April 29, 2014 (SEC File No. 0-24477)
4.4	Warrant, dated April 29, 2014, issued by the Company to Sol J. Barer, Ph.D.	Incorporated by reference to Exhibit 4.4 to the registrant's annual report on Form 10-K for the fiscal year ended December 31, 2014 (SEC File No. 0-24477)
4.5	Warrant, dated October 21, 2014, issued by the Company to Isaac Blech	Incorporated by reference to Exhibit 4.5 to the registrant's annual report on Form 10-K for the fiscal year ended December 31, 2014 (SEC File No. 0-24477)
4.6	Debt Conversion Agreement effective October 21, 2014 between the Company and Isaac Blech	Incorporated by reference to Exhibit 4.6 to the registrant's annual report on Form 10-K for the fiscal year ended December 31, 2014 (SEC File No. 0-24477)

Exhibit No.	Description	Method of Filing
4.7	Form of Diffusion Pharmaceuticals LLC Convertible Note Agreement	Filed herewith
10.1	Form of Stockholder Voting and Lock-Up Agreement in connection with Agreement and Plan of Merger dated as of December 15, 2015 among the Company, Arco Merger Sub, LLC and Diffusion Pharmaceuticals LLC	Incorporated by reference to Exhibit 10.1 to the registrant's current report on Form 8-K filed on January 8, 2016 (SEC File No. 0-24477)
10.2	Contingent Value Rights Agreement, dated as of January 8, 2016, by and between the Company and Computershare, Inc., as Rights Agent	Incorporated by reference to Exhibit 10.2 to the registrant's current report on Form 8-K filed on January 8, 2016 (SEC File No. 0-24477)
10.3	Form of Indemnification Agreement between the Company and each of its Directors and Officers**	Filed herewith
10.4	Diffusion Pharmaceuticals Inc. 2015 Equity Incentive Plan	Incorporated by reference to Exhibit 10.2 to the registrant's current report on Form 8-K as filed on June 18, 2015 (SEC File No. 0-24477)
10.5	Form of Incentive Stock Option Agreement under the Diffusion Pharmaceuticals Inc. 2015 Equity Incentive Plan	Incorporated by reference to Exhibit 10.3 to the registrant's current report on Form 8-K filed on June 18, 2015 (SEC File No. 0-24477)
10.6	Form of Non-Statutory Stock Option Agreement under the Diffusion Pharmaceuticals Inc. 2015 Equity Incentive Plan	Incorporated by reference to Exhibit 10.4 to the registrant's current report on Form 8-K filed on June 18, 2015 (SEC File No. 0-24477)
10.7	Resignation Agreement, dated April 30, 2015, between the Company and Yael Schwartz, Ph.D.**	Incorporated by reference to Exhibit 10.1 to the registrant's current report on Form 8-K filed on May 1, 2015 (SEC File No. 0-24477)
10.8	Executive Employment Agreement dated November 18, 2013 between the Company and Yael Schwartz, Ph.D.**	Incorporated by reference to Exhibit 10.2 to the registrant's current report on Form 8-K filed on November 22, 2013 (SEC File No. 0-24477)

Exhibit No.	Description	Method of Filing
10.9	Executive Employment Agreement dated March 5, 2014 between the Company and Stephen Simes**	Incorporated by reference to Exhibit 10.01 to the registrant's current report on Form 8-K filed on March 10, 2014 (SEC File No. 0-24477)
10.10	Executive Employment Agreement dated March 31, 2014 between the Company and David Sherris, Ph.D.**	Incorporated by reference to Exhibit 10.1 to the registrant's current report on Form 8-K filed on April 2, 2014 (SEC File No. 0-24477)
10.11	Executive Employment Agreement dated May 27, 2014 between the Company and Phillip Donenberg**	Incorporated by reference to Exhibit 10.1 to the registrant's current report on Form 8-K filed on May 30, 2014 (SEC File No. 0-24477)
10.12	Addendum to Executive Employment Agreement of Yael Schwartz, effective July 1, 2014, between the Company and Yael Schwartz**	Incorporated by reference to Exhibit 10.8 to the registrant's quarterly report on Form 10-Q for the fiscal quarter ended June 30, 2014 (SEC File No. 0-24477)
10.13	Addendum to Executive Employment Agreement of David Sherris, effective July 2, 2014, between the Company and David Sherris**	Incorporated by reference to Exhibit 10.5 to the registrant's quarterly report on Form 10-Q for the fiscal quarter ended September 30, 2014 (SEC File No. 0-24477)
10.14	Form of Stock Option Agreement between the Company and its former Executive Officers**	Incorporated by reference to Exhibit 10.12 to the registrant's annual report on Form 10-K for the fiscal year ended December 31, 2014 (SEC File No. 0-24477)
10.15	Form of Stock Option Agreement between the Company and its former Directors**	Incorporated by reference to Exhibit 10.13 to the registrant's annual report on Form 10-K for the fiscal year ended December 31, 2014 (SEC File No. 0-24477)
10.16	Option dated January 25, 2012 between the Company and Isaac Blech	Incorporated by reference to Exhibit 4.2 to the registrant's current report on Form 8-K filed January 31, 2012 (SEC File No. 0-24477)

Exhibit No.	Description	Method of Filing
10.17	Form of Subscription Agreement, dated as of April 29, 2014, among the Company and the Investors in the 2014 Private Placement	Incorporated by reference to Exhibit 10.1 to the registrant's current report on Form 8-K as filed on April 29, 2014 (SEC File No. 0-24477)
10.20	Securities Purchase Agreement dated May 24, 2011 among the Company and the Selling Stockholders party thereto	Incorporated by reference to Exhibit 10.01 to the registrant's current report on Form 8-K filed May 27, 2011 (SEC File No. 0-24477)
10.21	Registration Rights Agreement dated November 18, 2013 between the Company and Certain Holders	Incorporated by reference to Exhibit 10.4 to the registrant's current report on Form 8-K filed on November 22, 2013 (SEC File No. 0-24477)
10.22	Lease Agreement dated as of September 4, 2014 by and between the Company and Riverwalk South, L.L.C.	Incorporated by reference to Exhibit 10.1 to the registrant's current report on Form 8-K as filed on September 10, 2014 (SEC File No. 0-24477)
10.23	Amendment to Settlement Agreement and Stipulation, dated as of June 6, 2014, between the Company and ASC Recap LLC	Incorporated by reference to Exhibit 10.2 to the registrant's current report on Form 8-K as filed on June 9, 2014 (SEC File No. 0-24477)
10.24	Form of Diffusion Pharmaceuticals LLC Stock Option Award Agreement	Filed herewith
21.1	Subsidiaries of the Company	Filed herewith
23.1	Consent of Deloitte & Touche LLP, independent registered public accounting firm	Filed herewith
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 and SEC Rule 13a-14(a)	Filed herewith
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 and SEC Rule 13a-14(a)	Filed herewith

Exhibit No.	Description	Method of Filing
32.1	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Furnished herewith
32.2	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Furnished herewith
101	The following materials from the registrant's annual report on Form 10-K for the year ended December 31, 2015, formatted in XBRL (Extensible Business Reporting Language): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Cash Flows, and (iv) Notes to Consolidated Financial Statements	Filed herewith

* All exhibits and schedules to this agreement have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The registrant will furnish the omitted exhibits and schedules to the SEC upon request by the SEC.

** A management contract or compensatory plan or arrangement.

CERTIFICATE OF INCORPORATION OF DIFFUSION PHARMACEUTICALS INC. (AS AMENDED)

ARTICLE I
NAME

The name of the corporation is Diffusion Pharmaceuticals Inc. (the "Corporation").

ARTICLE II
REGISTERED OFFICE AND AGENT

The address of the registered office of the Corporation in the State of Delaware is 615 South Dupont Hwy., in the City of Dover, Zip Code of 19901, County of Kent. The name of the registered agent of the Corporation at that address is National Corporate Research, Ltd.

ARTICLE III
PURPOSE

The purpose of the Corporation is to engage in any lawful act or activity for which a corporation may be organized under the General Corporation Law of the State of Delaware ("DGCL").

ARTICLE IV
CAPITAL STOCK

A. The total number of shares of common stock which the Corporation shall have authority to issue is 1,000,000,000, at a par value of $0.001 per share ("Common Stock"), and the total number of shares of preferred stock which the Corporation shall have authority to issue is 5,000,000, at a par value of $0.001 per share ("Preferred Stock").

1. Common Stock. All preferences, voting powers, relative, participating, optional or other special rights and privileges, and qualifications, limitations, or restrictions of the Common Stock are expressly made subject and subordinate to those that may be fixed with respect to any shares of the Preferred Stock. Except as otherwise required by law or this Certificate of Incorporation, each share of Common Stock shall entitle the holder thereof to one (1) vote, in person or by proxy, on each matter submitted to a vote of stockholders of the Corporation. Subject to the preferential rights of the Preferred Stock, the holders of shares of Common Stock shall be entitled to receive, when and if declared by the Board of Directors, out of the assets of the Corporation which are by law available therefor, dividends payable either in cash, in property or in shares of capital stock. In the event of any dissolution, liquidation or winding up of the affairs of the Corporation, after distribution in full of the preferential amounts, if any, to be distributed to the holders of shares of the Preferred Stock, holders of Common Stock shall be entitled, unless otherwise provided by law or this Certificate of Incorporation, to receive all of the remaining assets of the Corporation of whatever kind available for distribution to stockholders ratably in proportion to the number of shares of Common Stock held by them respectively.

2. Preferred Stock. The Preferred Stock may be issued from time to time in one or more series, as determined by the Board of Directors of the Corporation (the "Board of Directors"). The Board of Directors is expressly authorized to provide for the issue, in one or more series, of all or any of the remaining shares of Preferred Stock and, in the resolution or resolutions providing for such issue, to establish for each such series the number of its shares, the voting powers, full or limited, of the shares of such series, or that such shares shall have no voting powers, and the designations, preferences and relative, participating, optional or other special rights, if any, of the shares of such series, and any qualifications, limitations or restrictions thereof. The powers, preferences and relative, participating, optional and other special rights of each series of preferred stock and the qualifications, limitations or restrictions thereof, if any, may differ from those of any and all other series at any time outstanding. The Board of Directors is further expressly authorized to increase or decrease (but not below the number of shares of any such series then outstanding) the number of shares of any series, the number of which was fixed by it, subsequent to the issuance of shares of such series then outstanding, subject to the powers, preferences and rights, and the qualifications, limitations and restrictions thereof stated in this Certificate of Incorporation or the resolution of the Board of Directors originally fixing the number of shares of such series. If the number of shares of any series is so decreased, then the shares constituting such decrease shall resume the status which they had prior to the adoption of the resolution originally fixing the number of shares of such series.

ARTICLE V
EXCULPATION AND INDEMNIFICATION

A. Limitation of Liability. A director of the Corporation shall not be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, except to the extent such exemption from liability or limitation thereof is not permitted under the DGCL as it presently exists or may hereafter be amended. Any amendment, modification or repeal of the foregoing sentence shall not adversely affect any right arising prior to the time of such amendment, modification or repeal.

B. Right of Indemnification. The Corporation shall indemnify and hold harmless, to the fullest extent permitted by applicable law as it presently exists or may hereafter be amended, any person (a "Covered Person") who was or is made or is threatened to be made a party or is otherwise involved in any action, suit or proceeding, whether civil, criminal, administrative or investigative (a "Proceeding"), by reason of the fact that he or she, or a person for whom he or she is the legal representative, is or was a director, officer, employee or agent of the Corporation or, while a director, officer, employee or agent of the Corporation, is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation or of a partnership, joint venture, trust, enterprise or nonprofit entity, including service with respect to employee benefit plans, against all liability and loss suffered and expenses (including attorneys' fees) reasonably incurred by such Covered Person. Notwithstanding the preceding sentence, except as otherwise provided in section D of this Article V, the Corporation shall not be required to indemnify a Covered Person in connection with a Proceeding (or part thereof) commenced by such Covered Person unless the commencement of such Proceeding (or part thereof) by the Covered Person was authorized in the specific case by the Board of Directors.

C. Prepayment of Expenses. The Corporation shall to the fullest extent not prohibited by applicable law pay the expenses (including attorneys' fees) incurred by a Covered Person in defending any Proceeding in advance of its final disposition, provided, however, that, to the extent required by law, such payment of expenses in advance of the final disposition of the Proceeding shall be made only upon receipt of an undertaking by the Covered Person to repay all amounts advanced if it should be ultimately determined that the Covered Person is not entitled to be indemnified under this Article V or otherwise.

D. Claims. If a claim for indemnification (following the final disposition of the Proceeding with respect to which indemnification is sought, including any settlement of such Proceeding) or advancement of expenses under this Article V is not paid in full within thirty (30) days after a written claim therefor by the Covered Person has been received by the Corporation, the Covered Person may file suit to recover the unpaid amount of such claim and, if successful in whole or in part, shall be entitled to be paid the expense of prosecuting such claim to the fullest extent permitted by applicable law. In any such action the Corporation shall have the burden of proving that the Covered Person is not entitled to the requested indemnification or advancement of expenses under this Article V and applicable law.

E. Non-Exclusivity of Rights. The rights conferred on any Covered Person by this Article V shall not be exclusive of any other rights which such Covered Person may have or hereafter acquire under any statute, any other provision of this Certificate of Incorporation, the Bylaws of the Corporation, or any agreement, vote of stockholders or disinterested directors or otherwise.

F. Insurance. The Corporation may purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the Corporation, or is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation or of a partnership, joint venture, trust, enterprise or nonprofit entity, including service with respect to employee benefit plans, against any liability asserted against such person and incurred by such person in any such capacity, or arising out of such person's status as such, whether or not the Corporation would have the power to indemnify such person against such liability under this Article V, the DGCL or otherwise.

G. Amendment or Repeal. Any right to indemnification or to advancement of expenses of any Covered Person arising hereunder shall not be eliminated or impaired by an amendment to or repeal of this Article V after the occurrence of the act or omission that is the subject of the civil, criminal, administrative or investigative action, suit or proceeding for which indemnification or advancement of expenses is sought.

H. Other Indemnification and Advancement of Expenses. This Article V shall not limit the right of the Corporation, to the extent and in the manner permitted by law, to indemnify and to advance expenses to persons other than Covered Persons when and as authorized by appropriate corporate action.

ARTICLE VI
MANAGEMENT

For the management of the business and for the conduct of the affairs of the Corporation, and in further definition, limitation and regulation of the powers of the Corporation, of its directors and of its stockholders or any class thereof, as the case may be, it is further provided that:

A. The management of the business and the conduct of the affairs of the Corporation shall be vested in the Board of Directors. The Board of Directors shall fix the number of directors that constitute the whole Board of Directors in the manner provided in the Bylaws of the Corporation, subject to any restrictions that may be set forth in this Certificate of Incorporation.

B. In furtherance and not in limitation of the powers conferred by statute, the Board of Directors is expressly empowered to adopt, amend or repeal the Bylaws of the Corporation or adopt new Bylaws of the Corporation without any action on the part of the stockholders. Any adoption, amendment or repeal of the Bylaws of the Corporation by the Board of Directors shall require the approval of a majority of the directors then in office. The stockholders of the Corporation shall also have the power to adopt, amend or repeal the Bylaws of the Corporation; provided, however, that, in addition to any vote of the holders of any class or series of stock of the Corporation required by law or by this Certificate of Incorporation, the affirmative vote of the holders of at least sixty-six and two-thirds percent (66-2/3%) of the voting power of all of the then-outstanding shares of the capital stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class, shall be required to adopt, amend or repeal any provision of the Bylaws of the Corporation.

C. The Corporation reserves the right to amend, alter, change or repeal any provision contained in this Certificate of Incorporation, in the manner now or hereafter prescribed by the DGCL, and all rights conferred upon stockholders herein are granted subject to this reservation.

ARTICLE VII
STOCKHOLDER MEETINGS

Meetings of stockholders may be held within or without the State of Delaware, as the Bylaws of the Corporation may provide. Elections of directors need not be by written ballot unless and except to the extent that the Bylaws of the Corporation so provide. Any action required to or which may be taken at a meeting of stockholders of the corporation may be taken without a meeting if authorized by a writing signed by all of the holders of shares who would be entitled to vote upon the action at a meeting for such purpose.

ARTICLE VIII
INCORPORATOR

The name and mailing address of the incorporator of the Corporation are as follows:

Amy E. Culbert
Oppenheimer Wolff & Donnelly LLP
Campbell Mithun Tower, Suite 2000
222 South Ninth Street
Minneapolis, MN 55402

ARTICLE IX
EFFECTIVE TIME

This Certificate of Incorporation shall be effective as of 5:00 p.m. Eastern Time on June 18, 2015.

The undersigned, being the incorporator named above, for the purpose of forming a corporation pursuant to the DGCL, does hereby make this Certificate of Incorporation, hereby acknowledging, declaring and certifying that the foregoing Certificate of Incorporation is the undersigned's act and deed and the facts herein stated are true, and accordingly has hereunto set the undersigned's hand this 17th day of June, 2015.

INCORPORATOR:

By: /s/ Amy E. Culbert
Amy E. Culbert

Amended: January 8, 2016

BYLAWS
OF
DIFFUSION PHARMACEUTICALS INC.
(AS AMENDED)

ARTICLE I
OFFICES

1.1 Registered Office. The address of the registered office of Diffusion Pharmaceuticals Inc. (the "Corporation") in the State of Delaware shall be 615 South Dupont Hwy., Dover, Kent County, Delaware 19901. The name of the registered agent of the Corporation at that address is National Corporate Research, Ltd.

1.2 Other Offices. The Corporation may have other offices, both within and without the State of Delaware, as the Board of Directors of the Corporation (the "Board of Directors"), from time to time shall determine or the business of the Corporation may require.

ARTICLE II
STOCKHOLDERS' MEETINGS

2.1 Place of Meetings. Meetings of the stockholders of the Corporation may be held at any place, either within or without the State of Delaware, as may be determined from time to time by the Board of Directors. The Board of Directors may, in its sole discretion, determine that a meeting of stockholders hall not be held at any place, but may instead be held solely by means of remote communication as authorized by Section 211(a)(2) of the General Corporation Law of the State of Delaware (as amended from time to time, the "DGCL"). In the absence of any such designation or determination, meetings of the stockholders of the Corporation shall be held at the Corporation's principal executive office.

2.2 Annual Meetings.

(a) The annual meeting of the stockholders of the Corporation, for the purpose of election of directors and for such other business as may lawfully come before it, shall be held on such date and at such time as may be designated from time to time by the Board of Directors. Nominations of persons for election to the Board of Directors of the Corporation and the proposal of business to be considered by the stockholders may be made at an annual meeting of stockholders: (i) pursuant to the Corporation's notice with respect to such meeting; (ii) by or at the direction of the Board of Directors; or (iii) by any stockholder of the Corporation who was a stockholder of record at the time of giving the stockholder's notice provided for in the following subsection (b), who is entitled to vote at the meeting and who complied with the notice procedures set forth below in this Section 2.2.

(b) At an annual meeting of the stockholders, only such business shall be conducted as shall have been properly brought before the meeting. For nominations or other business to be properly brought before an annual meeting by a stockholder pursuant to Section 2.2(a)(iii) above, (i) the stockholder must have given timely notice thereof in writing to the Secretary of the Corporation, (ii) such other business must be a proper matter for stockholder action under the DGCL, and (iii) if the stockholder, or the beneficial owner on whose behalf any such proposal or nomination is made, has provided the Corporation with a Solicitation Notice (as defined below in Section 2.2(d)(iii)(C)(2)), such stockholder or beneficial owner must, in the case of a proposal, have delivered a proxy statement and form of proxy to holders of at least the percentage of the Corporation's voting shares required under applicable law or the Corporation's Certificate of Incorporation (as the same may be amended and/or restated from time to time, the "Certificate of Incorporation") or these Bylaws (as the same may be amended and/or restated from time to time, the "Bylaws") to carry any such proposal, or, in the case of a nomination or nominations, have delivered a proxy statement and form of proxy to holders of a percentage of the Corporation's voting shares reasonably believed by such stockholder or beneficial owner to be sufficient to elect the nominee or nominees proposed to be nominated by such stockholder, and must, in either case, have included in such materials the Solicitation Notice.

(c) To be timely, a stockholder's notice shall be delivered to the Secretary at the principal executive offices of the Corporation not later than the close of business on the ninetieth (90th) day, nor earlier than the close of business on the one hundred twentieth (120th) day, prior to the first anniversary of the date of the proxy statement delivered to stockholders in connection with the preceding year's annual meeting; provided, however, that in the event (i) the date of the annual meeting is advanced more than thirty (30) days prior to or delayed by more than thirty (30) days after the anniversary of the preceding year's annual meeting, (ii) no proxy statement was delivered to stockholders in connection with the preceding year's annual meeting, or (iii) the Corporation did not hold an annual meeting in the preceding year, notice by the stockholder to be timely must be so delivered not earlier than the close of business on the ninetieth (90th) day prior to such annual meeting and not later than the close of business on the later of the sixtieth (60th) day prior to such annual meeting or the tenth (10th) day following the day on which public announcement of the date of such meeting is first made. In no event shall the public announcement of an adjournment of an annual meeting commence a new time period for the giving of a stockholder's notice as described above.

(d) Such stockholder's notice shall set forth:

(i) as to each person whom the stockholder proposes to nominate for election or reelection as a director, all information relating to such person that is required to be disclosed in solicitations of proxies for election of directors, or is otherwise required, in each case pursuant to Regulation 14A under the Securities Exchange Act of 1934, as amended (as amended from time to time, the "1934 Act") (including such person's written consent to being named in the proxy statement as a nominee and to serving as a director if elected);

(ii) as to any other business that the stockholder proposes to bring before the meeting, a brief description of the business desired to be brought before the meeting, the reasons for conducting such business at the meeting and any material interest in such business of such stockholder and the beneficial owner, if any, on whose behalf the proposal is made; and

(iii) as to the stockholder giving the notice and the beneficial owner, if any, on whose behalf the nomination or proposal is made:

(A) the name and address of such stockholder, as they appear on the Corporation's books, and of such beneficial owner;

(B) (1) the class and number of shares of the Corporation which are owned beneficially and of record by such stockholder and such beneficial owner; (2) any option, warrant, convertible security, stock appreciation right, or similar right with an exercise or conversion privilege or a settlement payment or mechanism at a price related to any class or series of shares of the Corporation or with a value derived in whole or in part from the value of any class or series of shares of the Corporation, whether such instrument or right shall be subject to settlement in the underlying class or series of capital stock of the Corporation or otherwise (a "Derivative Instrument") directly or indirectly owned beneficially by such stockholder and such beneficial owner and any other direct or indirect opportunity to profit or share in any profit derived from any increase or decrease in the value of shares of the Corporation; (3) any proxy, contract, arrangement, understanding, or relationship pursuant to which such stockholder has a right to vote any shares of any security of the Corporation; (4) any short interest in any security of the Corporation (for purposes of this Bylaw a person shall be deemed to have a short interest in a security if such person directly or indirectly, through any contract, arrangement, understanding, relationship or otherwise, has the opportunity to profit or share in any profit derived from any decrease in the value of the subject security) held directly or indirectly by such stockholder and such beneficial owner; (5) any rights to dividends on the shares of the Corporation owned beneficially and of record by such stockholder and such beneficial owner that are separated or separable from the underlying shares of the Corporation; (6) any proportionate interest in shares of the Corporation or Derivative Instruments held, directly or indirectly, by a general or limited partnership in which such stockholder or such beneficial owner is a general partner or, directly or indirectly, beneficially owns an interest in a general partner; and (7) any performance-related fees (other than an asset-based fee) that such stockholder or such beneficial owner is entitled to based on any increase or decrease in the value of shares of the Corporation or Derivative Instruments, if any, as of the date of such notice, in each case including without limitation any such interests held by members of such stockholder's or such beneficial owner's immediate family sharing the same household (which information shall be supplemented by such stockholder and beneficial owner, if any, not later than ten (10) days after the record date for the meeting to disclose such ownership as of the record date);

(C) any other information relating to such stockholder and beneficial owner, if any, that would be required to be disclosed in a proxy statement or other filings required to be made in connection with solicitations of proxies for, as applicable, the proposal and/or for the election of directors in a contested election pursuant to Section 14 of the 1934 Act and the rules and regulations promulgated thereunder, including without limitation:

(1) a description of all arrangements or understandings between the stockholder or beneficial owner and each proposed nominee and any other person or persons (including their names) pursuant to which the nomination(s) are to be made by such stockholder; and

(2) whether either such stockholder or beneficial owner intends to deliver a proxy statement and form of proxy to holders of, in the case of the proposal, at least the percentage of the Corporation's voting shares required under applicable law or the Certificate of Incorporation or these Bylaws to carry the proposal or, in the case of a nomination or nominations, a sufficient number of holders of the Corporation's voting shares to elect such nominee or nominees (an affirmative statement of such intent, a "Solicitation Notice").

(e) Notwithstanding anything in Section 2.2(c) of these Bylaws to the contrary, in the event that the number of directors to be elected to the Board of Directors of the Corporation is increased and there is no public announcement naming all of the nominees for director or specifying the size of the increased Board of Directors made by the Corporation at least seventy (70) days prior to the first anniversary of the preceding year's annual meeting (or, if the annual meeting is held more than thirty (30) days before or thirty (30) days after such anniversary date, at least seventy (70) days prior to such annual meeting) a stockholder's notice required by this Section 2.2 shall also be considered timely, but only with respect to nominees for any new positions created by such increase, if it shall be delivered to the Secretary at the principal executive offices of the Corporation not later than the close of business on the tenth (10th) day following the day on which such public announcement is first made by the Corporation.

(f) Only such persons who are nominated in accordance with the procedures set forth in this Section 2.2 shall be eligible to serve as directors and only such business shall be conducted at a meeting of stockholders as shall have been brought before the meeting in accordance with the procedures set forth in this Section 2.2. Except as otherwise provided by law, the chairman of the meeting shall have the power and duty to determine whether a nomination or any business proposed to be brought before the meeting was made, or proposed, as the case may be, in accordance with the procedures set forth in these Bylaws and, if any proposed nomination or business is not in compliance with these Bylaws, to declare that such defective proposal or nomination shall not be presented for stockholder action at the meeting and shall be disregarded.

(g) Notwithstanding the foregoing provisions of this Section 2.2, in order to include information with respect to a stockholder proposal in the proxy statement and form of proxy for a stockholders' meeting, stockholders must provide notice as required by the regulations promulgated under the 1934 Act. Nothing in these Bylaws shall be deemed to affect any rights of stockholders to request inclusion of proposals in the Corporation's proxy statement pursuant to Rule 14a-8 under the 1934 Act.

(h) For purposes of these Bylaws, "public announcement" shall mean disclosure in a press release reported by the Dow Jones News Service, Associated Press, PR Newswire, Reuters or comparable national news service or in a document publicly filed by the Corporation with the U.S. Securities and Exchange Commission pursuant to Section 13, 14 or 15(d) of the 1934 Act.

2.3 Special Meetings.

(a) Unless otherwise provided in the Certificate of Incorporation, special meetings of the stockholders of the Corporation may be called, for any purpose or purposes, only by (i) the Chairman of the Board of Directors, (ii) the Chief Executive Officer, or (iii) the Board of Directors pursuant to a resolution adopted by a majority of the directors then in office, and shall be held at such place, on such date and at such time as determined by the Board of Directors.

(b) If a special meeting is properly called by any person or persons other than the Board of Directors, the request shall be in writing, specifying the general nature of the business proposed to be transacted, and shall be delivered personally or sent by certified or registered mail, return receipt requested, to the Secretary of the Corporation. No business may be transacted at such special meeting otherwise than specified in such notice. The Board of Directors shall determine the time and place of such special meeting, which shall be held not less than thirty-five (35) nor more than one hundred twenty (120) days after the date of the receipt of the request. Upon determination of the time and place of the meeting, the Secretary shall cause notice to be given to the stockholders entitled to vote, in accordance with the provisions of Section 2.4 of these Bylaws. Nothing contained in this subsection (b) shall be construed as limiting, fixing or affecting the time when a meeting of stockholders called by action of the Board of Directors may be held.

(c) Nominations of persons for election to the Board of Directors may be made at a special meeting of stockholders at which directors are to be elected pursuant to the Corporation's notice of meeting (i) by or at the direction of the Board of Directors or (ii) by any stockholder of the Corporation who is a stockholder of record at the time of giving notice provided for in these Bylaws who shall be entitled to vote at the meeting and who complies with the notice procedures set forth in this Section 2.3(c). In the event the Corporation calls a special meeting of stockholders for the purpose of electing one or more directors to the Board of Directors, any such stockholder may nominate a person or persons (as the case may be), for election to such position(s) as specified in the Corporation's notice of meeting, if the stockholder's notice otherwise required by Section 2.2 of these Bylaws shall be delivered to the Secretary at the principal executive offices of the Corporation not earlier than the close of business on the one hundred twentieth (120th) day prior to such special meeting and not later than the close of business on the later of the ninetieth (90th) day prior to such meeting or the tenth (10th) day following the day on which public announcement is first made of the date of the special meeting and of the nominees proposed by the Board of Directors to be elected at such meeting. In no event shall the public announcement of an adjournment of a special meeting commence a new time period for the giving of a stockholder's notice as described above.

(d) Unless the Certificate of Incorporation provides otherwise, any special meeting of the stockholders may be cancelled by resolution duly adopted by a majority of the directors then in office upon public notice given prior to the date previously scheduled for such meeting of stockholders.

2.4 Notice of Meetings. Except as otherwise provided by law, notice, given in writing or by electronic transmission, of each meeting of stockholders shall be given not less than ten (10) nor more than sixty (60) days before the date of the meeting to each stockholder entitled to vote at such meeting as of the record date for determining the stockholders entitled to notice of the meeting. Such notice shall specify the place, date and hour of the meeting, the means of remote communication(s), if any, by which stockholders and proxyholders may be deemed to be present in person and vote at such meeting (as authorized by the Board of Directors in its sole discretion pursuant to Section 211(a)(2) of the DGCL), the record date for determining the stockholders entitled to vote at the meeting if such date is different from the record date for determining stockholders entitled to notice of the meeting, and, in the case of a special meeting, the purpose or purposes of the meeting. Notice of any meeting of stockholders, if mailed, is given when deposited in the United States mail, postage prepaid, directed to the stockholder at such stockholder's address as it appears on the records of the Corporation and otherwise is given when delivered. Notice of the time, place, and purpose of any meeting of stockholders may be waived in writing, signed by the person entitled to notice thereof, or by electronic transmission by such person, either before or after such meeting, and will be waived by any stockholder by his or her attendance thereat in person or by proxy, except when the stockholder attends a meeting for the express purpose of objecting, at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Any stockholder so waiving notice of such meeting shall be bound by the proceedings of any such meeting in all respects as if due notice thereof had been given. Neither the business to be transacted at, nor the purpose of, any annual or special meeting of the stockholders need be specified in any written waiver of notice or any waiver by electronic transmission.

2.5 Determination of Stockholders of Record.

(a) In order that the Corporation may determine the stockholders entitled to notice of any meeting of stockholders or any adjournment thereof, the Board of Directors may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the Board of Directors, and which record date shall not be more than sixty (60) nor less than ten (10) days before the date of such meeting. If the Board of Directors so fixes a date, such date shall also be the record date for determining the stockholders entitled to vote at such meeting unless the Board of Directors determines, at the time it fixes such record date, that a later date on or before the date of the meeting shall be the date for making such determination. If no record date is fixed by the Board of Directors, the record date for determining stockholders entitled to notice of or to vote at a meeting of stockholders shall be at the close of business on the day next preceding the day on which notice is given, or, if notice is waived, at the close of business on the day next preceding the day on which the meeting is held. A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting; provided, however, that the Board of Directors may fix a new record date for determination of stockholders entitled to vote at the adjourned meeting, and in such case shall also fix as the record date for stockholders entitled to notice of such adjourned meeting the same or an earlier date as that fixed for determination of stockholders entitled to vote at the adjourned meeting.

(b) In order that the Corporation may determine the stockholders entitled to consent to corporate action in writing without a meeting, the Board of Directors may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the Board of Directors, and which date shall not be more than ten (10) days after the date upon which the resolution fixing the record date is adopted by the Board of Directors. If no record date has been fixed by the Board of Directors, the record date for determining stockholders entitled to consent to corporate action in writing without a meeting, when no prior action by the Board of Directors is required by the DGCL, shall be the first date on which a signed written consent setting forth the action taken or proposed to be taken is delivered to the Corporation by delivery to its registered office in the State of Delaware, its principal place of business or an officer or agent of the Corporation having custody of the book in which proceedings of meetings of stockholders are recorded. Delivery made to the Corporation's registered office shall be by hand or by certified or registered mail, return receipt requested. If no record date has been fixed by the Board of Directors and prior action by the Board of Directors is required by the DGCL, the record date for determining stockholders entitled to consent to corporate action in writing without a meeting shall be at the close of business on the day on which the Board of Directors adopts the resolution taking such prior action.

2.6 Quorum. At all meetings of the stockholders, except where otherwise provided by law, the Certificate of Incorporation or these Bylaws, the presence, in person or by proxy duly authorized, of the holders of a majority of the outstanding shares of stock entitled to vote shall constitute a quorum for the transaction of business. In the absence of a quorum, any meeting of stockholders may be adjourned, from time to time, either by the chairman of the meeting or by vote of the holders of a majority of the shares represented thereat, but no other business shall be transacted at such meeting. The stockholders present at a duly called or convened meeting, at which a quorum is present, may continue to transact business until adjournment, notwithstanding the withdrawal of enough stockholders to leave less than a quorum. Where a separate vote by a class or series or classes or series is required, except where otherwise provided by law or by the Certificate of Incorporation or these Bylaws, a majority of the outstanding shares of such class or series or classes or series, present in person or represented by proxy duly authorized, shall constitute a quorum entitled to take action with respect to that vote on that matter.

2.7 Adjournment and Notice of Adjourned Meetings. Any meeting of stockholders, whether annual or special, may be adjourned from time to time either by the chairman of the meeting or by the vote of a majority of the shares present in person or represented by proxy at the meeting. When a meeting is adjourned to another time or place, notice need not be given of the adjourned meeting if the time and place thereof, and the means of remote communication(s), if any, by which stockholders and proxyholders may be deemed to be present in person and vote at such adjourned meeting (as authorized by the Board of Directors in its sole discretion pursuant to Section 211(a)(2) of the DGCL), are announced at the meeting at which the adjournment is taken. At the adjourned meeting, the Corporation may transact any business which might have been transacted at the original meeting. If the adjournment is for more than thirty (30) days, a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the meeting. If after the adjournment a new record date for stockholders entitled to vote is fixed for the adjourned meeting, the Board of Directors shall fix a new record date for notice of such adjourned meeting, and shall give notice of the adjourned meeting to each stockholder of record entitled to vote at such adjourned meeting as of the record date fixed for notice of such adjourned meeting.

2.8 Voting. Except as otherwise provided by law or by the Certificate of Incorporation or these Bylaws, in all matters other than the election of directors, the affirmative vote of the majority of shares present in person or represented by proxy at the meeting and entitled to vote generally on the subject matter shall be the act of the stockholders. Except as otherwise provided by law, the Certificate of Incorporation or these Bylaws, directors shall be elected by a plurality of the votes of the shares present in person or represented by proxy at the meeting and entitled to vote generally on the election of directors. Where a separate vote by a class or series or classes or series is required, except where otherwise provided by law or by the Certificate of Incorporation or these Bylaws, the affirmative vote of the majority (plurality, in the case of the election of directors) of shares of such class or series or classes or series present in person or represented by proxy at the meeting shall be the act of such class or series or classes or series.

2.9 Voting Rights. For the purpose of determining those stockholders entitled to vote at any meeting of the stockholders, except as otherwise provided by law, only persons in whose names shares stand on the stock records of the Corporation on the record date, as provided in Section 6.5 of these Bylaws, shall be entitled to vote at any meeting of stockholders. Every person entitled to vote shall have the right to do so either in person or by an agent or agents authorized by a proxy granted in accordance with the DGCL. An agent so appointed need not be a stockholder. No proxy shall be voted after three (3) years from its date of creation unless the proxy provides for a longer period.

2.10 Joint Owners of Stock. If shares or other securities having voting power stand of record in the names of two (2) or more persons, whether fiduciaries, members of a partnership, joint tenants, tenants in common, tenants by the entirety, or otherwise, or if two (2) or more persons have the same fiduciary relationship respecting the same shares, unless the Secretary is given written notice to the contrary and is furnished with a copy of the instrument or order appointing them or creating the relationship wherein it is so provided, their acts with respect to voting shall have the following effect: (a) if only one (1) votes, his or her act binds all; (b) if more than one (1) votes, the act of the majority so voting binds all; (c) if more than one (1) votes, but the vote is evenly split on any particular matter, each faction may vote the securities in question proportionally, or may apply to the Delaware Court of Chancery for relief as provided in Section 217(b) of the DGCL. If the instrument filed with the Secretary shows that any such tenancy is held in unequal interests, a majority or even-split for the purpose of clauses (b) and (c) shall be a majority or even-split in interest.

2.11 List of Stockholders. The officer who has charge of the stock ledger of the Corporation shall prepare and make, at least ten (10) days before every meeting of stockholders, a complete list of the stockholders entitled to vote at said meeting (provided, however, that if the record date for determining the stockholders entitled to vote is less than ten (10) days before the date of the meeting, the list shall reflect the stockholders entitled to vote as of the tenth (10) day before the meeting date), arranged in alphabetical order, showing the address of each stockholder and the number of shares registered in the name of each stockholder. Nothing contained in this Section 2.11 shall require the Corporation to include electronic mail addresses or other electronic contact information on such list. Such list shall be open to the examination of any stockholder, for any purpose germane to the meeting for a period of at least ten (10) days prior to the meeting, (a) on a reasonably accessible electronic network, provided that the information required to gain access to such list is provided with the notice of the meeting, or (b) during ordinary business hours, at the principal place of business of the Corporation. In the event the Corporation determines to make the list available on an electronic network, the Corporation may take reasonable steps to ensure that such information is available only to stockholders of the Corporation. If the meeting is to be held at a place, then a list of stockholders entitled to vote at the meeting shall be produced and kept at the time and place of the meeting during the whole time thereof and may be examined by any stockholder of the Corporation who is present. If the meeting is to be held solely by means of remote communication, then such list shall also be open to the examination of any stockholder of the Corporation during the whole time of the meeting on a reasonably accessible electronic network, and the information required to access such list shall be provided with the notice of the meeting.

2.12 Action Without Meeting.

(a) Any action to be taken at any annual or special meeting of stockholders may be taken without a meeting, without prior notice and without a vote, if a consent or consents in writing, setting forth the action to be so taken, shall be signed by the holders of outstanding stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted and shall be delivered (by hand or by certified or registered mail, return receipt requested) to the Corporation by delivery to its registered office in the State of Delaware, its principal place of business or an officer or agent of the Corporation having custody of the book in which proceedings of meetings of the stockholders are recorded.

(b) Every written consent shall bear the date of signature of each stockholder who signs the consent, and no written consent shall be effective to take the corporate action referred to therein unless, within sixty (60) days of the earliest dated consent delivered in the manner required by this Section 2.11, written consents signed by a sufficient number of holders to take action are delivered to the Corporation as aforesaid. Delivery made to the Corporation's registered office shall be by hand or by certified or registered mail, return receipt requested. Any person executing a consent may provide, whether through instruction to an agent or otherwise, that such a consent will be effective at a future time (including a time determined upon the happening of an event), no later than 60 days after such instruction is given or such provision is made, and, if evidence of such instruction or provision is provided to the Corporation, such later effective time shall serve as the date of signature. Unless otherwise provided, any such consent shall be revocable prior to its becoming effective.

(c) Any copy, facsimile or other reliable reproduction of a consent in writing may be substituted or used in lieu of the original writing for any and all purposes for which the original writing could be used, provided that such copy, facsimile or other reproduction shall be a complete reproduction of the entire original writing.

(d) Prompt notice of the taking of the corporate action without a meeting by less than unanimous written consent shall, to the extent required by applicable law, be given to those stockholders who have not consented in writing, and who, if the action had been taken at a meeting, would have been entitled to notice of the meeting if the record date for notice of such meeting had been the date that written consents signed by a sufficient number of holders to take the action were delivered to the Corporation.

2.13 Organization.

(a) At every meeting of stockholders, (i) the Chairman of the Board of Directors or, if a Chairman of the Board of Directors has not been appointed or is absent, (ii) the Vice Chairman of the Board of Directors, if any, or, if the Vice Chairman of the Board of Directors is absent or there is no Vice Chairman of the Board of Directors, (iii) the Chief Executive Officer or, if the Chief Executive Officer is absent, (iv) such person as the Chairman of the Board of Directors shall appoint or, if such Chairman has not been appointed, (v) any officer of the Corporation chosen by the Board of Directors, shall act as chairman of the meeting. The Secretary, or in the absence of the Secretary an Assistant Secretary, shall act as secretary of the meeting, but in the absence of the Secretary and any Assistant Secretary the chairman of the meeting may appoint any person to act as secretary of the meeting.

(b) The Board of Directors, in advance of any meeting of stockholders, may, and shall if required by law, appoint one (1) or more inspector(s), who may include individual(s) who serve the Corporation in other capacities, including without limitation as officers, employees or agents, to act at the meeting of stockholders and make a written report thereof. The Board of Directors may designate one (1) or more persons as alternate inspector(s) to replace any inspector who fails to act. If no inspector or alternate has been appointed or is able to act at a meeting of stockholders, the chairman of the meeting shall appoint one (1) or more inspector(s) to act at the meeting. Each inspector, before discharging his or her duties, shall take and sign an oath to faithfully execute the duties of inspector with strict impartiality and according to the best of his or her ability. The inspector(s) or alternate(s) shall have the duties prescribed pursuant to Section 231 of the DGCL or other applicable law.

(c) The Board of Directors of the Corporation shall be entitled to make such rules or regulations for the conduct of meetings of the stockholders as it shall deem necessary, appropriate or convenient. Subject to such rules and regulations of the Board of Directors, if any, the chairman of the meeting shall have the right and authority to prescribe such rules, regulations and procedures and to do all such acts as, in the judgment of such chairman, are necessary, appropriate or convenient for the proper conduct of the meeting, including, without limitation, establishing an agenda or order of business for the meeting, rules and procedures for maintaining order at the meeting and the safety of those present, limitations on participation in such meeting to stockholders of record of the Corporation and their duly authorized and constituted proxies and such other persons as the chairman shall permit, restrictions on entry to the meeting after the time fixed for the commencement thereof, limitations on the time allotted to questions or comments by participants and regulation of the opening and closing of the polls for balloting on matters which are to be voted on by ballot. The date and time of the opening and closing of the polls for each matter upon which the stockholders will vote at the meeting shall be announced at the meeting. Unless and to the extent determined by the Board of Directors or the chairman of the meeting, meetings of the stockholders shall not be required to be held in accordance with rules of parliamentary procedure.

2.14 Postponement and Cancellation of Meeting. Any previously scheduled annual or special meeting of stockholders may be postponed, and any previously scheduled annual or special meeting of stockholders may be cancelled, by resolution of the Board of Directors upon public notice given prior to the time previously scheduled for such meeting.

ARTICLE III
DIRECTORS

3.1 General Powers. The business and affairs of the Corporation shall be managed by or under the direction of the Board of Directors, except as may be otherwise provided in the DGCL or in the Certificate of Incorporation. The Board of Directors may adopt such rules and procedures, not inconsistent with the Certificate of Incorporation, these Bylaws or applicable law, as it may deem proper for the conduct of its meetings and the management of the Corporation, except as may be otherwise provided by the DGCL or by the Certificate of Incorporation.

3.2 Number, Term of Office and Qualifications. The Board of Directors shall consist of one or more members, the number thereof to be determined from time to time by resolution of the Board of Directors. Each director shall hold office until a successor is duly elected and qualified or until the director's earlier death, resignation, disqualification or removal. Directors shall be natural persons, but need not be stockholders of the Corporation unless otherwise required by the Certificate of Incorporation.

3.3 Vacancies. Unless otherwise provided in the Certificate of Incorporation and subject to the rights of the holders of any series of preferred stock then outstanding, any vacancies on the Board of Directors resulting from death, resignation, disqualification, removal or other causes and any newly created directorships resulting from any increase in the number of directors shall, unless the Board of Directors determines by resolution that any such vacancies or newly created directorships shall be filled by stockholders, be filled only by the affirmative vote of a majority of the directors then in office, even if less than a quorum of the Board of Directors. Any director elected in accordance with the preceding sentence shall hold office for the remainder of the full term of the director for which the vacancy was created or occurred and until such director's successor shall have been elected and qualified.

3.4 Resignation. Any director may resign at any time by delivering his or her notice in writing or by electronic transmission to theSecretary, such resignation to specify whether it will be effective at a particular time, upon receipt by the Secretary or at the pleasure of the Board of Directors. If no such specification is made, it shall be deemed effective at the pleasure of the Board of Directors. Verbal resignation shall not be deemed effective until confirmed by the director in writing or by electronic transmission to the Secretary. When one or more directors shall resign from the Board of Directors effective at a future date, a majority of the directors then in office, including those who have so resigned, shall have the power to fill such vacancy or vacancies, the vote thereon to take effect when such resignation or resignations shall become effective, and each director so chosen shall hold office for the unexpired portion of the term of the director whose place shall be vacated and until his or her successor shall have been duly elected and qualified.

3.5 Removal. Subject to the Certificate of Incorporation, any director or the entire Board of Directors may be removed, with or without cause, by the affirmative vote of the holders of a majority of the voting power of all of then outstanding shares of capital stock of the Corporation then entitled to vote in the election of directors, voting together as a single class. No reduction of the authorized number of directors shall have the effect of removing any director prior to the expiration of such director's term of office.

3.6 Meetings.

(a) Unless otherwise restricted by the Certificate of Incorporation, regular meetings of the Board of Directors may be held at any time or date and at any place within or without the State of Delaware which has been designated by the Board of Directors and publicized among all directors, either orally or in writing, by telephone, including a voice-messaging system or other system designed to record and communicate messages, facsimile, telegraph or telex, or by electronic mail or other electronic means. No further notice shall be required for regular meetings of the Board of Directors.

(b) Unless otherwise restricted by the Certificate of Incorporation, special meetings of the Board of Directors may be held at any time and place within or without the State of Delaware whenever called by the Chairman of the Board of Directors, the Chief Executive Officer, or a majority of the directors then in office.

(c) Any member of the Board of Directors, or of any committee thereof, may participate in a meeting by means of conference telephone or other communications equipment pursuant to which all persons participating in the meeting can hear each other, and participation in a meeting by such means shall constitute presence in person at such meeting.

(d) Notice of the time and place of all special meetings of the Board of Directors shall be given to each director (i) by giving notice to such director in person or by telephone, including a voice messaging system or other system designed to record and communicate messages, during normal business hours, at least twenty-four (24) hours before the meeting, (ii) by sending a telegram or delivering notice by facsimile transmission, by electronic mail or by hand, to such director at his or her last known business or home address, during normal business hours, at least twenty-four (24) hours before the meeting, or (iii) by mailing notice, via first class United States mail, to such director at his or her last known business or home address at least three (3) days in advance of the meeting. Notice of any meeting may be waived in writing, or by electronic transmission, at any time before or after the meeting and will be waived by any director by attendance thereat, except when the director attends the meeting for the express purpose of objecting, at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Notice of a special meeting of the Board of Directors need not specify the purpose of the meeting.

(e) The transaction of all business at any meeting of the Board of Directors, or any committee thereof, however called or noticed, or wherever held, shall be as valid as though had at a meeting duly held after regular call and notice, if a quorum be present and if, either before or after the meeting, each of the directors not present who did not receive notice shall sign a written waiver of notice or shall waive notice by electronic transmission. All such waivers shall be filed with the corporate records or made a part of the minutes of the meeting. Neither the business to be transacted at, nor the purpose of, any regular or special meeting of the Board of Directors need be specified in any written waiver of notice or any waiver by electronic transmission.

3.7 Quorum and Voting.

(a) Unless the Certificate of Incorporation requires a greater number, a quorum of the Board of Directors shall consist of a majority of the directors then in office. At any meeting whether a quorum be present or otherwise, a majority of the directors present may adjourn from time to time until the time fixed for the next regular meeting of the Board of Directors, without notice other than by announcement at the meeting.

(b) At each meeting of the Board of Directors at which a quorum is present, all questions and business shall be determined by the affirmative vote of a majority of the directors present at the meeting, unless a different vote be required by law, the Certificate of Incorporation or these Bylaws.

3.8 Action Without Meeting. Unless otherwise restricted by the Certificate of Incorporation or these Bylaws, any action required or permitted to be taken at any meeting of the Board of Directors, or of any committee thereof, may be taken without a meeting, if all members of the Board of Directors or committee, as the case may be, consent thereto in writing or by electronic transmission, and such writing or writings or transmission or transmissions are filed with the minutes of proceedings of the Board of Directors or committee. Such filing shall be in paper form if the minutes are maintained in paper form and shall be in electronic form if the minutes are maintained in electronic form. Any person (whether or not then a director) may provide, whether through instruction to an agent or otherwise, that a consent to action will be effective at a future time (including a time determined upon the happening of an event), no later than 60 days after such instruction is given or such provision is made and such consent shall be deemed to have been given at such effective time so long as such person is then a director and did not revoke the consent prior to such time. Any such consent shall be revocable prior to its becoming effective.

3.9 Fees and Compensation. Directors shall be entitled to such compensation for their services as may be approved by the Board of Directors, or any committee thereof, including, if so approved by resolution of the Board of Directors or such committee, a fixed sum and expenses of attendance, if any, for attendance at each regular or special meeting of the Board of Directors and at any meeting of a committee of the Board of Directors. Nothing herein contained shall be construed to preclude any director from serving the Corporation in any other capacity as an officer, agent, employee, or otherwise and receiving compensation therefor.

3.10 Committees.

(a) The Board of Directors may, from time to time, appoint such committees as may be permitted by law. Such committees appointed by the Board of Directors shall consist of one (1) or more members of the Board of Directors and shall have such powers and perform such duties as may be prescribed by the resolution or resolutions creating such committees, but no committee shall have the power or authority in reference to (i) approving or adopting, or recommending to the stockholders, any action or matter expressly required by the DGCL to be submitted to stockholders for approval, or (ii) adopting, amending or repealing any provision of these Bylaws.

(b) The Board of Directors, subject to any requirements of any outstanding series of preferred stock and the provisions of subsections (a) and (b) of this Section 3.10, may at any time increase or decrease the number of members of a committee or terminate the existence of a committee. The membership of a committee member shall terminate on the date of his or her death or voluntary resignation from the committee or from the Board of Directors. The Board of Directors may at any time for any reason remove any individual committee member and the Board of Directors may fill any committee vacancy created by death, resignation, removal or increase in the number of members of the committee. The Board of Directors may designate one or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the committee, and, in addition, in the absence or disqualification of any member of a committee, the member or members thereof present at any meeting and not disqualified from voting, whether or not he, she or they constitute a quorum, may unanimously appoint another member of the Board of Directors to act at the meeting in the place of any such absent or disqualified member.

(c) Unless the Board of Directors shall otherwise provide, regular meetings of any committee appointed pursuant to this Section 3.10 shall be held at such times and places as are determined by the Board of Directors, or by any such committee, and when notice thereof has been given to each member of such committee, no further notice of such regular meetings need be given thereafter. Special meetings of any such committee may be held at any place which has been determined from time to time by such committee, and may be called by any director who is a member of such committee, upon notice to the members of such committee of the time and place of such special meeting given in the manner provided for the giving of notice to members of the Board of Directors of the time and place of special meetings of the Board of Directors. Notice of any special meeting of any committee may be waived in writing at any time before or after the meeting and will be waived by any director by attendance thereat, except when the director attends such special meeting for the express purpose of objecting, at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Unless otherwise provided by the Board of Directors in the resolutions authorizing the creation of the committee, a majority of the members of any such committee shall constitute a quorum for the transaction of business, and the act of a majority of those present at any meeting at which a quorum is present shall be the act of such committee.

3.11 Organization. At every meeting of the directors, the Chairman of the Board of Directors, or, if a Chairman of the Board of Directors has not been appointed or is absent, the Vice Chairman of the Board of Directors, or if a Vice Chairman of the Board of Directors has not been appointed or is absent, the Chief Executive Officer (if a director), or if the Chief Executive Officer is absent, or, in the absence of any such person, a chairman of the meeting chosen by a majority of the directors present, shall preside over the meeting. The Secretary, or in the absence of the Secretary an Assistant Secretary, shall act as secretary of the meeting, but in the absence of the Secretary and any Assistant Secretary the chairman of the meeting may appoint any person to act as secretary of the meeting.

ARTICLE IV
OFFICERS

4.1 Positions; Election and Qualification. The officers of the Corporation shall be elected annually by the Board of Directors and shall include a President or Chief Executive Officer ("Chief Executive Officer"), a Chief Financial Officer, a Treasurer and a Secretary. The Board of Directors, in its discretion, may also elect a Chairman (who must be a director), one or more Vice Chairmen (who must be directors) and one or more Vice Presidents, Assistant Treasurers, Assistant Secretaries and other officers. The Board of Directors may assign such additional titles to one or more of the officers as it shall deem appropriate. Any two or more offices may be held by the same person. No officer need be a stockholder.

4.2 Term. Each officer of the Corporation shall hold office at the pleasure of the Board of Directors and until such officer's successor is elected and qualified or until such officer's earlier death, resignation or removal, subject to the rights, if any, of an officer under contract of employment. If the office of any officer becomes vacant for any reason, the vacancy may be filled by the Board of Directors. The election or appointment of an officer shall not of itself create contract rights

4.3 Duties.

(a) The Chairman of the Board of Directors shall, if present, preside at meetings of the Board of Directors and stockholders and exercise and perform such other powers and duties as may from time to time be assigned to him or her by the Board of Directors or as may be prescribed by these Bylaws.

(b) Subject to such supervisory powers, if any, as the Board of Directors may give to the Chairman of the Board of Directors, the Chief Executive Officer shall, subject to the control of the Board of Directors, have general supervision, direction and control of the business and affairs of the Corporation and shall report directly to the Board of Directors. All other officers, officials, employees and agents shall report directly or indirectly to the Chief Executive Officer. The Chief Executive Officer shall see that all orders and resolutions of the Board of Directors are carried into effect.

(c) In the absence or disability of the Chief Executive Officer, the Vice President(s), if any, in order of their rank as fixed by the Board of Directors or, if not ranked, a Vice President designated by the Board of Directors, shall perform all the duties of the Chief Executive Officer and, when so acting, shall have all the powers of, and be subject to all the restrictions upon, the Chief Executive Officer. The Vice President(s) shall have such other powers and perform such other duties as form time to time may be prescribed for them respectively by the Board of Directors, these Bylaws, the Chairman of the Board of Directors, the Chief Executive Officer. The Board of Directors may designate one or more Executive Vice Presidents or Senior Vice Presidents or may otherwise specify the order of seniority of the Vice Presidents.

(d) The Chief Financial Officer shall keep and maintain, or cause to be kept and maintained, adequate and correct books and records of accounts of the properties and business transactions of the Corporation, including accounts of its assets, liabilities, receipts, disbursements, gains, losses, capital and retained earnings. The Chief Financial Officer shall deposit all money and other valuables in the name and to the credit of the Corporation with such depositaries as may be designated by the Board of Directors or Chief Executive Officer. The Chief Financial Officer shall disburse the funds of the Corporation as may be ordered by the Board of Directors, shall render to the Board of Directors and Chief Executive Officer, whenever they request, an account of all of his or her transactions as Chief Financial Officer and of the financial condition of the Corporation, and shall have such other powers and perform such other duties as may be prescribed by the Board of Directors or these Bylaws. In lieu of any contrary resolution duly adopted by the Board of Directors, the Chief Financial Officer shall also be the Treasurer of the Corporation.

(e) The Secretary shall keep or cause to be kept, at the principal executive office of the Corporation, or such other place as the Board of Directors may direct, a book of minutes of all meetings and actions of directors, committees of directors, and stockholders. The minutes shall show the time and place of each meeting, whether regular or special (and, if special, how authorized and the notice given), the names of those present at directors' meetings or committee meetings, the number of shares present or represented at stockholders' meetings, and the proceedings thereof.

The Secretary shall keep, or cause to be kept, at the principal executive office of the Corporation or at the office of the Corporation's transfer agent or registrar, as determined by resolution of the Board of Directors, a share register, or a duplicate share register, showing the names of all stockholders and their addresses, the number and classes of shares held by each, the number and date of certificates evidencing such shares, and the number and date of cancellation of every certificate surrendered for cancellation.

The Secretary shall give, or cause to be given, notice of all meetings of the stockholders, the Board of Directors and any committee(s) of the Board of Directors, required to be given by law or by these Bylaws. The Secretary shall keep the seal of the Corporation, if one be adopted, in safe custody and shall have such other powers and perform such other duties as may be prescribed by the Board of Directors or by these Bylaws.

(f) The Vice Chairman of the Board, if any, shall, in the absence of the Chairman of the Board, or in the event of his or her inability or refusal to act, perform the duties and exercise the powers of the Chairman of the Board and shall perform such other duties and have such other powers as the Board of Directors may from time to time prescribe.

(g) The Assistant Secretary(ies), if any, in the order determined by the Board of Directors (or if there be no such determination, then in the order of their election) shall, in the absence of the Secretary or in the event of his or her inability or refusal to act, perform the duties and exercise the powers of the Secretary and shall perform such other duties and have such other powers as the Board of Directors may from time to time prescribe.

(h) The Assistant Treasurer(s), if any, in the order determined by the Board of Directors (or if there be no such determination, then in the order of their election), shall, in the absence of the Chief Financial Officer or in the event of his or her inability or refusal to act, perform the duties and exercise the powers of the Chief Financial Officer and shall perform such other duties and have such other powers as the Board of Directors may from time to time prescribe.

4.4 Delegation of Authority. The Board of Directors may from time to time delegate the powers or duties of any officer to any other officer or agent, notwithstanding any provision hereof.

4.5 Resignations. Any officer may resign at any time by giving notice in writing or by electronic transmission to the Chairman of the Board, or to the Chief Executive Officer or to the Secretary. Verbal resignation shall not be deemed effective until confirmed by the officer in writing or by electronic transmission to the Chairman of the Board, Chief Executive Officer or Secretary. Any such resignation shall be effective when received by the person or persons to whom such notice is given, unless a later time is specified therein, in which event the resignation shall become effective at such later time. Unless otherwise specified in such notice, the acceptance of any such resignation shall not be necessary to make it effective. Any resignation shall be without prejudice to the rights, if any, of the Corporation under any contract with the resigning officer.

4.6 Removal. Subject to the rights, if any, of an officer under contract of employment, any officer may be removed from office at any time, either with or without cause, by the affirmative vote of a majority of the directors in office at the time, or by the unanimous written consent of the directors in office at the time, or by any committee or superior officers upon whom such power of removal may have been conferred by the Board of Directors.

ARTICLE V
EXECUTION OF CORPORATE INSTRUMENTS AND VOTING OF SECURITIES OWNED BY THE CORPORATION

5.1 Execution of Corporate Instruments. The Board of Directors may, in its discretion, determine the method and designate the signatory officer or officers, or other person or persons, to execute on behalf of the Corporation any corporate instrument or document, or to sign on behalf of the Corporation the corporate name without limitation, or to enter into contracts on behalf of the Corporation, except where otherwise provided by law or these Bylaws, and such execution or signature shall be binding upon the Corporation.

All checks and drafts drawn on banks or other depositaries on funds to the credit of the Corporation or in special accounts of the Corporation shall be signed by such person or persons as the Board of Directors shall authorize so to do.

Unless authorized or ratified by the Board of Directors or within the agency power of an officer, no officer, agent or employee shall have any power or authority to bind the Corporation by any contract or engagement or to pledge its credit or to render it liable for any purpose or for any amount.

5.2 Voting of Securities Owned by the Corporation. All stock and other securities of other Corporations owned or held by the Corporation for itself, or for other parties in any capacity, shall be voted, and all proxies with respect thereto shall be executed, by the person authorized so to do by resolution of the Board of Directors, or, in the absence of such authorization, by the Chairman of the Board of Directors, the Chief Executive Officer or any Vice President.

ARTICLE VI
SHARES OF STOCK

6.1 Form and Execution of Certificates. Shares of stock of the Corporation shall be represented by certificates, or shall be uncertificated. Certificates for the shares of stock of the Corporation, if any, shall be in such form as is consistent with the Certificate of Incorporation and applicable law. Every holder of stock represented by certificate shall be entitled to have a certificate signed by or in the name of the Corporation by the Chairman of the Board of Directors, or the Chief Executive Officer or any Vice President and by the Treasurer or Assistant Treasurer or the Secretary or Assistant Secretary, certifying the number of shares owned by him or her in the Corporation. Any or all of the signatures on the certificate may be facsimiles. In case any officer, transfer agent, or registrar who has signed or whose facsimile signature has been placed upon a certificate shall have ceased to be such officer, transfer agent, or registrar before such certificate is issued, it may be issued with the same effect as if he or she were such officer, transfer agent, or registrar at the date of issue.

6.2 Transfers of Stock. Transfers of record of shares of stock of the Corporation shall be made only upon its books by the holders thereof, in person or by attorney duly authorized, and, in the case of stock represented by certificate, upon the surrender of a properly endorsed certificate or certificates for a like number of shares. To the extent designated by the Chief Executive Officer or any Vice President or the Treasurer of the Corporation, the Corporation may recognize the transfer of fractional uncertificated shares, but shall not otherwise be required to recognize the transfer of fractional shares. The Corporation shall have power to enter into and perform any agreement with any number of stockholders of any one or more classes of stock of the Corporation to restrict the transfer of shares of stock of the Corporation of any one or more classes owned by such stockholders in any manner not prohibited by the DGCL.

6.3 Transfer Agents and Registrars. The Board of Directors may appoint, or authorize any officer or officers to appoint, one or more transfer agents and one or more registrars.

6.4 Lost, Stolen or Destroyed Certificates. A new certificate or certificates or uncertificated shares shall be issued in place of any certificate or certificates theretofore issued by the Corporation alleged to have been lost, stolen or destroyed, upon the making of an affidavit of that fact by the person claiming the certificate of stock to be lost, stolen or destroyed. The Corporation may require, as a condition precedent to the issuance of a new certificate or certificates or uncertificated shares, the owner of such lost, stolen or destroyed certificate or certificates, or the owner's legal representative, to agree to indemnify the Corporation in such manner as it shall require or to give the Corporation a surety bond in such form and amount as it may direct as indemnity against any claim that may be made against the Corporation with respect to the certificate alleged to have been lost, stolen or destroyed.

6.5 Fixing Record Dates.

(a) In order that the Corporation may determine the stockholders entitled to notice of or to vote at any meeting of stockholders or any adjournment thereof, the Board of Directors may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the Board of Directors, and which record date shall not be more than sixty (60) nor less than ten (10) days before the date of such meeting. If the Board of Directors so fixes a date, such date shall also be the record date for determining the stockholders entitled to vote at such meeting unless the Board of Directors determines, at the time it fixes such record date, that a later date on or before the date of the meeting shall be the date for making such determination. If no record date is fixed by the Board of Directors, the record date for determining stockholders entitled to notice of or to vote at a meeting of stockholders shall be at the close of business on the day next preceding the day on which notice is given, or, if notice is waived, at the close of business on the day next preceding the day on which the meeting is held. A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting; provided, however, that the Board of Directors may fix a new record date for the determination of stockholders entitled to vote at the adjourned meeting and in such case shall also fix as the record date for stockholders entitled to notice of such adjourned meeting the same or an earlier date as that fixed for the determination of stockholders entitled to vote therewith at the adjourned meeting.

(b) In order that the Corporation may determine the stockholders entitled to consent to corporate action in writing without a meeting, the Board of Directors may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the Board of Directors, and which record date shall not be more than ten (10) days after the date upon which the resolution fixing the record date is adopted by the Board of Directors. If no record date has been fixed by the Board of Directors, the record date for determining stockholders entitled to consent to corporate action in writing without a meeting: (i) when no prior action by the Board of Directors is required by law, the record date for such purpose shall be the first date on which a signed written consent setting forth the action taken or proposed to be taken is delivered to the Corporation by delivery (by hand, or by certified or registered mail, return receipt requested) to its registered office in the State of Delaware, its principal place of business, or an officer or agent of the Corporation having custody of the book in which proceedings of meetings of the stockholders are recorded and (ii) if prior action by the Board of Directors is required by law, the record date for such purpose shall be at the close of business on the day on which the Board of Directors adopts the resolution taking such prior action.

(c) In order that the Corporation may determine the stockholders entitled to receive payment of any dividend or other distribution or allotment of any rights or the stockholders entitled to exercise any rights in respect of any change, conversion or exchange of stock, or for the purpose of any other lawful action, the Board of Directors may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted, and which record date shall be not more than 60 days prior to such action. If no record date is fixed, the record date for determining stockholders for any such purpose shall be at the close of business on the day on which the Board of Directors adopts the resolution relating thereto.

6.6 Registered Stockholders. The Corporation shall be entitled to recognize the exclusive right of a person registered on its books as the owner of shares to receive dividends, and to vote as such owner, and shall not be bound to recognize any equitable or other claim to or interest in such share or shares on the part of any other person whether or not it shall have express or other notice thereof, except as otherwise provided by applicable law.

ARTICLE VII
OTHER SECURITIES OF THE CORPORATION

7.1 Execution of Other Securities. All bonds, debentures and other corporate securities of the Corporation, other than stock certificates (covered in Section 6.1), may be signed by the Chairman of the Board of Directors, the Chief Executive Officer, the President or any Vice President, or such other person as may be authorized by the Board of Directors, and the corporate seal, if any, may be impressed thereon or a facsimile of such seal imprinted thereon and attested by the signature of the Secretary or an Assistant Secretary, or the Chief Financial Officer or Treasurer or an Assistant Treasurer; provided, however, that where any such bond, debenture or other corporate security shall be authenticated by the manual signature, or where permissible facsimile signature, of a trustee under an indenture pursuant to which such bond, debenture or other corporate security shall be issued, the signatures of the persons signing and, if applicable, attesting the corporate seal on such bond, debenture or other corporate security may be the imprinted facsimile of the signatures of such persons. Interest coupons appertaining to any such bond, debenture or other corporate security, authenticated by a trustee as aforesaid, shall be signed by the Treasurer or an Assistant Treasurer of the Corporation or such other person as may be authorized by the Board of Directors, or bear imprinted thereon the facsimile signature of such person. In case any officer who shall have signed or attested any bond, debenture or other corporate security, or whose facsimile signature shall appear thereon or on any such interest coupon, shall have ceased to be such officer before the bond, debenture or other corporate security so signed or attested shall have been delivered, such bond, debenture or other corporate security nevertheless may be adopted by the Corporation and issued and delivered as though the person who signed the same or whose facsimile signature shall have been used thereon had not ceased to be such officer of the Corporation.

ARTICLE VIII
DIVIDENDS

8.1 Declaration of Dividends. Dividends upon the capital stock of the Corporation, subject to the provisions of the Certificate of Incorporation and applicable law, if any, may be declared by the Board of Directors pursuant to law at any regular or special meeting. Dividends may be paid in cash, in property, or in shares of the capital stock, subject to the provisions of the Certificate of Incorporation and applicable law.

8.2 Dividend Reserve. Before payment of any dividend, there may be set aside out of any funds of the Corporation available for dividends such sum or sums as the Board of Directors from time to time, in their absolute discretion, think proper as a reserve or reserves to meet contingencies, or for equalizing dividends, or for repairing or maintaining any property of the Corporation, or for such other purpose as the Board of Directors shall think conducive to the interests of the Corporation, and the Board of Directors may modify or abolish any such reserve in the manner in which it was created.

ARTICLE IX
GENERAL PROVISIONS

9.1 Fiscal Year. The fiscal year of the Corporation shall be fixed from time to time by resolution of the Board of Directors.

9.2 Corporate Seal. The Corporation may, but need not, have a corporate seal. In the event the Corporation has a seal, the seal need not be affixed for any contract, resolution or other document executed by or on behalf of the Corporation to be valid and duly authorized.

9.3 Notices.

(a) Written notice to stockholders of stockholder meetings shall be given as provided in Section 2.4 herein. Without limiting the manner by which notice may otherwise be given effectively to stockholders under any agreement or contract with such stockholder, and except as otherwise required by law, written notice to stockholders for purposes other than stockholder meetings may be sent by United States mail or nationally recognized overnight courier, or by facsimile, telegraph or telex or by electronic mail or other electronic means.

(b) Notice to directors of special meetings shall be given as provided in Section 3.7(d) herein. Subject to the preceding sentence and except as expressly stated otherwise herein, notice may otherwise be given by the methods stated in subsection (a) above.

(c) An affidavit of mailing, executed by a duly authorized and competent employee of the Corporation or its transfer agent appointed with respect to the class of stock affected, or other agent, specifying the name and address or the names and addresses of the stockholder or stockholders, or director or directors, to whom any such notice or notices was or were given, and the time and method of giving the same, shall in the absence of fraud, be prima facie evidence of the facts therein contained.

(d) It shall not be necessary that the same method of giving notice be employed in respect of all recipients of notice, but one permissible method may be employed in respect of any one or more recipients, and any other permissible method or methods may be employed in respect of any other or others.

(e) Whenever notice is required to be given, under any provision of the DGCL, the Certificate of Incorporation or these Bylaws, to any person with whom communication is unlawful, the giving of such notice to such person shall not be required and there shall be no duty to apply to any governmental authority or agency for a license or permit to give such notice to such person. Any action or meeting which shall be taken or held without notice to any such person with whom communication is unlawful shall have the same force and effect as if such notice had been duly given. In the event the action taken by the Corporation is such as to require the filing of a certificate under any provision of the DGCL, the certificate shall state, if such is the fact and if notice is required, that notice was given to all persons entitled to receive notice except such persons with whom communication is unlawful.

(f) Whenever notice is required to be given, under any provision of the DGCL, the Certificate of Incorporation or these Bylaws, to any stockholder to whom (i) notice of two (2) consecutive annual meetings, or (ii) all, and at least two (2), payments (if sent by first-class mail) of dividends or interest on securities during a twelve (12) month period, have been mailed addressed to such person at such person's address as shown on the records of the Corporation and have been returned undeliverable, the giving of such notice to such person shall not be required. Any actions or meeting which shall be taken or held without notice to such person shall have the same force and effect as if such notice had been duly given. If any such person shall deliver to the Corporation a written notice setting forth such person's then current address, the requirement that notice be given to such person shall be reinstated. In the event that the action taken by the Corporation is such as to require the filing of a certificate under any provision of the DGCL, the certificate need not state that the Corporation did not give notice to persons not required to be given notice pursuant to Section 230(b) of the DGCL. The exception in clause (i) above to the requirement that notice be given shall not be applicable to any notice returned as undeliverable if the notice was given by electronic transmission.

(g) Except as otherwise prohibited under the DGCL, any notice given under the provisions of the DGCL, the Certificate of Incorporation or these Bylaws shall be effective if given by a single written notice to stockholders who share an address if consented to by the stockholders at that address to whom such notice is given. Such consent shall be deemed to have been given if such stockholder fails to object in writing to the Corporation within sixty (60) days of having been given notice by the Corporation of its intention to send the single notice. Any consent shall be revocable by the stockholder by written notice to the Corporation.

(h) Without limiting the manner by which notice otherwise may be given effectively to stockholders, any notice to stockholders given by the Corporation under any provision of the DGCL, the Certificate of Incorporation or these Bylaws shall be effective if given by a form of electronic transmission previously consented to by the stockholder to whom the notice is given. Any such consent shall be revocable by the stockholder by written notice to the Corporation. Any such consent shall be deemed revoked if (i) the Corporation is unable to deliver by electronic transmission two (2) consecutive notices given by the Corporation in accordance with such consent, and (ii) such inability becomes known to the Secretary or an Assistant Secretary of the Corporation, the transfer agent or other person responsible for the giving of notice; provided, however, the inadvertent failure to treat such inability as a revocation shall not invalidate any meeting or other action.

Notice given pursuant to the above paragraph shall be deemed given (i) if by facsimile telecommunication, when directed to a number at which the stockholder has consented to receive notice, (ii) if by electronic mail, when directed to an electronic mail address at which the stockholder has consented to receive notice, (iii) if by a posting on an electronic network together with a separate notice to the stockholder of such specific posting, upon the later of (A) such posting and (B) the giving of such separate notice, and (iv) if by any other form of electronic transmission, when directed to the stockholder. An affidavit of the Secretary or Assistant Secretary, the transfer agent or other agent of the Corporation that the notice has been given by a form of electronic transmission shall in the absence of fraud, be prima facie evidence of the facts stated therein.

For purposes of these Bylaws, "electronic transmission" means any form of communication, not directly involving the physical transmission of paper, that creates a record that may be retained, retrieved and reviewed by a recipient thereof, and that may be directly reproduced in paper form by such a recipient through an automated process. This Section 9.3 shall not apply to Section 164 (failure to pay for stock; remedies), Section 296 (adjudication of claims; appeal), Section 311 (revocation of voluntary dissolution), Section 312 (renewal, revival, extension and restoration of certificate of incorporation) or Section 324 (attachment of shares of stock) of the DGCL.

9.4 Construction. Unless the context requires otherwise, the general provisions, rules of construction and definitions in the DGCL shall govern the construction of these Bylaws. The singular number includes the plural, and the plural number includes the singular. All pronouns used in these Bylaws shall be deemed to refer to the masculine, feminine and/or neuter, as the identity of the person or persons so designated may require.

9.5 Conflict With Applicable Law or Certificate of Incorporation. These Bylaws are adopted subject to any applicable law and the Certificate of Incorporation. Whenever these Bylaws may conflict with any applicable law or the Certificate of Incorporation, such conflict shall be resolved in favor of such law or the Certificate of Incorporation.

ARTICLE X
INDEMNIFICATION AND ADVANCEMENT OF EXPENSES

10.1 Right to Indemnification. The Corporation shall indemnify and hold harmless, to the fullest extent permitted by applicable law as it presently exists or may hereafter be amended, any person (an "Indemnitee") who was or is made or is threatened to be made a party or is otherwise involved in any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (a "Proceeding"), by reason of the fact that he or she, or a person for whom he or she is the legal representative, is or was a director, officer, employee or agent of the Corporation or, is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation or of a partnership, joint venture, trust or other enterprise, including service with respect to employee benefit plans (any such entity, an "Other Entity"), against all liability and loss suffered (including, but not limited to expenses (including but not limited to, attorneys' fees and expenses), judgments, fines and amounts paid in settlement actually and reasonably incurred by such Indemnitee in connection with any such Proceeding) provided, that the Indemnitee acted in good faith and in a manner such Indemnitee reasonably believed to be in or not opposed to the best interests of the Corporation and, with respect to any Proceeding that is criminal in nature, had no reasonable cause to believe that his or her conduct was unlawful. The termination of any Proceeding by judgment, order, settlement, conviction or upon a plea of nolo contendere or its equivalent, does not, of itself, create a presumption that the Indemnitee did not act in good faith and in a manner in which he or she reasonably believed to be in or not opposed to the best interests of the Corporation, or that, with respect to any criminal proceeding he or she had reasonable cause to believe that his or her conduct was unlawful. The Corporation shall not indemnify an Indemnitee for any claim, issue or matter as to which the Indemnitee has been adjudged by a court of competent jurisdiction, after exhaustion of all appeals therefrom, to be liable to the Corporation or for any amounts paid in settlement to the Corporation, unless and only to the extent that the court in which the Proceeding was brought or other court of competent jurisdiction determines upon application that in view of all the circumstances of the case, the Indemnitee is fairly and reasonably entitled to indemnity for such amounts as the court deems proper.

10.2 Advancement of Expenses. The Corporation shall to the fullest extent not prohibited by applicable law pay the expenses (including attorneys' fees) incurred by an Indemnitee in defending any Proceeding in advance of its final disposition, provided, however, that, to the extent required by law, such payment of expenses in advance of the final disposition of the Proceeding shall be made only upon receipt of an undertaking by the Indemnitee to repay all amounts advanced if it should be ultimately determined that the Indemnitee is not entitled to be indemnified under this Article X or otherwise.

10.3 Former Directors, Officers, Employees and Agents. Indemnification pursuant to this Article X shall continue as to an Indemnitee who has ceased to be a director, officer, employee or agent of the Corporation or member, manager or managing member of a predecessor limited liability company or affiliate of such limited liability company or a director, officer, employee, agent, partner, member, manager or fiduciary of, or to serve in any other capacity for, another corporation or any partnership, joint venture, limited liability company, trust, or other enterprise and shall inure to the benefit of his or her heirs, executors and administrators.

10.4 Claims. If a claim for indemnification (following the final disposition of the Proceeding with respect to which indemnification is sought, including any settlement of such Proceeding) or advancement of expenses under this Article X is not paid in full within sixty (60) days after a written claim therefor by the Indemnitee has been received by the Corporation, the Indemnitee may file suit to recover the unpaid amount of such claim and, if successful in whole or in part, shall be entitled to be paid the expense of prosecuting such claim to the fullest extent permitted by applicable law. In any such action the Corporation shall have the burden of proving that the Indemnitee is not entitled to the requested indemnification or advancement of expenses under this Article X and applicable law.

10.5 Non-Exclusivity of Rights. The rights conferred on any Indemnitee by this Article X shall not be exclusive of any other rights which such Indemnitee may have or hereafter acquire under any statute, the Certificate of Incorporation, these Bylaws, or any agreement, vote of stockholders or disinterested directors or otherwise.

10.6 Insurance. The Corporation may purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the Corporation, or is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation or of a partnership, joint venture, trust or other enterprise, including service with respect to employee benefit plans, against any liability asserted against such person and incurred by such person in any such capacity, or arising out of such person's status as such, whether or not the Corporation would have the power to indemnify such person against such liability under this Article X, the DGCL or otherwise.

10.7 Amendment or Repeal. Any right to indemnification or to advancement of expenses of any Indemnitee arising hereunder shall not be eliminated or impaired by an amendment to or repeal of this Article X after the occurrence of the act or omission that is the subject of the Proceeding for which indemnification or advancement of expenses is sought.

10.8 Saving Clause. If this Article X or any portion hereof shall be invalidated on any ground by any court of competent jurisdiction, then the Corporation shall nevertheless indemnify each director, officer, employee and agent to the fullest extent not prohibited by any applicable portion of this Article X that shall not have been invalidated, or by any other applicable law. If this Article X shall be invalid due to the application of the indemnification provisions of another jurisdiction, then the Corporation shall indemnify each director, officer, employee and agent to the fullest extent under any other applicable law.

ARTICLE XI
EXCLUSIVE JURISDICTION FOR CERTAIN ACTIONS

11.1 Exclusive Jurisdiction for Certain Actions. Unless the Corporation consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of the Corporation, (ii) any action asserting a claim for breach of a fiduciary duty owed by any director, officer, employee or agent of the Corporation to the Corporation or the Corporation's stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL, the Certificate of Incorporation or the Bylaws of the Corporation or (iv) any action asserting a claim governed by the internal affairs doctrine, in each case subject to said Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein.

ARTICLE XII
AMENDMENTS

12.1 Amendments. The Board of Directors is expressly empowered to adopt, amend or repeal these Bylaws or adopt new Bylaws of the Corporation. Any adoption, amendment or repeal of these Bylaws or adoption of new Bylaws of the Corporation by the Board of Directors shall require the approval of a majority of the directors then in office. Notwithstanding the foregoing, the stockholders of the Corporation shall also have power to adopt, amend or repeal the Bylaws of the Corporation; provided, however, that, in addition to any vote of the holders of any class or series of stock of the Corporation required by law or by the Certificate of Incorporation, the affirmative vote of the holders of at least sixty-six and two-thirds percent (66-2/3%) of the voting power of all of the then-outstanding shares of the capital stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class, shall be required to adopt, amend or repeal any provision of the Bylaws of the Corporation.

Adopted as of June 18, 2015.

Amended: January 8, 2016.

THIS CONVERTIBLE PROMISSORY NOTE (THIS "NOTE") AND THE SECURITIES ISSUABLE UPON CONVERSION HEREOF HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), OR ANY STATE SECURITIES LAW. NO SALE, TRANSFER, PLEDGE, ASSIGNMENT OR OTHER DISPOSITION OF THIS NOTE OR THE SECURITIES ISSUABLE UPON CONVERSION HEREOF SHALL BE VALID OR EFFECTIVE UNLESS (A) SUCH TRANSFER IS MADE PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT AND IN COMPLIANCE WITH ANY APPLICABLE STATE SECURITIES LAW, OR (B) THE HOLDER SHALL DELIVER TO THE COMPANY AN OPINION OF COUNSEL IN FORM AND SUBSTANCE REASONABLY ACCEPTABLE TO THE COMPANY THAT SUCH TRANSFER IS EXEMPT FROM THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND APPLICABLE STATE SECURITIES LAWS.

DIFFUSION PHARMACEUTICALS LLC
CONVERTIBLE [____]% PROMISSORY NOTE

[_____] [___], 20[__]
Charlottesville, Virginia $[_____]

Diffusion Pharmaceuticals LLC, a Virginia limited liability company (the "Company"), for value received, hereby promises to pay "Investor" or registered assigns (the "Holder") on [_____] [___], 20[__] (the "Maturity Date"), at the principal offices of the Company located at 2020 Avon Court #4, Charlottesville, Virginia 22902 (the "Principal Office"), the principal sum of $[_____], plus interest on such amount accruing at a rate of [___]% per annum, unless and until the Company's obligation with respect to the payment of such principal sum shall be discharged as herein provided. Unless converted as set forth in paragraph 3, principal and accrued interest shall be payable in cash on the Maturity Date. This Note is one of a series of convertible unsecured promissory notes issued by the Company in conjunction herewith (such series not including this Note, the "Other Notes," and the Other Notes together with this Note, the "Company Notes") and is being issued pursuant to the terms of a Subscription Agreement dated on or about the date hereof by and between the Company and the Holder (the "Subscription Agreement").

1. Ranking.

The Company Notes will constitute general, unsecured obligations of the Company

2. Events of Default.

(a) An "Event of Default" shall mean (x) the failure of the Company to pay any of its payment obligations under this Note when due, or (y) the Company admits in writing its inability to pay its debts generally as they become due; makes an assignment for the benefit of its creditors; consents to or acquiesces in the appointment of a receiver, liquidator, fiscal agent, or trustee of itself or any substantial portion of its property; files a petition under bankruptcy or other laws for the relief of debtors; consents to any reorganization, arrangement, workout, liquidation, dissolution, or similar relief; or any court adjudicates the Company as bankrupt and such adjudication shall remain unvacated, not set aside, or unstayed for an aggregate of 60 days, whether or not consecutive.

(b) In the event of default in payment under the terms of paragraph 2(a)(x) as the same becomes due and such default is not cured within thirty (30) days after written notice thereof is received by the Company, or default under the terms of paragraph 2(a)(y) and such default is not cured within forty five (45) days after written notice thereof is received by the Company, and at any time during the continuation of any such Event of Default, the Holder may, upon notice to the Company, (i) declare the aggregate outstanding amount of this Note to be immediately due and payable and may exercise any rights or remedies permitted under applicable law and/or (ii) elect to convert this Note, in whole or in part, together with accrued but unpaid interest, into Membership Units (as defined in the Company's Operating Agreement, as amended and restated effective February 25, 2005 (as such may be hereafter amended from time-to-time, the "Operating Agreement")) of the Company (the "Units") at a price per Unit equal to $[____] (as adjusted from time-to-time pursuant to the terms hereof, the "Conversion Price"). In connection with the foregoing, the Company waives notice of intent to demand, demand, presentment for payment, notice of nonpayment, protest, notice of protest, grace, notice of dishonor, notice of intent to accelerate, and all other notices, except those with respect to defaults as described within this paragraph.

3. Conversion.

(a) At any time and from time-to-time prior to the Maturity Date, the Holder may elect to convert this Note, in whole or in part, together with accrued but unpaid interest, into Units at a price per Unit equal to the Conversion Price.

(b) In the event of a Change of Control of the Company or a Qualified Financing, the Holder may, upon notice to the Company, (x) declare the aggregate outstanding amount of this Note to be immediately due and payable and may exercise any rights or remedies permitted under applicable law and/or (y) elect to convert this Note, in whole or in part, together with accrued but unpaid interest as if such conversion took place on the Maturity Date, into Units at a price per Unit equal to the Conversion Price, with such conversion to be effective immediately prior to the effective time of the Change of Control or Qualified Financing, as applicable. In connection with the foregoing, the Company waives notice of intent to demand, demand, presentment for payment, notice of nonpayment, protest, notice of protest, grace, notice of dishonor, notice of intent to accelerate, and all other notices. For purposes of this paragraph, (i) the term "Change of Control" shall mean (a) a merger or consolidation in which the Members (as defined in the Operating Agreement) immediately prior to the transaction do not own, directly or indirectly, more than 50% of the membership interest of the surviving company; (b) the acquisition of more than 50% of the Company's outstanding Membership Interest (as defined in the Operating Agreement) by a single person, entity or group or persons or entities acting in concert, or (c) the sale or transfer of all or substantially all of the assets of the Company, and (ii) a "Qualified Financing" shall mean a sale of Units or other transaction that results in gross proceeds to the Company of at least $50,000,000, including the conversion of the Company Notes.

(c) If the Holder elects to convert this Note into Units pursuant to the terms hereof, the Holder shall notify the Company (such notice, the "Conversion Notice") of the conversion. The effective date of the conversion shall be the date of the Conversion Notice, except as otherwise set forth in Section 3(b) above. On conversion of this Note, (i) the Holder shall surrender this Note at the Principal Office, (ii) the Holder will become a party to the Operating Agreement, if the Holder is not already a party to the Operating Agreement, (iii) the Units issued upon conversion of the Note will have the rights set forth in the Operating Agreement, and (iv) the Company shall issue and deliver to the Holder a new note or notes reflecting the portion, if any, of the principal amount hereof not so converted. Prior to the conversion of this Note, Holder shall not be entitled by reason of the Holder's status as a holder of this Note to any rights of a Member of the Company except as explicitly set forth herein.

Prepayment.

Full or partial prepayment of the Company Notes will be permitted at any time and from time-to-time on a pari passu basis; provided, that upon receipt of notice of any such prepayment, the Holder shall have the option to convert this Note at Holder's sole discretion pursuant to the terms of paragraph 3(a).

4. Notices.

Any notice required by this Note shall be in writing and shall be deemed effectively given: (a) upon personal delivery to the party to be notified, (b) when sent by confirmed facsimile if sent during normal business hours of the recipient; if not, then on the next business day, (c) five (5) days after having been sent by certified mail, return receipt requested, postage prepaid, or (d) one (1) day after deposit with a nationally recognized overnight courier, specifying next day delivery, with written verification of receipt. All notices shall be addressed to the Holder at the address of the holder appearing on the books of the Company. Any notices shall be addressed to the Company at its Principal Office. Any party may change the location at which it will receive notice hereunder by providing the other party with notice of such change pursuant to the provisions of this paragraph 5.

5. No Dilution or Impairment.

(a) If the Company, at any time on or after the date hereof: (i) makes a distribution or distributions on its Units or any other equity or equity equivalent securities payable in Units (which, for avoidance of doubt, shall not include any Units issued by the Company pursuant to the Company Notes), (ii) subdivides outstanding Units into a larger number of Units, (iii) combines outstanding Units into a smaller number of Units, or (iv) issues by reclassification of Units any ownership interest of the Company, then in each case the Conversion Price shall be multiplied by a fraction of which the numerator shall be the number of Units outstanding immediately before such event and of which the denominator shall be the number of Units immediately after such event and the number of Units issuable upon conversion of this Note shall be proportionately adjusted. Any adjustment made pursuant to this paragraph 6(a) shall become effective immediately after the record date for the determination of Members entitled to receive such distribution or shall become effective immediately after the effective date in the case of a subdivision, combination or re-classification.

(b) Without the consent of a majority in interest of the holders of the Company Notes, the Company shall not, for the purpose of avoiding or seeking to avoid the observance or performance of any of the terms to be observed or performed hereunder by the Company, amend the Operating Agreement or take any other voluntary action in connection therewith.

6. Information Rights.

The Holder shall have the information rights of a "Member" under Section 15.03 of the Operating Agreement.

7. Miscellaneous.

(a) This Note has been issued by the Company pursuant to authorization of the Board of Directors of the Company.

(b) This Note is nonnegotiable, and no transfer, assignment or other disposition of this Note or of any interest or right herein or in the indebtedness evidenced hereby shall be effected except as provided herein and in that certain Subscription Agreement pursuant to which the Holder subscribed for this Note (the "Subscription Agreement").

(c) The Company may consider and treat the person in whose name this Note shall be registered as the absolute owner thereof for all purposes whatsoever and the Company shall not be affected by any notice to the contrary. Subject to the limitations set forth herein and in the Subscription Agreement and any other contractual restrictions, the registered owner of this Note shall have the right to transfer this Note by assignment, and the transferee thereof shall, upon his or her registration as owner of this Note, become vested with all the powers and rights of the transferor. Registration of any new owners shall take place upon presentation of this Note to the Company at the Principal Office, together with a duly authenticated assignment. In case of transfer by operation of law, the transferee agrees to notify the Company of such transfer and of his or her address, and to submit appropriate evidence regarding the transfer so that this Note may be registered in the name of the transferee. This Note is transferable only on the books of the Company. Notice sent to any registered owner shall be effective as against all the Holders or transferees of this Note not registered at the time of sending the communication.

(d) All payments of interest and principal shall be in lawful money of the United States of America.

(e) The Company agrees to pay the Holder's reasonable costs in collecting and enforcing this Note, including reasonable attorneys' fees.

(f) THIS NOTE SHALL BE CONSTRUED AND ENFORCED IN ACCORDANCE WITH THE LAWS OF THE COMMONWEALTH OF VIRGINIA WITHOUT REGARD TO THE CONFLICTS OF LAW PRINCIPLES THEREOF. VENUE FOR ANY DISPUTE ARISING HEREUNDER SHALL BE PROPER EXCLUSIVELY IN THE CITY OF CHARLOTTESVILLE, VIRGINIA.

(g) No recourse shall be had for the payment of the principal of this Note against any past, present or future member, manager, officer, director, agent or attorney of the Company, or of any successor Company, either directly or through the Company or any successor Company, all such liability of the members, managers, officers, directors, agents and attorneys being waived, released and surrendered by the Holder hereof by the acceptance of this Note.

(h) This Note may not be altered, amended, modified or waived except by a written instrument signed by the Company and the Holder.

IN WITNESS WHEREOF, the Company has caused this Note to be issued in its name by its authorized officer on the date first set forth above.

THE COMPANY:

DIFFUSION PHARMACEUTICALS LLC

By:_____
Name: David G. Kalergis, MBA/JD
Title: Chief Executive Officer

HOLDER:

[_____]

By:_____
Name: [_____]
Title: [_____]

Exhibit 10.3

INDEMNIFICATION AGREEMENT

This Indemnification Agreement (the "**Agreement**") is made and entered into this ___ day of January, 2016, by and between Diffusion Pharmaceuticals Inc. (f/k/a RestorGenex Corporation), a Delaware corporation (the "**Company**," which term shall include, where appropriate, any Entity (as hereinafter defined) controlled directly or indirectly by the Company), and _____ (the "**Indemnitee**").

WHEREAS, it is essential to the Company that it be able to retain and attract as directors and officers the most capable persons available;

WHEREAS, increased corporate litigation has subjected directors and officers to litigation risks and expenses, and the limitations on the availability of directors and officers liability insurance have made it increasingly difficult for the Company to attract and retain such persons;

WHEREAS, the Company's Certificate of Incorporation, as amended, and Bylaws (the "**Certificate**" and the "**Bylaws**," respectively), provide that the Company is authorized to indemnify its directors and officers to the fullest extent permissible by applicable law and permit it to make other indemnification arrangements and agreements;

WHEREAS, the Company desires to provide Indemnitee with specific contractual assurance of Indemnitee's rights to full indemnification against litigation risks and expenses (regardless, among other things, of any amendment to or revocation of the Certificate or Bylaws or any change in the ownership of the Company or the composition of its board of directors (the "**Board of Directors**"));

WHEREAS, the Company intends that this Agreement provide Indemnitee with greater protection than that which is provided by the Certificate and Bylaws; and

WHEREAS, Indemnitee is relying upon the rights afforded under this Agreement in becoming or continuing as a director and/or officer of the Company.

NOW, THEREFORE, in consideration of the promises and the covenants contained herein, the Company and Indemnitee do hereby covenant and agree as follows:

1. Definitions.

(a) "**Corporate Status**" describes the status of a person who is serving or has served (i) as a director and/or officer of the Company, (ii) in any capacity with respect to any employee benefit plan of the Company or (at the request of the Company) any employee benefit plan of any other Entity, or (iii) as a director and/or officer of any other Entity at the request of the Company. For purposes of subsections (ii) and (iii) of this Section 1(a), if Indemnitee is serving or has served as a director and/or officer of a Subsidiary (as defined below), or in any capacity with respect to any employee benefit plan of a Subsidiary, Indemnitee shall be deemed to be serving at the request of the Company. If Indemnitee is an employee of the Company, Corporate Status shall not include actions taken by Indemnitee in any capacity other than as a director and/or officer or as a representative of any employee benefit plan.

(b) "**Entity**" shall mean any corporation, partnership, limited liability company, joint venture, trust, foundation, association, organization or other legal entity.

(c) "**Expenses**" shall mean all fees, costs and expenses incurred by Indemnitee in connection with any Proceeding (as defined below), including, without limitation, reasonable attorneys' fees, disbursements and retainers (including, without limitation, any such fees, disbursements and retainers incurred by Indemnitee pursuant to Sections 11 and 12(c) of this Agreement), fees and disbursements of expert witnesses, private investigators and professional advisors (including, without limitation, accountants and investment bankers), court costs, transcript costs, fees of experts, travel expenses, duplicating, printing and binding costs, telephone and fax transmission charges, postage, delivery services, secretarial services and other disbursements and expenses.

(d) "**Indemnifiable Expenses**," "**Indemnifiable Liabilities**" and "**Indemnifiable Amounts**" shall have the meanings ascribed to those terms in Section 3(a) below.

(e) "**Liabilities**" shall mean judgments, damages, liabilities, losses, penalties, excise taxes, fines and amounts paid in settlement.

(f) "**Proceeding**" shall mean any threatened, pending or completed claim, action, suit, arbitration, alternate dispute resolution process, investigation, administrative hearing, appeal or any other proceeding, whether civil, criminal, administrative, arbitrative or investigative, whether formal or informal, including a proceeding initiated by Indemnitee pursuant to Section 11 of this Agreement to enforce Indemnitee's rights hereunder.

(g) "**Subsidiary**" shall mean any corporation, partnership, limited liability company, joint venture, trust or other Entity of which the Company owns (either directly or through or together with another Subsidiary of the Company) either (i) a general partner, managing member or other similar interest or (ii) (A) 50% or more of the voting power of the voting capital equity interests of such corporation, partnership, limited liability company, joint venture or other Entity or (B) 50% or more of the outstanding voting capital stock or other voting equity interests of such corporation, partnership, limited liability company, joint venture or other Entity.

(h) "**to the fullest extent permissible by applicable law**" shall include, but not be limited to: (i) the fullest extent permitted by the provisions of the General Corporation Law of the State of Delaware (the "**DGCL**") that authorize or contemplate additional or supplementary indemnification by agreement, or the corresponding provisions of any amendment to or replacement of the DGCL or such provisions thereof; and (ii) the fullest extent authorized or permitted by any amendments to or replacements of the DGCL adopted after the date of this Agreement that increase the extent to which a corporation may indemnify its directors and/or officers.

2. Services of Indemnitee. In consideration of the Company's covenants and commitments hereunder, Indemnitee agrees to serve or continue to serve as a director and/or officer of the Company. However, this Agreement shall not impose any obligation on Indemnitee or the Company to continue Indemnitee's service to the Company beyond any period otherwise required by law or by other agreements or commitments of the parties, if any.

3. Agreement to Indemnify. The Company agrees to hold harmless and indemnify Indemnitee to the fullest extent permissible by applicable law as follows:

(a) Proceedings. Subject to the exceptions contained in Section 4(a) below, if Indemnitee was or is a party or is threatened to be made a party to any Proceeding by reason of Indemnitee's Corporate Status, Indemnitee shall be indemnified by the Company against all Expenses and Liabilities actually and reasonably incurred or paid by Indemnitee in connection with such Proceeding (referred to herein as "**Indemnifiable Expenses**" and "**Indemnifiable Liabilities**," respectively, and collectively as "**Indemnifiable Amounts**").

(b) Conclusive Presumption Regarding Standard of Care. In making any determination required to be made under Delaware law with respect to entitlement to indemnification hereunder, the person, persons or entity making such determination shall presume that Indemnitee is entitled to indemnification under this Agreement if Indemnitee submitted a request therefor in accordance with Section 5 of this Agreement, and the Company shall have the burden of proof to overcome that presumption in connection with the making by any person, persons or Entity of any determination contrary to that presumption.

4. Exceptions to Indemnification. Subject to Section 20 below, Indemnitee shall be entitled to indemnification under Section 3(a) above in all circumstances and with respect to each and every specific claim, issue or matter involved in the Proceeding out of which Indemnitee's claim for indemnification has arisen to the fullest extent permissible by applicable law, except as follows:

(a) Proceedings. If indemnification is requested under Section 3(a) and it has been finally adjudicated by a court of competent jurisdiction that, in connection with such specific claim, issue or matter, Indemnitee failed to act (i) in good faith and (ii) in a manner Indemnitee reasonably believed to be in or not opposed to the best interests of the Company, or, with respect to any criminal Proceeding, Indemnitee had reasonable cause to believe that Indemnitee's conduct was unlawful, Indemnitee shall not be entitled to payment of Indemnifiable Amounts hereunder to the extent that they arise out of such claim, issue or matter.

(b) Insurance Proceeds. To the extent payment is actually made to the Indemnitee under a valid and collectible insurance policy maintained at the expense of the Company in respect of Indemnifiable Amounts in connection with such specific claim, issue or matter, Indemnitee shall not be entitled to payment of Indemnifiable Amounts hereunder except in respect of any excess of such Indemnifiable Amounts beyond the amount of payment under such insurance.

5. Procedure for Payment of Indemnifiable Amounts. Indemnitee shall submit to the Company a written request specifying the Indemnifiable Amounts for which Indemnitee seeks payment under Section 3 of this Agreement and the basis for the claim. The Company shall pay such Indemnifiable Amounts to Indemnitee promptly, but in no event later than thirty (30) calendar days after receipt of such request. At the request of the Company, Indemnitee shall furnish such documentation and information as are reasonably available to Indemnitee and necessary to establish that Indemnitee is entitled to indemnification hereunder.

6. Indemnification for Expenses of a Party Who is Wholly or Partly Successful. Notwithstanding any other provision of this Agreement, and without limiting any such provision, to the extent that Indemnitee is, by reason of Indemnitee's Corporate Status, a party to and is successful, on the merits or otherwise, in any Proceeding, Indemnitee shall be indemnified to the fullest extent permissible by applicable law against all Expenses actually and reasonably incurred by Indemnitee or on Indemnitee's behalf in connection therewith. If Indemnitee is not wholly successful in such Proceeding but is successful, on the merits or otherwise, as to one or more but less than all claims, issues or matters in such Proceeding, the Company shall indemnify to the fullest extent permissible by applicable law Indemnitee against all Expenses actually and reasonably incurred by Indemnitee or on Indemnitee's behalf in connection with each successfully resolved claim, issue or matter. For purposes of this Agreement, the termination of any claim, issue or matter in such a Proceeding by dismissal, with or without prejudice, by reason of settlement, judgment, order or otherwise, shall be deemed to be a successful result as to such claim, issue or matter.

7. Effect of Certain Resolutions. Neither the settlement nor termination of any Proceeding nor the failure of the Company to award indemnification or to determine that indemnification is payable shall create a presumption that Indemnitee is not entitled to indemnification hereunder. In addition, the termination of any Proceeding by judgment, order, settlement, conviction or upon a plea of nolo contendere or its equivalent shall not create a presumption that Indemnitee did not act in good faith and in a manner which Indemnitee reasonably believed to be in or not opposed to the best interests of the Company or, with respect to any criminal Proceeding, had reasonable cause to believe that Indemnitee's action was unlawful.

8. Agreement to Advance Expenses; Undertaking. The Company shall advance to the fullest extent permissible by applicable law all Expenses actually and reasonably incurred by or on behalf of Indemnitee in connection with any Proceeding in which Indemnitee is involved by reason of such Indemnitee's Corporate Status within thirty (30) calendar days after the receipt by the Company of a written statement from Indemnitee requesting such advance or advances from time to time, whether prior to or after final disposition of such Proceeding. Advances shall be unsecured and interest free. Advances shall be made without regard to Indemnitee's ability to repay the expenses and without regard to Indemnitee's ultimate entitlement to indemnification under the other provisions of this Agreement. To the extent required by Delaware law, Indemnitee hereby undertakes to repay any and all of the amount of Indemnifiable Expenses paid to Indemnitee if it is finally determined by a court of competent jurisdiction that Indemnitee is not entitled under this Agreement to indemnification with respect to such Expenses. This undertaking is an unlimited general obligation of Indemnitee.

9. Procedure for Advance Payment of Expenses. Indemnitee shall submit to the Company a written request specifying the Indemnifiable Expenses for which Indemnitee seeks an advancement under Section 8 of this Agreement, together with documentation evidencing that Indemnitee has incurred such Indemnifiable Expenses.

10. Indemnification for Expenses of a Witness. Notwithstanding any other provision of this Agreement, to the extent that Indemnitee is, by reason of his or her Corporate Status, a witness in any Proceeding to which Indemnitee is not a party, he or she shall be indemnified to the fullest extent permissible by applicable law against all Expenses actually and reasonably incurred by him or her or on his or her behalf in connection therewith.

11. Remedies of Indemnitee.

(a) Right to Petition Court. In the event that Indemnitee makes a request for payment of Indemnifiable Amounts under Sections 3 and 5 above or a request for an advancement of Indemnifiable Expenses under Sections 8 and 9 above and the Company fails to make such payment or advancement in a timely manner pursuant to the terms of this Agreement, Indemnitee may petition the Court of Chancery of the State of Delaware to enforce the Company's obligations under this Agreement.

(b) Burden of Proof. In any judicial proceeding brought under Section 11(a) above, the Company shall have the burden of proving that Indemnitee is not entitled to payment of Indemnifiable Amounts hereunder.

(c) Expenses. The Company agrees to reimburse Indemnitee in full for any Expenses in connection with any Proceeding incurred by Indemnitee in connection with investigating, preparing for, litigating, defending or settling any action brought by Indemnitee under Section 11(a) above, or in connection with any claim or counterclaim brought by the Company in connection therewith, whether or not Indemnitee is successful in whole or in part in connection with any such action, except to the extent that it has been finally adjudicated by a court of competent jurisdiction that such reimbursement would be unlawful.

(d) Failure to Act Not a Defense. The failure of the Company (including its Board of Directors or any committee thereof, independent legal counsel or stockholders) to make a determination concerning the permissibility of the payment of Indemnifiable Amounts or the advancement of Indemnifiable Expenses under this Agreement shall not be a defense in any action brought under Section 11(a) above, and shall not create a presumption that such payment or advancement is not permissible.

12. Defense of the Underlying Proceeding.

(a) Notice by Indemnitee. Indemnitee agrees to notify the Company promptly upon being served with any summons, citation, subpoena, complaint, indictment, information or other document relating to any Proceeding which may result in the payment of Indemnifiable Amounts or the advancement of Indemnifiable Expenses hereunder; provided, however, that the failure to give any such notice shall not disqualify Indemnitee from the right, or otherwise affect in any manner any right of Indemnitee, to receive payments of Indemnifiable Amounts or advancements of Indemnifiable Expenses unless the Company's ability to defend in such Proceeding is materially and adversely prejudiced thereby.

(b) Defense by Company. Subject to the provisions of the last sentence of this Section 12(b) and of Section 12(c) below, the Company shall have the right to defend Indemnitee in any Proceeding which may give rise to the payment of Indemnifiable Amounts hereunder; provided, however, that the Company shall notify Indemnitee of any such decision to defend within ten (10) calendar days of the Company's receipt of notice of any such Proceeding under Section 12(a) above. The Company shall not, without the prior written consent of Indemnitee, consent to the entry of any judgment against Indemnitee or enter into any settlement or compromise which (i) includes an admission of fault of Indemnitee or (ii) does not include, as an unconditional term thereof, the full release of Indemnitee from all liability in respect of such Proceeding, which release shall be in form and substance reasonably satisfactory to Indemnitee. This Section 12(b) shall not apply to a Proceeding brought by Indemnitee under Section 11(a) above or pursuant to Section 20 below.

(c) Indemnitee's Right to Counsel. Notwithstanding the provisions of Section 12(b) above, in any Proceeding to which Indemnitee is a party by reason of Indemnitee's Corporate Status, at the Indemnittee's option Indemnitee shall have the right to retain counsel of Indemnitee's choice, at the expense of the Company, to represent Indemnitee in connection with any such matter and the Expenses incurred by Indemnitee in any such matter shall constitute Indemnifiable Expenses.

13. Representations and Warranties of the Company. The Company hereby represents and warrants to Indemnitee as follows:

(a) Authority. The Company has all necessary power and authority to enter into, and be bound by the terms of, this Agreement, and the execution, delivery and performance of the undertakings contemplated by this Agreement have been duly authorized by the Company.

(b) Enforceability. This Agreement, when executed and delivered by the Company in accordance with the provisions hereof, shall be a legal, valid and binding obligation of the Company, enforceable against the Company in accordance with its terms, except as such enforceability may be limited by applicable bankruptcy, insolvency, moratorium, reorganization or similar laws affecting the enforcement of creditors' rights generally.

14. Insurance. The Company shall, from time to time, make the good faith determination whether or not it is practicable for the Company to obtain and maintain a policy or policies of insurance with a reputable insurance company providing the Indemnitee with coverage for losses from wrongful acts. For so long as Indemnitee shall have Corporate Status, Indemnitee shall be named as an insured in all policies of director and officer liability insurance in such a manner as to provide Indemnitee the same rights and benefits as are accorded to the most favorably insured of the Company's officers and directors. If, at the time of the receipt of a notice of a claim pursuant to the terms of this Agreement, the Company has director and officer liability insurance in effect, the Company shall give prompt notice of the commencement of such proceeding to the insurers in accordance with the procedures set forth in the respective policies. The Company shall thereafter take all necessary or desirable action to cause such insurers to pay, on behalf of the Indemnitee, all amounts payable as a result of such proceeding in accordance with the terms of such policies. Notwithstanding the foregoing, the Company shall have no obligation to obtain or maintain such insurance if the Company determines in good faith that such insurance is not reasonably available, if the premium costs for such insurance are disproportionate to the amount of coverage provided, or if the coverage provided by such insurance is limited by exclusions so as to provide an insufficient benefit.

15. No Duplication of Payments. The Company shall not be liable under this Agreement to make any payment in connection with any claim made against Indemnitee to the extent Indemnitee has otherwise actually received payment under any insurance policy, provision of the Certificate or the Bylaws or otherwise of the amounts otherwise indemnifiable hereunder. The Company's obligation to indemnify or advance Expenses hereunder to Indemnitee as a result of the Indemnitee's Corporate Status with an Entity other than the Company shall be reduced by any amount Indemnitee has actually received as indemnification or advancement of Expenses from such other Entity.

16. Contract Rights Not Exclusive. The rights to payment of Indemnifiable Amounts and advancement of Indemnifiable Expenses provided by this Agreement shall be in addition to, but not exclusive of, any other rights which Indemnitee may have at any time under applicable law, the Certificate or Bylaws, or any other agreement, vote of stockholders or directors (or a committee of directors) or otherwise, both as to action in Indemnitee's official capacity and as to action in any other capacity as a result of Indemnitee's serving as a director of the Company.

17. Successors. This Agreement shall be (a) binding upon all successors and assigns of the Company (including any transferee of all or a substantial portion of the business, stock and/or assets of the Company and any direct or indirect successor by merger or consolidation or otherwise by operation of law) and (b) binding on and shall inure to the benefit of the heirs, personal representatives, executors and administrators of Indemnitee. This Agreement shall continue for the benefit of Indemnitee and such heirs, personal representatives, executors and administrators after Indemnitee has ceased to have Corporate Status.

18. Change in Law. To the extent that a change in Delaware law (whether by statute or judicial decision) or the Certificate shall permit broader indemnification or advancement of expenses than is provided under the terms of the Bylaws and this Agreement, Indemnitee shall be entitled to such broader indemnification and advancements, and this Agreement shall be deemed to be amended to such extent.

19. Severability. Whenever possible, each provision of this Agreement shall be interpreted in such a manner as to be effective and valid under applicable law, but if any provision of this Agreement, or any clause thereof, shall be determined by a court of competent jurisdiction to be illegal, invalid or unenforceable, in whole or in part, such provision or clause shall be limited or modified in its application to the minimum extent necessary to make such provision or clause valid, legal and enforceable, and the remaining provisions and clauses of this Agreement shall remain fully enforceable and binding on the parties.

20. Indemnitee as Plaintiff. Except as provided in Section 11(c) of this Agreement and in the next sentence, Indemnitee shall not be entitled to payment of Indemnifiable Amounts or advancement of Indemnifiable Expenses with respect to any Proceeding brought by Indemnitee against the Company, any Subsidiary, any Entity which it controls, any director or officer thereof or any third party, unless the Board of Directors has consented to the initiation of such Proceeding or the Company provides indemnification, in its sole discretion, pursuant to the powers vested in the Company under applicable law. This Section shall not apply to counterclaims or affirmative defenses asserted by Indemnitee in an action brought against Indemnitee.

21. Modifications and Waivers; Counterparts. Except as provided in Section 18 above with respect to changes in Delaware law which broaden the right of Indemnitee to be indemnified by the Company or to receive advancements, no supplement, modification or amendment of this Agreement shall be binding unless executed in writing by each of the parties hereto. No waiver of any of the provisions of this Agreement shall be deemed or shall constitute a waiver of any other provisions of this Agreement (whether or not similar), nor shall such waiver constitute a continuing waiver. This Agreement may also be executed and delivered by facsimile signature and in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same Agreement.

22. General Notices. All notices, requests, demands and other communications hereunder shall be in writing and shall be deemed to have been duly given (a) when delivered by hand, (b) when transmitted by facsimile and receipt is acknowledged during normal business hours, and if not, the next business day after transmission or (c) if mailed by certified or registered mail with postage prepaid, on the third business day after the date on which it is so mailed:

(i) If to Indemnitee, to:

[●]

(ii) If to the Company, to:

Diffusion Pharmaceuticals Inc.
2020 Avon Court, Suite 4
Charlottesville, VA 22902
Attn: David G. Kalergis, Chairman and Chief Executive Officer
Facsimile: (434) 220-0722

or to such other address as may have been furnished in the same manner by any party to the others.

23. Governing Law; Consent to Jurisdiction; Service of Process. This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware without regard to its rules of conflict of laws. Each of the Company and Indemnitee hereby irrevocably and unconditionally consents to submit to the exclusive jurisdiction of the Court of Chancery of the State of Delaware and the courts of the United States of America located in the State of Delaware (the "**Delaware Courts**") for any litigation arising out of or relating to this Agreement and the transactions contemplated hereby (and agrees not to commence any litigation relating thereto except in such courts), waives any objection to the laying of venue of any such litigation in the Delaware Courts and agrees not to plead or claim in any Delaware Court that such litigation brought therein has been brought in an inconvenient forum. Each of the parties hereto agrees, (a) to the extent such party is not otherwise subject to service of process in the State of Delaware, to appoint and maintain an agent in the State of Delaware as such party's agent for acceptance of legal process, and (b) that service of process may also be made on such party by prepaid certified mail with a proof of mailing receipt validated by the United States Postal Service constituting evidence of valid service. Service made pursuant to (a) or (b) above shall have the same legal force and effect as if served upon such party personally within the State of Delaware. For purposes of implementing the parties' agreement to appoint and maintain an agent for service of process in the State of Delaware, each such party does hereby appoint The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, New Castle County, Delaware 19801, as such agent and each such party hereby agrees to complete all actions necessary for such appointment.

24. Joinders. Subsidiaries of the Company may from time to time join this Agreement by signing a joinder in substantially the form attached hereto as Exhibit A. The Company and all Subsidiaries that have joined this Agreement shall be jointly and severally liable for all obligations of the Company under this Agreement.

25. Assignment. Except as otherwise set forth herein, neither this Agreement nor any of the rights, interests or obligations hereunder may be assigned by any party hereto, without the prior written consent of all of the other parties hereto.

26. Entire Agreement. Without limitation to the Certificate and the Bylaws, this Agreement constitutes the entire agreement between the parties hereto with respect to the subject matter hereof and supersedes all prior agreements and understandings, oral, written and implied, between the parties hereto with respect to the subject matter hereof.

[The remainder of this page is intentionally blank]

IN WITNESS WHEREOF, the parties hereto have executed this Indemnification Agreement as of the day and year first above written.

DIFFUSION PHARMACEUTICALS INC.

By: /s/
Name:
Title:

INDEMNITEE

/s/
Name:

[Signature Page to Fund Indemnification Agreement]

EXHIBIT A

JOINDERS

The undersigned hereby join in the obligations of Diffusion Pharmaceuticals Inc. under this Indemnification Agreement as provided in Section 24 above on this ___ day of _____, 20[__].

[ ]

By: /s/ _____
Name:
Title:

[ ]

By: /s/ _____
Name:
Title:

[Signature Page to Joinder to Indemnification Agreement]

Diffusion Pharmaceuticals LLC *Fueling Life™*

Option Agreement

THIS OPTION AGREEMENT is made and entered into effective as of **[_____] [__], 20[__]** by and between Diffusion Pharmaceuticals LLC (the "Company"), a limited liability company organized under the laws of the Commonwealth of Virginia with a principal business address at 2020 Avon Court, #4, Charlottesville, Virginia 22902, and **[_____]** ("Recipient").

WITNESSETH:

WHEREAS the Company desires to give its directors, officers, employees and consultants an added incentive to promote the growth of the Company through participation in the equity of the Company;

NOW, THEREFORE, for and in consideration of the premises and the mutual agreements and covenants hereinafter set forth and of other good and valuable consideration, the receipt, adequacy and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. GRANT OF OPTIONS. Subject to the terms and conditions of this Agreement, the Company hereby irrevocably grants to the Recipient the right and option (the "Option") to purchase up to **[_____]** Units of the Company vesting as set forth in Section 3 herein. The Units which are subject to these options are sometimes referred to herein as the "Option Units."

2. OPTION.

(a) Option Price. The purchase price of each Unit subject to this Option shall be **$[____] per Unit**.

(b) Exercise of Option. Subject to subparagraph (f) hereof, the Recipient may exercise this Option with respect to all or any portion of his/her Option Units at any time prior to ten years from the date hereof.

(c) Manner of Exercise. This Option may be exercised by delivering written notice of exercise to the Managing Director of the Company, in person, or by mail, postage prepaid, addressed to the attention of the Chief Executive Officer at the location at which the Company then maintains its principal office, and if so mailed, the date of mailing will be considered the date of exercise.

(d) Person Who May Exercise Option. During the lifetime of the Recipient, this Option shall be exercisable only by the Recipient, or if the Recipient is disabled, by his/her duly appointed guardian or legal representative. Recipient's personal representative may exercise the Option within ninety (90) days after his/her death by written notice of exercise.

(e) Operating Agreement. In accordance with the Company's Operating Agreement, all Units of the Company are subject to certain restrictions. Upon the exercise of an Option, the Recipient (or his or her guardian, legal representative, or personal representative, as applicable) agrees to be bound by the terms and conditions of such Operating Agreement, as a precondition of being issued any Units.

(f) Termination of Option. Notwithstanding any other provisions to the contrary, this Option, to the extent that it has not previously been exercised, will terminate upon the earliest to occur of (i) the expiration of the term of this Option as set forth in subparagraph 2(b) hereof, or (ii) the expiration of a period of ninety (90) days after the Recipients' termination from employment with the Company for any reason, including termination by resignation or by reason of death or disability.

3. VESTING. The Options granted hereunder will vest monthly in equal **1/36th increments during the three years** from the date of this agreement. In the event that the company is purchased by another company (a "Liquidity Event"), the Options shall fully vest simultaneously with such Liquidity Event.

4. TRANSFERABILITY. This Agreement and any rights hereunder are not transferable and or assignable by the Recipient.

5. ADJUSTMENT OF UNITS. In the event of any recapitalization, reclassification, split-up or consolidation of, or other change in, the Units, or an exchange of the outstanding Units of the Company, in connection with a merger, consolidation or other reorganization of the Company for a different number of Units or for shares of stock or other securities of the Company or for Units or other securities of the other company, then the Board of Directors shall, in such manner as they shall determine in their sole discretion, appropriately adjust the number of the Option Units or the number of Units or other securities that shall then be subject to this Option and/or the purchase price per Unit or share that must be paid thereafter upon exercise of this Option.

6. INVESTMENT REPRESENTATION. The Recipient hereby represents, warrants and agrees that:

(a) He understands the offer of Units under this Agreement is made pursuant to a claim of exemption from the registration provisions of the Securities Act of 1933, as amended (the "Act") and applicable state securities law;

(b) The Company is not obligated to issue Units upon exercise of this Option to any party until there has been compliance with any and all Federal or state laws or regulations that the Company may deem applicable;

(c) The Option Units will be purchased for his/her own account for investment purposes only and not with a view to resale or distribution thereof;

(d) The Option Units may be unregistered and, if so, will be required to be held indefinitely, unless such Units are subsequently registered or an exemption from registration is then available; and

(e) The Company is under no obligation to register the Option Units, to comply with any such exemption or to supply the Recipient with any information necessary to enable him to make routine sales of such Units under Rule 144 or any other rule or regulation of the Securities and Exchange Commission.

7. NO RIGHTS AS MEMBER OR TO EMPLOYMENT. The Recipient shall not have any interest in or membership rights with respect to any Units that are subject to this Option until such Units have been issued and delivered to the Recipient pursuant to the exercise of this Option. Furthermore, this Option does not confer upon the Recipient any rights of employment with the Company, including without limitation any right to continue in the employ of the Company, nor does it affect the right of the Company to terminate the employment of the Recipient at any time, with or without cause, or to continue or alter the terms of such employment.

8. DRAG-ALONG PROVISIONS. The Recipient hereby agrees (a) to sell his/her Option Units to a buyer, if the members of the Board of Directors agree to sell, and sell, all or substantially all of their Units to that buyer, (b) to vote his/her Option Units to approve a merger of the Company or sale of substantially all of its assets if recommended and approved by the Board of Directors, and (c) to execute whatever documentation is necessary to effect the foregoing.

9. WITHHOLDING TAXES. As a condition of exercise of this Option, the Company may, in its sole discretion, withhold or require the Recipient to pay or reimburse the Company for any taxes which the Company determines are required to be withheld in connection with the grant or any exercise of this Option. The Recipient understands that the Option granted hereunder does not qualify for favorable tax treatment under Section 422 of the Internal Revenue Code as an "incentive stock option."

10. HEIRS AND SUCCESSORS. This Agreement and all terms and conditions hereof shall be binding upon the Company and its successors and assigns, and upon Recipient and his or her heirs, legatees and legal representatives.

IN WITNESS WHEREOF, the Company has caused this Agreement to be executed by its Chief Executive Officer and the Recipient has executed this Agreement, all as of the date and year first above written.

Diffusion Pharmaceuticals LLC	Recipient
By: /s/	By: /s/
David G. Kalergis, CEO	

Exhibit 21.1

SUBSIDIARIES OF THE REGISTRANT

Name of Subsidiary	State or Other Jurisdiction of Incorporation or Organization	Direct or Indirect Ownership Interest by RestorGenex
Canterbury Laboratories, LLC	DE	100%
Hygeia Therapeutics, Inc.	DE	100%
Paloma Pharmaceuticals, Inc.	DE	100%
VasculoMedics, Inc.	DE	100%
Diffusion Pharmaceuticals LLC	VA	100%

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-206408 and 333-206409 on Form S-8 of our report dated March 25, 2016 relating to the financial statements of Diffusion Pharmaceuticals Inc. (formerly known as RestorGenex Corporation) (which report expresses an unqualified opinion and includes explanatory paragraphs relating to the ability of Diffusion Pharmaceuticals Inc. to continue as a going concern and the acquisition via merger of Diffusion Pharmaceuticals LLC in January 2016) appearing in this Annual Report on Form 10-K of Diffusion Pharmaceuticals Inc. for the year ended December 31, 2015.

/s/ Deloitte & Touche LLP

Chicago, Illinois
March 25, 2016

Exhibit 31.1

CERTIFICATION OF CEO PURSUANT TO SECTION 302 OF THE SARBANES OXLEY ACT OF 2002 AND SEC RULE 13a-14(a)

I, David G. Kalergis, certify that:

1. I have reviewed this annual report on Form 10-K of Diffusion Pharmaceuticals Inc.;

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

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

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

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

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

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

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

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: March 25, 2016

/s/ David G. Kalergis
David G. Kalergis
Chairman and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF CFO PURSUANT TO SECTION 302 OF THE SARBANES OXLEY ACT OF 2002 AND SEC RULE 13a-14(a)

I, Ben Shealy, certify that:

1. I have reviewed this annual report on Form 10-K of Diffusion Pharmaceuticals Inc.;

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

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

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

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

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

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

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

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: March 25, 2016

/s/ Ben Shealy
Ben Shealy
Senior Vice President – Finance and Treasurer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF CEO PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Diffusion Pharmaceuticals Inc. (the "Company") on Form 10-K for the year ended December 31, 2015 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David G. Kalergis, Chairman and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

/s/ David G. Kalergis
David G. Kalergis
Chairman and Chief Executive Officer
March 25, 2016

Exhibit 32.2

CERTIFICATION OF CEO PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Diffusion Pharmaceuticals Inc. (the "Company") on Form 10-K for the year ended December 31, 2015 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Ben Shealy, Senior Vice President – Finance and Treasurer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

/s/ Ben Shealy
Ben Shealy
Senior Vice President – Finance and Treasurer
March 25, 2016