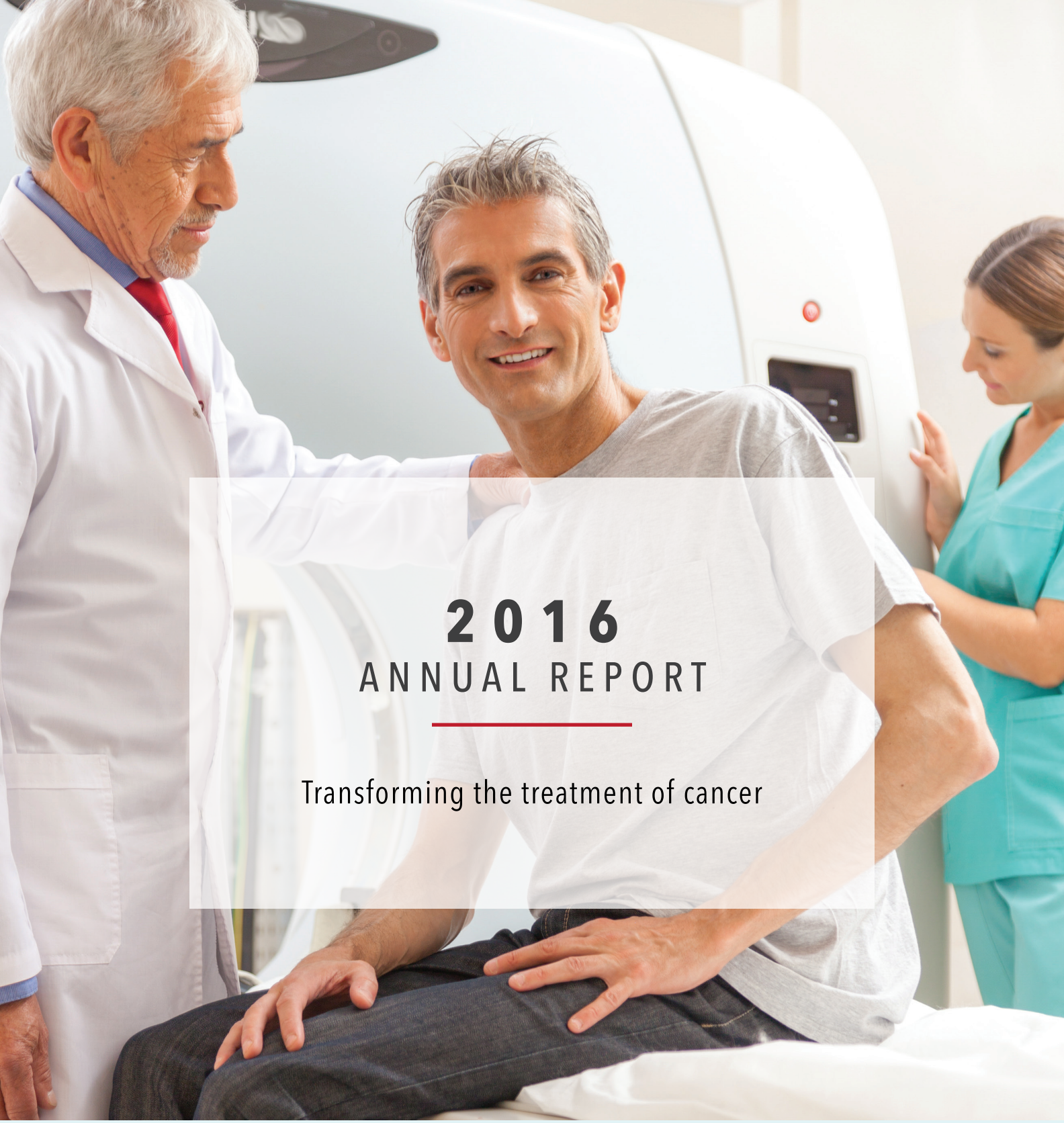

2016
ANNUAL REPORT

Transforming the treatment of cancer

rexahn
PHARMACEUTICALS

CEO Letter to Stockholders

Dear Rexahn Stockholders,

Rexahn is developing novel targeted cancer therapeutics, with recent data showing efficacy against the toughest to treat cancers and minimized side effects. In 2016, we advanced clinical testing of our three proprietary product candidates and reported positive findings from each of our drug-development programs. The data we are generating from these programs suggest that RX-3117, Supinoxin™ and Archexin® are emerging as first-in-class or best-in-class therapeutics with promising clinical benefits in patients with cancers that are very difficult to treat. In the year ahead, we look forward to reporting new findings from our studies that will be important valuation catalysts for our products and our company.

RX-3117 is currently in a Phase IIa clinical proof-of-concept study for the treatment of metastatic pancreatic cancer and advanced bladder cancer. It is a novel, oral small molecule nucleoside analogue which has demonstrated activity against drug-resistant cancers such as pancreatic, bladder, colon and other cancers. We recently initiated the second stage of a Phase IIa clinical trial in patients with metastatic pancreatic cancer, following encouraging findings of safety and preliminary efficacy in the first stage of the trial which we reported in November 2016 at the European Society for Medical Oncology (ESMO) Congress. More recent data from the study were presented in January at the American Society for Clinical Oncology (ASCO) 2017 Gastrointestinal Cancer Symposium, demonstrating the drug's positive effects on progression-free survival among patients who have failed three or more prior cancer therapies. Current options for these patients are usually limited to palliative or best supportive care; there are no drugs approved for metastatic pancreatic cancer patients that have failed two or more prior therapies.

We are greatly encouraged by these findings which support the development of RX-3117 as both monotherapy and, in a study to be started later this year, as a combination therapy with Abraxane® for the treatment of pancreatic cancer. We expect to report additional data from the current Phase IIa monotherapy study this year. RX-3117 has been designated an orphan drug by the FDA for the treatment of pancreatic cancer.

During the third quarter of 2016, we launched a Phase IIa study of RX-3117 in patients with advanced muscle invasive bladder cancer for which where there is a high unmet need for new treatments. This multi-center, open-label study is measuring progression-free survival and changes in tumor size. Initial results are expected to be available during the second half of 2017.

Supinoxin is currently in development as a treatment for patients with triple-negative breast cancer (TNBC). It is an orally active inhibitor of a unique cancer protein that has shown activity against more than 100 human cancer cell lines. In October at ESMO, we presented Phase I findings showing no dose-limiting toxicities from the drug at the doses we tested and preliminary evidence of efficacy in patients with a range of different cancer tumors. We recently initiated a Phase IIa study of Supinoxin in patients with metastatic triple negative breast cancer; we expect to report initial data from this trial during the second half of 2017. Based on the outcome of this initial study, we may conduct additional studies of Supinoxin in combination with other anticancer agents in TNBC.

Archexin, our novel inhibitor of the cancer cell-signaling protein AKT-1, has advanced into the second stage of Phase IIa testing for the treatment of metastatic renal cell carcinoma. As we reported at ASCO in June, Archexin has been safe and well tolerated at the doses we have tested and has shown preliminary evidence of dose-dependent reductions in tumor size for patients in stage one of the trial. We look forward to completing enrollment and reporting results of the Phase IIa study later this year.

Our commitment to innovation in cancer treatment was reflected in the U.S. patent we received in October for our chemotherapeutic RX-21101 that combines Rexahn's nano-drug delivery and targeting technology with docetaxel, a widely used cancer drug. RX-21101 has been selected for preclinical development by the National Cancer Institute (NCI) because of its potential to treat a variety of cancers, while minimizing nerve damage, a frequent side effect of standard of care docetaxel.

In 2017, we look forward to reporting data from all of our ongoing Phase IIa studies – RX-3117 in pancreatic and bladder cancer, Supinoxin in breast cancer and Archexin in metastatic renal cell carcinoma. Thanks to the expansion of our management team and our successful stock offerings in 2016, we believe we have the human and financial resources to execute our clinical programs successfully this year as we work to create value for shareholders and create innovative new medicines for patients.

We greatly appreciate your continued support of Rexahn and look forward to reporting on our progress in 2017.

Sincerely,

Peter D. Suzdak, Ph.D.
Chief Executive Officer

Rexahn Oncology Pipeline Overview

Rexahn's mission is to improve the lives of cancer patients by developing next generation cancer therapies that specifically target cancer cells leading to increased efficacy while minimizing side effects traditionally associated with cancer treatment. The Company has built a diverse portfolio of novel oncology assets that includes three clinical-stage investigational anti-cancer compounds currently in clinical trials, and a robust oncology research platform.

Clinical-Stage Oncology Programs:

RX-3117 – An orally-administered next generation, cancer cell specific nucleoside agent that induces apoptotic cell death selectively in cancer cells. RX-3117 is currently in Phase IIa clinical trials in both metastatic pancreatic cancer and muscle invasive bladder cancer.

Supinoxin™ - An orally administered potential first-in-class small molecule inhibitor of phosphorylated-p68, a protein that we believe plays a key role in cancer cell growth, progression and metastasis. We have recently initiated a Phase IIa clinical trial of Supinoxin in patients with triple negative breast cancer.

Archexin® - A unique anti-cancer drug candidate which inhibits the activated form of the cancer cell signaling protein phosphorylated Akt-1 which is found only in cancer cells and is involved in cancer cell growth and drug resistance. Archexin is currently in Phase IIa clinical trial in metastatic renal cell carcinoma (RCC).

RX-3117 – A Novel Next Generation Nucleoside Compound

RX-3117 is an orally bioavailable, small molecule, investigational anti-cancer therapy that works through a well-proven mechanism of action but is unique in that it is activated only in cancer cells, thus sparing healthy cells from destruction.

A novel, cancer-cell specific nucleoside analogue, RX-3117 is a prodrug activated by the enzyme Uridine Cytidine Kinase, or 'UCK2', which is present predominantly in cancer cells. Once activated by UCK2, RX-3117 inhibits DNA and RNA synthesis leading to cancer cell death. Because UCK2 is overexpressed in multiple human tumors – but has a very limited presence in healthy tissues, RX-3117 offers the potential for a targeted anti-cancer therapy with an improved efficacy and safety profile.

Preclinical studies of RX-3117 in patient-derived and cancer cell xenograft models have demonstrated broad anti-tumor activity and – most importantly, an ability to treat cancer cells that have become resistant to gemcitabine, an anticancer treatment that is widely used for pancreatic cancer, bladder cancer and other indications. Approximately, 25-40% of tumors eventually become resistant to gemcitabine, leading to disease progression and limited options for further treatment. RX-3117 may be effective in some of those patients.

RX-3117 has shown broad spectrum anti-tumor activity against over 100 different human cancer cell lines and efficacy in 17 different mouse xenograft models. In preclinical mouse xenograft studies, RX-3117 demonstrated superior efficacy to gemcitabine. In addition, RX-3117 retained its full anti-tumor activity in human cancer cell lines made resistant to the anti-tumor effects of gemcitabine, supporting a unique, highly-targeted mechanism of action.

RX-3117 is currently being investigated in a Phase IIa multicenter, open-label single-agent study that is ongoing at 10 clinical centers in the United States. These patients have failed all conventional therapies with a life expectancy measured in weeks. The study follows a two-stage design. In stage 1 of the trial, up to 10 patients with relapsed or refractory metastatic pancreatic cancer were enrolled. Based on predefined criteria, if 20% or more of the patients show progression free survival of > 4 months, or an objective clinical response rate and reduction in tumor size, then an additional 40 pancreatic cancer patients can be enrolled into stage 2.

An update from this study was presented in January 2017 at the American Society for Clinical Oncology (ASCO) 2017 Gastrointestinal Cancer Symposium. In the current study more than 20% of patients treated with RX-3117 exhibited progression free survival of greater than 5.6 months (with one patient having progression free survival of 7.2 months). An additional 20%, for a total of 40%, of the patients exhibited progression free survival of 2.5 months. These patients had already failed 3 or more prior cancer therapies. Current options for these patients are usually limited to palliative or best supportive care and these patients normally have an expected survival of less than 2 months. RX-3117 was shown to be safe and well tolerated in this patient group.

Patients in Stage 1 of the clinical trial are still being monitored for survival. However, since the predefined efficacy criteria have been achieved, stage 2 of the study has been initiated which entails enrolling an additional 40 metastatic pancreatic cancer patients. An initial data read out from stage 2 of the trial is expected in late 2Q or early 3Q 2017.

Rexahn's development strategy for RX-3117 in pancreatic cancer is to continue to develop the drug candidate as monotherapy for patients with metastatic disease who have failed on two or more prior therapies, and also, in parallel, to develop RX-3117 in combination with Abraxane® (paclitaxel protein bound) for patients with metastatic pancreatic cancer who have received no prior chemotherapy treatment. Since there are currently no drugs approved for patients who have failed two or more therapies, there may be an accelerated regulatory pathway for approval for this patient population, assuming RX-3117 continues to generate efficacy data. Rexahn plans to initiate a Phase IIa clinical trial of RX-3117 in combination with Abraxane® in newly diagnosed metastatic pancreatic cancer patients who have received no prior chemotherapy. RX-3117 has Orphan Designation in the US for pancreatic cancer.

Rexahn has also initiated the first stage of a Phase IIa study of RX-3117 in patients with muscle-invasive bladder cancer. The initial readout of the first stage is expected during 2017.

Supinoxin – A Potential First-in-Class Inhibitor of a Unique Cancer Protein

Supinoxin™ (RX-5902) is an orally administered, potential first-in-class, small molecule inhibitor of a unique cancer protein – phosphorylated-p68 (P-p68) which is present mainly in cancer cells and absent in normal cells. P-p68 is believed to interact with and increase the

activity of multiple cancer-related genes, and play a prominent role in tumor progression and metastasis. High levels of P-p68 has been observed in many solid tumors, including, melanoma, colon, ovarian, breast and lung tumors.

In preclinical studies, Supinoxin has been shown to inhibit proliferation of cancer cells in over 100 different human cancer cell lines, including, breast, ovarian, colon, pancreas, and stomach cancers, and has shown potent activity in drug-resistant cancer cells. In preclinical animal models, where human cancer cells from triple negative breast cancer, ovarian, melanoma, pancreas, or renal tumors were grafted into animals, treatment with Supinoxin resulted in a significant reduction in tumor growth.

Supinoxin has been evaluated in a Phase I multi-center, dose-finding, open-label, single agent clinical study in patients with advanced or metastatic solid tumors. Updated results from this trial were presented in October 2016 at the ESMO conference, showing continued evidence of single-agent, clinical activity. Initial signs of clinical activity have been observed in patients with breast, neuroendocrine, paraganglioma, head and neck and colorectal cancers, with seven patients experiencing disease stabilization and three patients continuing treatment beyond one year.

A Phase IIa clinical study in patients with triple negative breast cancer (TNBC) patients was initiated in February 2017. The Phase IIa clinical proof-of-concept study is an open-label evaluation of the safety and efficacy of Supinoxin™ monotherapy in patients with metastatic triple negative breast cancer who have failed multiple prior chemotherapeutic regimens. The study will recruit an initial 10 patients and can be extended up to 50 patients, if warranted, based on the data readout from the initial cohort of patients. The primary endpoint is progression free survival. Patients will be enrolled at seven study sites in the United States. Based on the initial clinical data, we may conduct additional clinical studies looking at the combination of Supinoxin together with other anti-cancer agents in TNBC.

Archexin – A Potential Best-in-Class Akt-1 Inhibitor

Archexin is a unique antisense oncology drug candidate that specifically inhibits the cancer cell signaling protein Akt-1, which is highly overexpressed in cancer cells. Archexin is the only specific inhibitor of Akt-1 in clinical development. The activated form of Akt-1, which is involved in cancer cell growth, survival, angiogenesis, and drug resistance, has been shown to be present or elevated in more than 12 different human cancer cell lines, including pancreatic and renal cell carcinoma.

In two clinical trials, Archexin appeared to be safe and well tolerated at all dose levels tested with no dose-limiting toxicities. The FDA has granted Orphan Drug Designation to Archexin in the treatment of five cancers: renal cell, pancreatic, ovarian, stomach, and glioblastoma.

Rexahn is currently conducting a Phase IIa clinical trial of Archexin in patients with metastatic renal cell carcinoma (RCC). This is a multi-center study designed to evaluate the efficacy of Archexin in combination with everolimus to treat metastatic renal cell carcinoma patients. Everolimus is widely used in the treatment of RCC but resistance develops over time, partly due to raised Akt-1 levels. Our expectation is that the combination with Archexin may improve overall efficacy and delay the onset on resistance. This trial is being conducted in two stages. The first stage is a dose ranging study to determine the maximum tolerated dose of Archexin in combination with everolimus. Results from Stage 1, presented at ASCO 2016, showed that in metastatic RCC patients that have previously received multiple anti-

cancer therapies, Archexin treatment produced both stable disease, which persisted for up to 383 days or a median of 165.5 days, and a reduction in tumor burden.

At the dose levels tested to date, Archexin appeared to be safe and well tolerated. The most commonly reported adverse event in patients taking both Archexin and everolimus was thrombocytopenia. To date, no adverse events have been dose limiting.

Stage 2 of the Phase IIa clinical study, which commenced enrolling patients in 2016, is a randomized, open-label, two-arm study of Archexin in combination with everolimus, versus everolimus alone, to determine safety and efficacy of the combination. The trial is anticipated to enroll up to 30 metastatic RCC patients who will be randomized to receive either Archexin in combination with everolimus, or everolimus alone, in a ratio of 2:1. The maximum tolerated dose of 250 mg/m^2/day of Archexin – identified in Stage 1, will be administered along with 10 mg of everolimus versus 10 mg everolimus alone.

The primary endpoint of Stage 2 is the percentage of progression free patients following eight cycles of therapy. Patients are scanned (CT or MRI) for the assessment of tumor progression after every 2 cycles of therapy. Secondary endpoints include pharmacokinetic profile, incidence of adverse events, changes in clinical laboratory tests and vital signs over time, tumor response, duration of response, time to response, and response rate. Exploratory endpoints include blood levels of Akt pathway biomarkers, tumor apoptosis biomarkers, or other relevant biomarkers. Data from Stage 2 of this ongoing clinical study are expected to be available mid-2017.

Metastatic RCC represents an attractive market opportunity with an estimated annual incidence of 90,000 patients worldwide. Metastatic RCC patients receiving standard of care treatment have a poor prognosis with an overall survival of less than two years.

Oncology Research Programs

Nano-Drug Delivery Platform for FDA-Approved Chemotherapy Drugs:

Rexahn's Nano-Polymer-Drug Conjugate System (NPDCS) combines FDA-approved chemotherapies with a proprietary polymer carrier that is designed to target the delivery chemotherapy drugs directly into the tumor while bypassing healthy cells. This approach minimizes the level of freely-circulating drug in the body while maximizing the drug exposure at the tumor site, potentially increasing efficacy and minimizing toxic side effects.

RX-21101 – A Proprietary Nano-Polymer Anti-Cancer Therapeutic

RX-21101 combines Rexahn's nano-drug delivery system with docetaxel, a widely-used, FDA-approved chemotherapy drug. RX-21101 may enhance efficacy while reducing the systemic toxicity of traditional docetaxel delivery by specifically targeting the tumor site and reducing drug exposure elsewhere in the body. The National Cancer Institute's (NCI) Nanotechnology Characterization Laboratory has selected RX-21101 for funding of the further preclinical development of this program, under NCI's preclinical characterization program.

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☑ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF
THE
SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended **December 31, 2016**

OR

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

For the transition period from _____ to _____

Commission File No.:001-34079

Rexahn Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**11-3516358**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification Number)*

15245 Shady Grove Road, Suite 455
Rockville, MD 20850
(Address of principal executive offices, including zip code)

Telephone: (240) 268-5300
(Registrant's telephone number, including area code)

Title of Each Class	**Name of Each Exchange On Which Registered**
Common Stock, $0.0001 par value per share	NYSE MKT

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined by 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 Exchange 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 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 definition of "accelerated filer," "large accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large Accelerated Filer	☐	Accelerated Filer	☑
Non-Accelerated Filer	☐	Smaller reporting company	☐
(Do not check if a smaller reporting company)			

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

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter: **As of June 30, 2016, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was $51,498,946 based on the closing price reported on NYSE MKT.**

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date:

Class	**Outstanding as of February 24, 2017**
Common Stock, $0.0001 par value per share	237,443,785 shares

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the registrant's Definitive Proxy Statement for its 2017 Annual Meeting of Stockholders, which is expected to be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the registrant's fiscal year ended December 31, 2016, are incorporated by reference into Part III of this Annual Report on Form 10-K.

Cautionary Statement Regarding Forward-Looking Statements.

This Annual Report on Form 10-K contains statements (including certain projections and business trends) accompanied by such phrases as "believe," "estimate," "expect," "anticipate," "will," "intend" and other similar expressions, that are "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. We caution that forward-looking statements are based largely on our expectations and are subject to a number of known and unknown risks and uncertainties that are subject to change based on factors that are, in many instances, beyond our control. Actual results, performance or achievements may differ materially from those contemplated, expressed or implied by the forward-looking statements.

Although we believe that the expectations reflected in our forward-looking statements are reasonable as of the date we make them, actual results could differ materially from those currently anticipated due to a number of factors, including risks relating to:

- our understandings and beliefs regarding the role of certain biological mechanisms and processes in cancer;
- our drug candidates being in early stages of development, including in pre-clinical development;
- our ability to initially develop drug candidates for orphan indications to reduce the time-to-market and take advantage of certain incentives provided by the U.S. Food and Drug Administration;
- our ability to transition from our initial focus on developing drug candidates for orphan indications to candidates for more highly prevalent indications;
- our ability to successfully and timely complete clinical trials for our drug candidates in clinical development;
- uncertainties related to the timing, results and analyses related to our drug candidates in pre-clinical development;
- our ability to obtain the necessary U.S. and international regulatory approvals for our drug candidates;
- our reliance on third-party contract research organizations and other investigators and collaborators for certain research and development services;
- our ability to maintain or engage third-party manufacturers to manufacture, supply, store and distribute supplies of our drug candidates for our clinical trials;
- our ability to form strategic alliances and partnerships with pharmaceutical companies and other partners for sales and marketing of certain of our product candidates;
- demand for and market acceptance of our drug candidates;
- the scope and validity of our intellectual property protection for our drug candidates and our ability to develop our candidates without infringing the intellectual property rights of others;

- our lack of profitability and the need for additional capital to operate our business; and

- other risks and uncertainties, including those set forth herein under the caption “Risk Factors” and those detailed from time to time in our filings with the Securities and Exchange Commission.

These forward-looking statements are made only as of the date hereof, and we undertake no obligation to update or revise the forward-looking statements, whether as a result of new information, future events or otherwise.

REXAHN PHARMACEUTICALS, INC.
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PART I

Unless the context requires otherwise, any references in this Annual Report on Form 10-K to "we," "us," "our," the "Company" or "Rexahn" refers to Rexahn Pharmaceuticals, Inc.

Item 1. Description of Business

Overview

We are a clinical stage biopharmaceutical company dedicated to the discovery, development and commercialization of innovative treatments for cancer. Our mission is to improve the lives of cancer patients by developing next-generation cancer therapies that are designed to maximize efficacy while minimizing the toxicity and side effects traditionally associated with cancer treatment. Our clinical pipeline features three oncology product candidates in Phase II clinical development and additional compounds in pre-clinical development. Our strategy is to continue building a significant pipeline of innovative oncology product candidates that we intend to commercialize with partners. Our three clinical stage drug candidates in active development are RX-3117, Supinoxin™ (RX-5902) and Archexin®.

- *RX-3117* is a small molecule nucleoside compound with an anti-metabolite mechanism of action, and we believe it has therapeutic potential in a broad range of cancers, including pancreatic, bladder, colon, and lung cancer. We completed an exploratory Phase I clinical study of RX-3117 that showed a level of oral bioavailability of RX-3117 in humans. In this trial, RX-3117 appeared to be safe and well tolerated with a predictable pharmacokinetic profile for an orally administered agent, with preliminary evidence of single agent activity. We are currently conducting a Phase IIa clinical trial of RX-3117 in patients with relapsed or refractory pancreatic cancer, and a Phase IIa clinical trial in patients with advanced muscle-invasive bladder cancer. RX-3117 has received "orphan drug designation" from the U.S. Food and Drug Administration ("FDA") for pancreatic cancer. Orphan drug designation provides tax incentives for clinical research and a waiver from user fees under certain circumstances. In addition, an orphan drug generally receives seven years of exclusivity after approval for a designated use, during which time, the FDA generally cannot approve another product with the same active moiety for the same indication.

- *Supinoxin*, or RX-5902, is a potential first-in-class small molecule inhibitor of phosphorylated-p68, a protein that we believe plays a key role in cancer cell growth, progression and metastasis through its interaction with beta-catenin. Phosphorylated p68, which is highly expressed in cancer cells, but not in normal cells, results in up-regulation of cancer-related genes and a subsequent proliferation of cancer cells and tumor growth. Supinoxin selectively blocks phosphorylated p68, thereby decreasing the proliferation or growth of cancer cells in preclinical models. We have evaluated Supinoxin in a Phase I dose escalation study in patients with a diverse range of metastatic, treatment-refractory tumors, including breast, ovarian, colorectal, and neuro-endocrine tumors. In February, 2017, we initiated a Phase IIa clinical study of Supinoxin in patients with metastatic triple negative breast cancer ("TNBC").

- *Archexin* is a potential best-in-class, potent inhibitor of the protein kinase Akt-1, which we believe plays a critical role in cancer cell proliferation, survival, angiogenesis, metastasis and drug resistance. Archexin has received orphan drug designation from the FDA for renal cell carcinoma ("RCC"), glioblastoma, ovarian cancer, stomach cancer and pancreatic cancer. We have completed a pilot Phase IIa clinical trial of Archexin for the treatment of pancreatic cancer. We are currently conducting a Phase IIa proof-of-concept clinical trial of Archexin in patients

with metastatic renal cell carcinoma who have failed first line treatment to evaluate its safety and efficacy in combination with AFINITOR® (everolimus).

We also have one drug candidate in pre-clinical development: RX-21101, an N-(2-Hydroxypropyl) methacrylamide-docetaxel-folate, which we believe may provide increased efficacy against tumors with potentially fewer side effects as a result of specific tumor targeting and increased stability in the body.

In addition to our drug development efforts, we are also working on proprietary research technologies, including our multi-target aimed ligands platform and nano-based drug delivery systems. Our unique ligand discovery platform, The Inhibitors of Multi-Expression Signals ("TIMES"), permits us to identify potentially important targets that control multiple genes or signaling events in cancer cells. Our 3-D Gateway of Ligand Discovery ("3-D GOLD") integrates three-dimensional molecular modeling with databases of chemicals and proteins and ligand filtering and generation, which helps us discover novel lead compounds. Leveraging this system, we believe that we are able to effectively develop predictive models, formulate and test hypotheses for optimizing efficacy, and increase drug safety and bioavailability early in the drug discovery process. Our nano-based drug delivery systems, such as those used in the multiple nanoliposomal- and nanopolymer-based anti-cancer drugs that we are currently testing, may increase the availability of a drug at the disease site, minimize adverse reactions, and provide longer duration of action.

Company Background

We trace our history to the March 2001 founding of Rexahn, Corp, which in 2005 merged with and into Rexahn Pharmaceuticals, Inc. (formerly Corporate Road Show.com Inc.). Dr. Peter Suzdak, our Chief Executive Officer since February 2013, has extensive experience in corporate management and drug development, particularly in the field of oncology. Dr. Chang Ahn, our founder, Chief Scientist and Chairman Emeritus of our Board of Directors, is a former FDA reviewer and National Cancer Institute ("NCI") research scientist. He guided our initial research and commercialization efforts in targeted oncology drugs.

Our common stock is currently listed on the NYSE MKT under the trading symbol "RNN." Our principal corporate office is located at 15245 Shady Grove Road, Suite 455, Rockville, Maryland 20850 in Maryland's I-270 technology corridor. Our telephone number is (240) 268-5300.

Industry and Disease Markets

Market Overview

Our primary research and development focus is on oncology therapeutics. A key component of our strategy is to develop innovative drugs that are potential first-in-class or market-leading compounds for the treatment of cancer. According to the Centers for Disease Control and Prevention, cancer claims the lives of more than half a million Americans each year and is the second leading cause of death among Americans. In 2017, the World Health Organization estimated that 14 million new cases of cancer are diagnosed annually worldwide and that the incidence will to increase to 24 million by 2022. A 2017 American Cancer Society report projected that an estimated 1.7 million new cancer cases will be diagnosed in the United States in 2017. In 2015, Evaluate Pharma projected that global annual sales of cancer drugs would grow to $153 billion by 2020.

Current Cancer Treatments

Traditional cancer treatments involve surgery, radiation therapy and chemotherapy. Surgery is widely used to treat cancer, but may result in related or significant complications and may be ineffective if metastasis has occurred. Radiation therapy, or radiotherapy, can be highly effective in treating certain types of cancer. In radiation therapy, ionizing radiation deposits energy that injures or destroys cells in the area being treated by damaging their genetic material, making it impossible for these cells to continue to grow. Although radiation damages both cancer cells and normal cells, the normal cells are generally able to repair themselves and function properly. Chemotherapy involves the use of cytotoxic cancer drugs to destroy cancer cells by interfering with various stages of the cell division process. For certain cancers and in certain patients, these drugs have limited efficacy and debilitating adverse side effects. Administration of cytotoxic cancer drugs may also result in the development of multiple drug, or multi-drug, resistance, which is a condition that results when certain tumor cells that have survived treatment with cytotoxic drugs are no longer susceptible to treatment by those and other drugs. Recent advances in cancer treatment include the use of immunotherapies to stimulate the body's own immune system to kill cancer cells. Immunotherapy can significantly improve survival in certain cancers, including melanoma, non-small cell lung cancer, head and neck tumors, lymphoma and renal cell carcinoma. However, immunotherapy approaches have not been effective in all tumor types and there is a risk of over-stimulation of the immune system that can lead to life-threatening side-effects, such as colitis, pneumonia, and hepatitis.

Unmet Needs in Cancer

Despite significant advances in cancer research and treatments, many unmet needs still remain including:

- *Long-term management of cancers*: Surgery, radiation therapy or chemotherapy may not result in long-term remission, although surgery and radiation therapies are considered effective methods for some cancers. There is a need for more effective drugs and adjuvant therapies to treat relapsed and refractory cancers.

- *Multi-drug resistance*: Multi-drug resistance is a major obstacle to effectively treating various cancers with chemotherapy.

- *Debilitating toxicity by chemotherapy*: Chemotherapy as a mainstay of cancer treatment can induce severe adverse reactions and toxicities, adversely affecting quality of life or life itself.

Market Opportunity

There are several factors that we believe are favorable for commercializing new cancer drugs that may have the potential to be first-in-class or market leaders, including:

- *Expedited Regulatory or Commercialization Pathways*. Drugs for life-threatening diseases such as cancer are often candidates for fast track designation, breakthrough therapy designation, priority review and accelerated approval, each of which may lead to approval sooner than would otherwise be the case.

- *Favorable Environment for Formulary Access and Reimbursement*. We believe cancer drugs with proven efficacy would gain rapid market uptake, formulary listing and third-party payor reimbursement. Drugs with orphan designations are generally reimbursed by third-party payors because there are few, if any, alternatives.

- *Low Marketing Costs*. We believe the marketing of new drugs to oncologists can be accomplished with a smaller sales force and lower related costs than a sales force that markets widely to primary care physicians and general practitioners.

Our Strategy

Our strategy is to continue building a significant product pipeline of innovative drug candidates that we intend to commercialize alone or with partners. This strategy has several key components.

Develop Innovative Therapeutics with the Potential to be First-in-Class or Market Leaders

We plan to focus our research and development pipeline on potential first-in-class or market-leading compounds for the treatment of cancer. By expanding the breadth and depth of our oncology pipeline, we aim to develop an industry-leading oncology therapeutics franchise. Our pipeline spans several major classes of cancer drugs, including molecular targeted therapies and nano-medicines for targeted delivery of compounds and small molecule cytotoxic compounds. Differentiated target product profiles and proprietary discovery and research technology platforms further support these strategic efforts.

Clinically Develop Drug Candidates as Orphan Drugs

We intend to initially develop drug candidates for cancers that are orphan indications. Under the Orphan Drug Act, the FDA may grant orphan drug designation to new drugs developed to treat diseases generally affecting less than 200,000 patients. Benefits associated with orphan drug designation include tax incentives for research and development and an exemption from user fees under certain circumstances. Although the standards for orphan drug approval are not different than for non-orphan products, the path to approval may be faster because clinical trials may be smaller due to the smaller patient population. Further, a drug that is approved for its orphan-designated indication generally receives seven years of orphan drug exclusivity, during which the FDA generally may not approve any other application for a product containing the same active moiety and proposed for the same indication. An approved orphan drug also may qualify for an exemption from the branded prescription drug fee. We plan to develop drug candidates for cancers that are orphan indications in order to take advantage of the benefits of orphan drug designation during development and the exclusivity available under the Orphan Drug Act for approved products, as well as the potential for reduced time to market. Drugs intended to treat rare diseases or conditions also may qualify for fast track designation, breakthrough therapy

designation, accelerated approval and/or priority review, any or all of which may speed the development and approval process.

Establish Partnerships with Large Pharmaceutical Companies

We seek to establish strategic alliances and partnerships with larger pharmaceutical companies for the commercialization and co-development of our drug candidates.

In-License Unique Technology

We continually review opportunities to in-license and advance compounds in oncology that have value-creating potential and will strengthen our clinical development pipeline.

Capitalize on Our Management Team's Expertise for Drug Development

Our management team possesses clinical development experience in oncology and several other therapeutic areas which facilitates strategic approaches to and competitive advantages in, the design, risk assessment and implementation of drug development programs. Our management team also has prior experience in pharmaceutical alliances, product launches and marketing.

Our Pipeline Drug Candidates

Clinical Stage Pipeline

RX-3117: Oral Small Molecule Nucleoside

RX-3117 is a novel, investigational oral small molecule nucleoside compound. In pre-clinical models when activated (phosphorylated) by uridine-cytidine kinase 2, a protein that is overexpressed in various human cancer cells, RX-3117 is incorporated into DNA or RNA of cells and inhibits both DNA and RNA synthesis, which induces apoptotic cell death of tumor cells. We believe RX-3117 has therapeutic potential in a broad range of cancers including pancreatic, bladder, lung, cervical, non-small cell lung cancer and colon cancer. RX-3117 has received orphan drug designation from the FDA for the treatment of patients with pancreatic cancer. RX-3117 has also been shown in animal models to inhibit the growth of gemcitabine-resistant human cancers and improve overall survival.

RX-3117 has demonstrated broad spectrum anti-tumor activity against over 100 different human cancer cell lines and efficacy in 17 different mouse xenograft models. Notably, the efficacy of RX-3117 in the mouse xenograft models was superior to that of gemcitabine. Further, RX-3117 still retains its full anti-tumor activity in human cancer cell lines made resistant to the anti-tumor effects of gemcitabine. In August 2012, we reported the completion of an exploratory Phase I clinical trial of RX-3117 in cancer patients conducted in Europe, to investigate the oral bioavailability, safety and tolerability of the compound. In this study, oral administration of a 50 mg dose of RX-3117 demonstrated an oral bioavailability of 56% and a plasma half-life ($T_{1/2}$) of 14 hours. In addition, RX-3117 appeared to be safe and well tolerated in all subjects throughout the dose range tested.

Final results from the Phase Ib clinical trial of RX-3117 presented at the American Society of Clinical Oncology Annual Meeting in June 2016 showed evidence of single agent activity. Patients in the study had generally received four or more cancer therapies prior to enrollment. In this study, 12 patients experienced stable disease persisting for up to 276 days and three patients showed evidence of tumor burden reduction. A maximum tolerated dose of 700 mg was identified in the study. At the doses tested

to date, RX-3117, administered orally, appeared to be safe and well tolerated with a predictable pharmacokinetic profile following oral administration.

In March 2016, we initiated a multi-center Phase IIa clinical trial of RX-3117 in patients with relapsed or refractory pancreatic cancer to further evaluate the safety and anti-cancer properties of this compound. Patients in the trial will receive a 700 mg daily oral dose of RX-3117, for five consecutive days, followed by two days off, for three weeks, followed by a week of rest, in a 28 day cycle for up to eight treatment cycles, or until their disease progresses. The study is designed as a two-stage study with 10 patients in stage 1 and an additional 40 in stage 2. According to pre-set criteria, if greater than 20% of the patients have an increase in progression free survival of more than four months, or an objective clinical response rate and reduction in tumor size, then an additional 40 pancreatic cancer patients would be enrolled into stage 2. Secondary endpoints include time to disease progression, overall response rate and duration of response, as well as pharmacokinetic assessments and safety parameters.

In September 2016, we initiated stage 2 of this Phase IIa clinical trial. The decision to proceed was based on satisfying the predefined criteria for preliminary efficacy for stage 1 of the trial. RX-3117 was safe and well tolerated with preliminary efficacy seen in pancreatic cancer patients for whom three or more prior therapies had been ineffective.

In September 2016, we commenced enrollment in a Phase IIa trial of RX-3117 in patients with advanced bladder cancer. This Phase IIa clinical trial is a multicenter, open-label, single-agent study of RX-3117 being conducted at 10 clinical centers in the United States. RX-3117 is being administered orally five times weekly on a three weeks on, one week off dosing schedule. The primary endpoint for the trial is an assessment of the progression free survival rate or an objective clinical response rate and reduction in tumor size. Secondary endpoints include time to disease progression, overall response rate and duration of response, as well as pharmacokinetic assessments and safety.

Based on the progress of the RX-3117 clinical development program and the level of interest expressed from a number of oncology-focused pharmaceutical companies, we are continuing discussions with multiple companies to explore collaborative business structures in an effort to maximize the potential value of the program.

Supinoxin: Potential First-in-Class p68 RNA Helicase Inhibitor

Supinoxin is a potential first-in-class small molecule inhibitor of phosphorylated-p68, a protein that we believe plays a key role in cancer growth, progression and metastasis. Phosphorylated p68, which is highly expressed in cancer cells, but not in normal cells, results in up-regulation of cancer-related genes and a subsequent proliferation of cancer cells and tumor growth. Supinoxin selectively blocks phosphorylated p68, thereby decreasing the proliferation or growth of cancer cells. In pre-clinical tissue culture models and *in-vivo* xenograft models, Supinoxin has exhibited single-agent tumor growth inhibition, potential synergy with cytotoxic agents and activity against drug resistant cancer cells. In particular, in *in-vivo* xenograft models of human triple negative breast cancer and pancreatic cancer, treatment with Supinoxin on days one through 20 in mouse models produced a dose-dependent inhibition of tumor growth and a survival benefit.

Supinoxin was evaluated in a Phase I dose-escalation clinical trial in cancer patients with solid tumors designed to evaluate the safety, tolerability, dose-limiting toxicities and the recommended Phase II dose. Secondary endpoints include pharmacokinetic analyses and an evaluation of the preliminary anti-tumor effects of Supinoxin. We completed enrollment in this study in 2016.

Updated results from the Phase I clinical trial of Supinoxin were presented in October 2016 at the 2016 European Society for Medical Oncology Congress.

The results showed evidence of single-agent, clinical activity of Supinoxin. In this study, Supinoxin preliminarily appeared to be safe and well tolerated at the doses and dosing schedules tested with no dose limiting toxicities or treatment-related serious adverse events. The most frequently reported drug related adverse events were mild nausea, vomiting and fatigue. Initial signs of clinical activity have been observed. Twenty-four subjects were enrolled (11 female, 13 male), and seven subjects experienced stable disease in breast, neuroendocrine, paraganglioma, head/neck or colorectal cancer. Three subjects received treatment for more than one year. Approximately 55% of the subjects had received four or more therapies prior to their enrollment in the Phase I clinical study.

We initiated a Phase IIa study of Supinoxin in patients with triple negative breast cancer in February 2017. The study will evaluate the safety and preliminary efficacy of Supinoxin in patients with metastatic triple negative breast cancer who have failed prior treatments. We also plan to evaluate Supinoxin in combination with other anticancer agents in TNBC, assuming positive data from this initial study.

Based on the progress of the Supinoxin clinical development program and the level of interest expressed from a number of oncology-focused pharmaceutical companies, we are continuing our discussions with multiple companies to explore collaborative business structures in an effort to maximize the potential commercial value of the program.

Archexin: *Potential Best-in-Class Anti-Cancer Akt-1 Inhibitor*

Archexin is a potential best-in-class, potent inhibitor of the protein kinase Akt-1, which we believe plays a critical role in cancer cell proliferation, survival, angiogenesis, metastasis and drug resistance. Archexin has received orphan drug designation from the FDA for RCC, glioblastoma, ovarian cancer, stomach cancer and pancreatic cancer. We believe Archexin is differentiated from other Akt-1 inhibitors by its ability to inhibit both activated and inactivated forms of Akt-1, and as a result it is not expected to lead to drug resistance, which has been observed with other protein kinase inhibitors. Other targeted drugs may only inhibit inactivated Akt-1 and may also cause drug resistance. Akt-1 is over-activated in patients with many cancers, including breast, colorectal, gastric, pancreatic, prostate and melanoma cancers. Akt-1 activity may be inhibited by signaling molecules upstream of Akt-1 in cancer cells through the use of vascular endothelial growth factor and epidermal growth factor receptor inhibitors, but this treatment only indirectly affects the activity of native Akt-1. Because signal transmission for cancer progression and resistance occurs when Akt-1 is activated, we believe it is also important to inhibit activated Akt-1. We believe Archexin inhibits both activated and native Akt-1.

Archexin is an antisense oligonucleotide compound that is complementary to Akt-1 mRNA and highly selective for inhibiting mRNA expression, which leads to reduced production of Akt-1 protein. Archexin preliminarily appeared to be safe and well tolerated with minimal side effects in a Phase I study in patients with advanced cancers, where Grade 3 fatigue was the only dose-limiting toxicity and no significant hematological abnormalities were observed. The main objectives of the Phase I study were to determine the maximum tolerated dose, dose limiting toxicity and pharmacokinetic parameters for Archexin monotherapy. The Archexin Phase I study design was an open label, single arm ascending dose, safety and tolerability study.

We completed a Phase IIa clinical trial for Archexin that was designed to assess the safety and efficacy of Archexin in combination with gemcitabine. Gemcitabine is used to treat pancreatic, breast, ovarian, and lung cancers, and may be used for other cancers as well. The study enrolled 31 patients with

metastatic pancreatic cancer in the United States and India and showed that treatment with Archexin in combination with gemcitabine provided a median survival rate of 9.1 months compared to the historical survival rate of 5.7 months for single-agent gemcitabine therapy. We are not currently seeking to further develop Archexin in combination with gemcitabine.

We are conducting an ongoing Phase IIa proof-of-concept clinical trial of Archexin to study its safety and efficacy in patients with metastatic RCC. In this trial, Archexin is being administered in combination with Afinitor® (everolimus). The trial is being conducted in two stages. Stage 1 was a dose ranging study, with up to three dose groups with three RCC patients each, to determine its maximum tolerated dose ("MTD") in combination with everolimus. In January 2016, we completed Stage 1 of the study and commenced enrollment in Stage 2, which is a randomized, open-label, two-arm dose expansion study of everolimus versus Archexin in combination with everolimus to determine safety and efficacy of the combination. This phase of the trial (Stage 2) is anticipated to enroll up to 30 RCC patients who will be randomized to receive either Archexin in combination with everolimus, or everolimus alone, in a ratio of 2:1 The MTD was determined to be 250 mg/m^2/day of Archexin, which was identified in Stage 1 and will be administered in Stage 2 along with 10 mg of everolimus compared to 10 mg everolimus alone.

Pre-Clinical Pipeline

RX-21101: Nano-polymer Anti-cancer Drug

RX-21101 is an investigational anti-cancer nano-polymer drug that we believe can mitigate some of the limitations of cytotoxic compounds, such as poor solubility and severe adverse reactions. Conjugating water-soluble and non-toxic N-(2-Hydroxypropyl)methacrylamide to conventional anti-cancer compounds may bolster efficacy while lowering toxicity by specific tumor targeting and increased stability in the body. In June 2015, RX-21101 was selected by NCI's Nanotechnology Characterization Laboratory for its pre-clinical characterization program to facilitate the advancement of RX-21101 towards human clinical trials.

Research and Development Process

We have engaged third-party contract research organizations and other investigators and collaborators, such as universities and medical institutions, to conduct our pre-clinical studies, toxicology studies and clinical trials. Engaging third-party contract research organizations is typical practice in our industry. However, relying on such organizations means that the clinical trials and other studies described above are being conducted at external locations and that the completion of these trials and studies is not within our direct control. Trials and studies may be delayed due to circumstances outside our control, and such delays may result in additional expenses for us.

Competition

We compete against fully integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies, as well as academic institutions, government agencies and other public and private research organizations. Many of these competitors, either alone or together with their collaborative partners, operate larger research and development programs or have substantially greater financial resources than we do, as well as more experience in:

- developing drugs;
- undertaking pre-clinical testing and human clinical trials;

- obtaining FDA and other regulatory approvals of drugs;
- formulating and manufacturing drugs; and
- launching, marketing and selling drugs.

Large pharmaceutical companies currently sell both generic and proprietary compounds for the treatment of cancer. In addition, companies developing oncology therapies represent substantial competition. Many of these organizations have substantially greater capital resources, larger research and development staff and facilities, longer drug development history in obtaining regulatory approvals and greater manufacturing and marketing capabilities than we do. These organizations also compete with us to attract qualified personnel, parties for acquisitions, joint ventures or other collaborations.

We are aware of products under development by our competitors that target the same indications as our clinical stage drug candidates. If approved, Archexin could compete with other Akt-1 inhibitors under development by other companies including Merck & Company, Inc., GlaxoSmithKline, AstraZeneca, Gilead Sciences, MEI Pharma, PIQUR Therapeutics and others. Archexin will also compete with carbozantinib (Exelexis) and lenvatinib (Eisai), multi-kinase inhibitors that were approved for RCC in 2016, and also with FDA-approved immunotherapy nivolumab (BMS). If approved, RX-3117 could compete with other compounds with an anti-metabolite mechanism of action in cancers, such as sapacitabine, which is under development by Cyclacel. We are not currently aware of known inhibitors of phosphorylated p68 that would compete with Supinoxin if Supinoxin were approved, but other drugs with a different mechanism of action are in development for the same indications, such as Immunomedics' sacitazumab govitecan and Celldex's Glenbatumumab vedotin, both in development for triple negative breast cancer. Our competitors may succeed in developing products that are more safe and/or effective than ours, which could render our product candidates less competitive prior to recovery by us of expenses incurred with respect to their development.

Government Regulation

Regulation by governmental authorities in the United States and in other countries is a significant consideration in our product development, manufacturing and marketing strategies. We expect that all of our drug candidates will require regulatory approval by the FDA and by similar regulatory authorities in foreign countries prior to commercialization and will be subjected to rigorous pre-clinical, clinical, and post-approval testing to demonstrate safety and effectiveness, as well as other significant regulatory requirements and restrictions in each jurisdiction in which we would seek to market our products. U.S. federal laws and regulations govern the testing, development, manufacture, quality control, safety, effectiveness, approval, storage, labeling, record keeping, reporting, distribution, import, export and marketing of all biopharmaceutical products intended for therapeutic purposes. We believe that we and the third parties that work with us are in compliance in all material respects with currently applicable rules and regulations, however, any failure to comply could have a material negative impact on our ability to successfully develop and commercialize our products, and therefore on our financial performance. In addition, these rules and regulations are subject to change. For example, in December 2016, the 21st Century Cures Act ("Cures Act") was signed into law. The Cures Act included numerous provisions that may be relevant to our product candidates, including provisions designed to speed development of innovative therapies and provide funding for certain cancer-related research and technology development. Because the Cures Act has only recently been enacted, it is difficult to know whether, how, or when it may affect our business. Similarly, further legislative and regulatory changes appear possible in the 115th United States Congress and under the Trump Administration, and it is difficult to foresee whether, how, or when such changes may affect our business.

Obtaining governmental approvals and maintaining ongoing compliance with applicable regulations are expected to require the expenditure of significant financial and human resources not currently at our disposal. We plan to fulfill our short-term needs through consulting agreements and joint ventures with academic or corporate partners while developing our own internal infrastructure for long-term corporate growth.

Development and Approval

The process to obtain approval for biopharmaceutical compounds for commercialization in the United States and many other countries is lengthy, complex and expensive, and the outcome is far from certain. Although foreign requirements for conducting clinical trials and obtaining approval may be different than in the United States, they often are equally rigorous and the outcome cannot be predicted with confidence. A key component of any submission for approval in any jurisdiction is pre-clinical and clinical data demonstrating the product's safety and effectiveness.

Pre-clinical Testing. Before testing any compound in humans in the United States, a company must develop pre-clinical data, generally including laboratory evaluation of product chemistry and formulation, as well as toxicological and pharmacological studies in animal species to assess safety and quality. Certain types of animal studies must be conducted in compliance with the FDA's Good Laboratory Practice regulations and the Animal Welfare Act, which is enforced by the Department of Agriculture.

IND Application. In the United States, FDA regulations require that the person or entity sponsoring or conducting a clinical study for the purpose of investigating a candidate's safety and effectiveness submit to the FDA an investigational new drug ("IND") application, which contains pre-clinical testing results and provides a basis for the FDA to conclude that there is an adequate basis for testing the drug in humans. If the FDA does not object to the IND application within 30 days of submission, the clinical testing proposed in the IND may begin. Even after the IND has gone into effect and clinical testing has begun, the FDA may put the clinical trials on "clinical hold," suspending (or in some cases, ending) them because of safety concerns or for other reasons.

Clinical Trials. Clinical trials involve administering a drug to human volunteers or patients, under the supervision of a qualified clinical investigator. Clinical trials are subject to extensive regulation. In the United States, this includes compliance with the FDA's bioresearch monitoring regulations and Good Clinical Practice ("GCP") requirements, which establish standards for conducting, recording data from, and reporting the results of, clinical trials, with the goal of assuring that the data and results are credible and accurate and that study participants' rights, safety and well-being are protected. Each clinical trial must be conducted under a protocol that details the study objectives, parameters for monitoring safety and the efficacy criteria, if any, to be evaluated. The protocol is submitted to the FDA as part of the IND and reviewed by the agency before the study begins. Additionally, each clinical trial must be reviewed, approved and conducted under the auspices of an Institutional Review Board ("IRB"). The sponsor of a clinical trial, the investigators and IRBs each must comply with requirements and restrictions that govern, among other things, obtaining informed consent from each study subject, complying with the protocol and investigational plan, adequately monitoring the clinical trial, and timely reporting adverse events. Foreign studies conducted under an IND must meet the same requirements applicable to studies conducted in the United States. However, if a foreign study is not conducted under an IND, the data may still be submitted to the FDA in support of a product application, if the study was conducted in accordance with GCP and the FDA is able to validate the data.

Sponsors of clinical trials are required to make public certain information about active clinical trials and trial results by posting the information on government or independent websites, such as http://clinicaltrials.gov. Clinical testing is typically performed in three phases.

In Phase I, the drug is administered to a small number of human subjects to confirm its safety and to develop detailed profiles of its pharmacological and pharmacokinetic actions (*i.e.*, absorption, distribution, metabolism, and excretion). Although Phase I trials typically are conducted in healthy human subjects, in some instances (including, for example, with some cancer therapies) the study subjects are patients with the targeted disease or condition.

In Phase II, the drug is administered to groups of patients (usually no more than several hundred) to develop initial data regarding efficacy against the targeted disease and determine the requisite dose and dose intervals, and generate additional information regarding the drug's safety. In a typical development program, additional animal toxicology studies precede this phase. In some cases, the trial can be split into Phase IIa and IIb studies in order to test smaller subject pools. Some Phase I clinical studies may proceed in parallel with some Phase II studies.

In Phase III, the drug is administered to a larger group of patients (usually from several hundred to several thousand or more). Phase III studies also can include patients with concomitant diseases and medications. Larger patient populations are evaluated in Phase III at multiple study sites and registration studies may be conducted concurrently for the sake of time and efficiency. The extensive clinical testing is intended to obtain additional information about product safety and effectiveness necessary to evaluate the drug's overall risk-benefit profile and to provide a basis for physician labeling. Phase III data often form the core basis on which the FDA evaluates the product's safety and effectiveness when considering an application to market the drug.

The study sponsor, the FDA or an IRB may suspend or terminate a clinical trial at any time on various grounds, including a determination that study subjects are being exposed to an unacceptable health risk. Additionally, success in early-stage clinical trials does not assure success in later-stage clinical trials, and data from clinical trials are not always conclusive and may be subject to alternative interpretations that could delay, limit or prevent approval.

NDA Submission and Review. After completing the clinical studies, a sponsor seeking approval to market a drug in the United States submits to the FDA a New Drug Application ("NDA"). The NDA is a comprehensive, multi-volume application intended to demonstrate the product's safety and effectiveness and includes, among other things, pre-clinical and clinical data, information about the drug's composition, the sponsor's plans for manufacturing and packaging and proposed labeling. When an NDA is submitted, the FDA makes an initial determination as to whether the application is sufficiently complete to be accepted for review. If the application is not, the FDA may refuse to accept the NDA for filing and request additional information. A refusal to file, which requires resubmission of the NDA with the requested additional information, delays review of the application.

FDA performance goals regarding the timeliness of NDA review generally provide for action on an NDA within 12 months of its submission. That deadline can be extended under certain circumstances, including by the FDA requests for additional information. The targeted action date can also be shortened to eight months after submission, for products that are intended to treat serious or life-threatening conditions and demonstrate the potential to address unmet medical needs. Additionally, the FDA has programs for enhanced communication and consultation and other steps to expedite submission and consideration of such products. For example, the Fast Track program is intended to expedite or facilitate the process for reviewing new drugs that demonstrate the potential to address unmet medical needs involving serious or life-threatening diseases or conditions. If a drug receives Fast Track

designation, the FDA may consider reviewing sections of the NDA on a rolling basis, rather than requiring the entire application to be submitted to begin the review. Products with Fast Track designation also may be eligible for more frequent meetings and correspondence with the FDA about the product's development. Other FDA programs intended to expedite development and review include Accelerated Approval, which allows approval on the basis of a surrogate endpoint that is reasonably likely to predict clinical benefit and Breakthrough Therapy designation, which is available for drugs under development for serious or life-threatening conditions and where preliminary clinical evidence shows that the drug may have substantial improvement on at least one clinically significant endpoint over available therapy. If a drug receives Breakthrough Therapy designation, it will be eligible for all of the benefits of Fast Track designation, as well as for more intensive guidance from the FDA on an efficient drug development program and a commitment from the agency to involve senior FDA managers in such guidance. Even if a product qualifies for Fast Track designation or Breakthrough Therapy designation, the FDA may later decide that the product no longer meets the conditions for qualification, and/or may determine that the product does not meet the standards for approval. We anticipate, but cannot ensure, that our product candidates will qualify for such programs.

If it concludes that an NDA does not meet the regulatory standards for approval, the FDA typically issues a Complete Response letter, which communicates the reasons for the agency's decision not to approve the application and may request additional information, including additional clinical data. An NDA may be resubmitted with the deficiencies addressed, but that does not guarantee approval. Data from clinical trials are not always conclusive, and the FDA's interpretation of data may differ from the sponsor's. Obtaining approval can take years, requires substantial resources and depends on a number of factors, including the severity of the targeted disease or condition, the availability of alternative treatments, and the risks and benefits demonstrated in clinical trials. Additionally, as a condition of approval, the FDA may impose restrictions that could affect the commercial prospects of a product, such as a Risk Evaluation and Mitigation Strategy, and could require post-approval commitments to conduct additional studies or conduct surveillance programs to monitor the drug's effects.

Moreover, once a product is approved, information about its safety or effectiveness from actual use can limit or prevent successful commercialization, either because of regulatory action or market forces. Post-approval modifications to a drug product, such as changes in indications, labeling or manufacturing processes or facilities, may require development and submission of additional information or data in a new or supplemental NDA, which would also require FDA approval.

One of our drug candidates, Archexin is an antisense oligonucleotide ("ASO") compound. To date, the FDA has not approved any NDAs for any ASO compounds for cancer treatment; however, the FDA has approved the ASO compounds fomivirsen (marketed as Vitravene®) as a treatment for cytomegalovirus retinitis, and mipomersen sodium (marketed as Kynamro®), as a treatment for homozygous familial hypercholesterolemia. In addition, Archexin is in a drug class known as Akt-1 inhibitors, and drugs from this class have not been approved by the FDA to date.

We have not submitted an NDA for any of our drug candidates.

Exclusivity and Patent Protection. In the United States and elsewhere, certain regulatory exclusivities and patent rights can provide an approved drug product with protection from certain competitors' products for a period of time and within a certain scope. In the United States, those protections include exclusivity under the Orphan Drug Act, which is available for drugs intended to treat rare diseases or conditions, which generally are diseases or conditions that affect fewer than 200,000 persons in the United States. If a sponsor demonstrates that a drug is intended to treat a rare disease or condition and meets other qualifying criteria, the FDA grants orphan drug designation to the product for that use. A product that has received orphan drug designation is eligible for research and

development tax credits and is exempt from user fees under certain circumstances. Additionally, a drug that is approved for its orphan-designated indication generally receives seven years of orphan drug exclusivity. During that period, the FDA generally may not approve any other application for a product containing the same active moiety and proposed for the same indication. There are exceptions, however, most notably when the later product is shown to be clinically superior to the product with exclusivity. An approved orphan drug also may qualify for an exemption from the branded prescription drug fee. Products that qualify for orphan designation may also qualify for other FDA programs that are intended to expedite the development and approval process and, as a practical matter, clinical trials for orphan products may be smaller, simply because of the smaller patient population. Nonetheless, the same approval standards apply to orphan-designated products as for other drugs.

Archexin has received orphan drug designation from the FDA for RCC, glioblastoma, ovarian cancer, stomach cancer and pancreatic cancer. RX-3117 received orphan drug designation for pancreatic cancer in September 2014.

Generic Competition. Any drug candidates approved for commercial marketing under an NDA would be subject to the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act. Among other things, the Hatch-Waxman Act establishes two abbreviated approval pathways for drug products that are in some way follow-on versions of already approved NDA products, including generic versions of the approved product, which may be approved under an Abbreviated New Drug Application by a showing that the generic product is the "same as" the approved product in key respects. Those abbreviated approval pathways generally are available, however, after expiration of certain periods of regulatory exclusivity and/or extended patent protection, which the Hatch-Waxman Act also provides. These protections include: (1) five years of regulatory exclusivity for a new chemical entity (generally, the first approval of a product containing a particular active moiety), during which an application for a follow-on product cannot be accepted for review; (2) three years of exclusivity for the approval of an NDA or supplemental NDA that contains data from new clinical investigations that were necessary for approval, during which the follow-on product may not receive final approval; and (3) up to five years' extension of the term of a patent covering a drug that contains an active ingredient not previously approved. The Hatch-Waxman Act also provides a means for the sponsor of an approved NDA to act before approval of a proposed ANDA to sue to protect patents claiming the drug substance, drug product, or an approved method of using the drug. The laws of other key markets likewise create both opportunities for exclusivity periods and patent protections and the possibility of generic competition once such periods or protections have either expired or have been successfully challenged by generic entrants.

Post-Approval Regulation

Once approved, products are subject to continuing extensive regulation by the FDA. If ongoing regulatory requirements are not met, or if safety problems occur after a product reaches market, the FDA may take actions to change the conditions under which the product is marketed, including suspending or even withdrawing approval. In addition to FDA regulation, the healthcare industry, and therefore our business, is also subject to extensive federal, state, local and foreign regulation.

Good Manufacturing Practices. Companies engaged in manufacturing drug products or their components must comply with applicable current Good Manufacturing Practice ("cGMP") requirements, which include requirements regarding organization and training of personnel, building and facilities, equipment, control of components and drug product containers, closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls and records and reports. The FDA inspects equipment, facilities and manufacturing processes before approval and conducts periodic re-inspections after approval. Failure to comply with applicable cGMP requirements or the

conditions of the product's approval may lead the FDA to take administrative enforcement action. Although we periodically monitor FDA compliance of the third parties on which we rely for manufacturing our drug products, we cannot be certain that our present or future third-party manufacturers will consistently comply with cGMP or other applicable FDA regulatory requirements.

Sales and Marketing. Once a product is approved, its advertising, promotion and marketing will be subject to close regulation, including with regard to promotion to healthcare practitioners, direct-to-consumer advertising, communications regarding unapproved uses, industry-sponsored scientific and educational activities and promotional activities involving the internet. In addition to FDA restrictions on marketing of pharmaceutical products, state and federal fraud and abuse laws have been applied to restrict certain marketing practices in the pharmaceutical industry for many years. Some of the pertinent laws are open to a variety of interpretations. In addition, these laws and their interpretations are subject to change.

Other Requirements. Companies that manufacture or distribute drug products pursuant to approved NDAs must meet numerous other regulatory requirements, including adverse event reporting, submission of periodic reports, and record-keeping obligations.

Fraud and Abuse Laws. At such time as we market, sell and distribute any products for which we obtain marketing approval, it is possible that our business activities could be subject to scrutiny and enforcement under one or more federal or state health care fraud and abuse laws and regulations, which could affect our ability to operate our business. These restrictions under applicable federal and state health care fraud and abuse laws and regulations that may affect our ability to operate include:

- The federal Anti-Kickback Law, which prohibits, among other things, knowingly or willingly offering, paying, soliciting or receiving remuneration, directly or indirectly, in cash or in kind, to induce or reward the purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any health care items or service for which payment may be made, in whole or in part, by federal healthcare programs such as Medicare and Medicaid. This statute has been interpreted to apply to arrangements between pharmaceutical companies on one hand and prescribers, purchasers and formulary managers on the other. Further, the Affordable Care Act clarified among other things that liability may be established under the federal Anti-Kickback Law without proving actual knowledge of the statute or specific intent to violate it. In addition, the Affordable Care Act amended the Social Security Act to provide that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Law constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Although there are a number of statutory exemptions and regulatory safe harbors to the federal Anti-Kickback Law protecting certain common business arrangements and activities from prosecution or regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that do not fit squarely within an exemption or safe harbor, or for which no exception or safe harbor is available, may be subject to scrutiny;
- The federal civil False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds or knowingly making, using or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly concealing or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the federal government. Many pharmaceutical and other healthcare companies have been investigated and have reached substantial financial settlements with the federal government under the civil False Claims Act for a variety of

alleged improper marketing activities, including: providing free product to customers with the expectation that the customers would bill federal programs for the product; providing sham consulting fees, grants, free travel and other benefits to physicians to induce them to prescribe the company's products; and inflating prices reported to private price publication services, which are used to set drug payment rates under government healthcare programs. In addition, in recent years the government has pursued civil False Claims Act cases against a number of pharmaceutical companies for causing false claims to be submitted as a result of the marketing of their products for unapproved, and thus non-reimbursable, uses. Pharmaceutical and other healthcare companies also are subject to other federal false claim laws, including, among others, federal criminal healthcare fraud and false statement statutes that extend to non-government health benefit programs;

- Analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to items or services reimbursed under Medicaid and other state programs or, in several states, apply regardless of the payor. Some state laws also require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to certain healthcare providers in the states. Other states prohibit providing meals to prescribers or other marketing related activities. In addition, California, Connecticut, Nevada and Massachusetts require pharmaceutical companies to implement compliance programs or marketing codes of conduct.

- The federal Physician Payment Sunshine Act, being implemented as the Open Payments Program, requires certain pharmaceutical manufacturers to engage in extensive tracking of payments and other transfers of value to physicians and teaching hospitals, and to submit such data to the Centers for Medicare and Medicaid Services ("CMS"), which will then make all of this data publicly available on the CMS website. Pharmaceutical manufacturers with products for which payment is available under Medicare, Medicaid or the State Children's Health Insurance Program are required to track reportable payments and must submit a report to CMS on or before the 90th day of each calendar year disclosing reportable payments made in the previous calendar year. Failure to comply with the reporting obligations may result in civil monetary penalties;

- The federal Foreign Corrupt Practices Act of 1997 and other similar anti-bribery laws in other jurisdictions generally prohibit companies and their intermediaries from providing money or anything of value to officials of foreign governments, foreign political parties, or international organizations with the intent to obtain or retain business or seek a business advantage. Recently, there has been a substantial increase in anti-bribery law enforcement activity by U.S. regulators, with more frequent and aggressive investigations and enforcement proceedings by both the Department of Justice and the U.S. Securities and Exchange Commission (the "SEC"). Violations of United States or foreign laws or regulations could result in the imposition of substantial fines, interruptions of business, loss of supplier, vendor or other third-party relationships, termination of necessary licenses and permits and other legal or equitable sanctions. Other internal or government investigations or legal or regulatory proceedings, including lawsuits brought by private litigants, may also follow as a consequence.

Violations of any of the laws described above or any other governmental regulations are punishable by significant civil, criminal and administrative penalties, damages, fines and exclusion from government-funded healthcare programs, such as Medicare and Medicaid. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

Privacy Laws. We are also subject to laws and regulations covering data privacy and the protection of health-related and other personal information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which may affect our business, including recently enacted laws in all jurisdictions where we operate. Numerous federal and state laws, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use and disclosure of personal information. Failure to comply with such laws and regulations could result in government enforcement actions and create liability for us (including the imposition of significant penalties), private litigation and/or adverse publicity that could negatively affect our business. In addition, if we successfully commercialize our drug candidates, we may obtain patient health information from healthcare providers who prescribe our products and research institutions we collaborate with, and they are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act ("HIPAA"). Although we are not directly subject to HIPAA other than with respect to providing certain employee benefits, we could potentially be subject to criminal penalties if we knowingly obtain or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any drug candidates for which we may obtain regulatory approval. The regulations that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenues we are able to generate from the sale of the product in that particular country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates even if our product candidates obtain marketing approval.

Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available in a timely manner from government third-party payors, including government healthcare programs such as Medicare and Medicaid, commercial health insurers and managed care organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, determine which medications they will cover and establish reimbursement levels. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of FDA approved products for a particular indication. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government healthcare programs and other third-party payors are increasingly challenging the prices charged for medical products and services and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy, and have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party

payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that coverage and reimbursement will be available promptly or at all for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Moreover, eligibility for coverage and reimbursement does not imply that any drug will be paid for in all cases. Limited coverage may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval.

Payors also are increasingly considering new metrics as the basis for reimbursement rates, such as average sales price ("ASP"), average manufacturer price ("AMP") and actual acquisition cost. The existing data for reimbursement based on these metrics is relatively limited, although certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates. CMS surveys and publishes retail community pharmacy acquisition cost information in the form of National Average Drug Acquisition Cost ("NADAC") files to provide state Medicaid agencies with a basis of comparison for their own reimbursement and pricing methodologies and rates. It may be difficult to project the impact of these evolving reimbursement mechanics on the willingness of payors to cover our products for which we receive regulatory approval.

If we successfully commercialize any of our products, we may participate in the Medicaid Drug Rebate Program. Participation is required for federal funds to be available for our products under Medicaid and Medicare Part B. Under the Medicaid Drug Rebate Program, we would be required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and Part B of the Medicare program.

Federal law requires that any company that participates in the Medicaid Drug Rebate Program also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B drug pricing program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients.

In addition, in order to be eligible to have its products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, a manufacturer also must participate in the Department of Veterans Affairs Federal Supply Schedule ("FSS"), pricing program, established by Section 603 of the Veterans Health Care Act of 1992 (the "VHCA"). Under this program, the manufacturer is obligated to make its innovator and single source products available for procurement on an FSS contract and charge a price to four federal agencies, Department of Veterans Affairs, Department of Defense ("DoD"), Public Health Service, and Coast Guard, that is no higher than the statutory Federal Ceiling Price. Moreover, pursuant to regulations issued by the DoD TRICARE Management Activity ("TMA"), now the Defense Health Agency ("DHA"), to implement Section 703 of the National Defense Authorization Act for Fiscal Year 2008, manufacturers are required to provide rebates on utilization of their innovator and single source products that are dispensed to TRICARE beneficiaries by TRICARE network retail pharmacies. The formula for determining the rebate is established in the regulations and is based on the difference between the annual non-federal average manufacturer price and the Federal Ceiling Price (these price points are required to be calculated by us under the VHCA). The requirements under the 340B, FSS, and TRICARE programs could reduce the

revenue we may generate from any products that are commercialized in the future and could adversely affect our business and operating results.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Limited coverage may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. Third-party payors also may seek additional clinical evidence, including expensive pharmacoeconomic studies, beyond the data required to obtain marketing approval, demonstrating clinical benefits and value in specific patient populations, before covering our products for those patients. If reimbursement is available only for limited indications, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

United States Healthcare Reform

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidate for which we obtain marketing approval. The United States government, state legislatures and foreign governments also have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs.

In recent years, Congress has considered reductions in Medicare reimbursement levels for drugs administered by physicians. CMS, the agency that administers the Medicare and Medicaid programs, also has authority to revise reimbursement rates and to implement coverage restrictions for some drugs. Cost reduction initiatives and changes in coverage implemented through legislation or regulation could decrease utilization of and reimbursement for any approved products, which in turn would affect the price we can receive for those products. While Medicare regulations apply only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from federal legislation or regulation may result in a similar reduction in payments from private payors.

In March 2010, President Obama signed into law the Affordable Care Act. This law substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The Affordable Care Act is intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers, and impose additional health

policy reforms. Among other things, the Affordable Care Act expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum Medicaid rebate for both branded and generic drugs, expanded the 340B program, and revised the definition of AMP, which could increase the amount of Medicaid drug rebates manufacturers are required to pay to states. The legislation also extended Medicaid drug rebates, previously due only on fee-for-service Medicaid utilization, to include the utilization of Medicaid managed care organizations as well and created an alternative rebate formula for certain new formulations of certain existing products that is intended to increase the amount of rebates due on those drugs. On February 1, 2016, CMS issued final regulations to implement the changes to the Medicaid Drug Rebate program under the Affordable Care Act. These regulations became effective on April 1, 2016. Moreover, legislative changes to the Affordable Care Act remain possible and appear likely in the 115th United States Congress and under the Trump Administration, which could include changes that, among other things, decrease the number of individuals with health coverage. We expect that the Affordable Care Act, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future could have a material adverse effect on our industry generally and on our ability to successfully commercialize our product candidates, if approved.

The Affordable Care Act requires pharmaceutical manufacturers of branded prescription drugs to pay a branded prescription drug fee to the federal government. Each individual pharmaceutical manufacturer pays a prorated share of the branded prescription drug fee of $3.0 billion in 2016, based on the dollar value of its branded prescription drug sales to certain federal programs identified in the law. Furthermore, the new law requires manufacturers to provide a 50% discount off the negotiated price of prescriptions filled by beneficiaries in the Medicare Part D coverage gap, referred to as the "donut hole."

The Affordable Care Act also expanded the Public Health Service's 340B drug pricing discount program. As noted above, the 340B drug pricing program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. The Affordable Care Act expanded the 340B program to include additional types of covered entities: certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, each as defined by the Affordable Care Act. The Affordable Care Act exempts "orphan drugs"—those designated under section 526 of the Food, Drug, and Cosmetic Act—from the ceiling price requirements for these newly-eligible entities. Because the 340B ceiling price is determined based on AMP and Medicaid drug rebate data, the revisions to the Medicaid rebate formula and AMP definition could cause the required 340B discounts to increase.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, recent legislative enactments have resulted in Medicare payments being subject to a two percent reduction, referred to as sequestration, until 2025. Continuation of sequestration or enactment of other reductions in Medicare reimbursement for drugs could affect our ability to achieve a profit on any candidate products that are approved for marketing.

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

Foreign Regulation

In addition to regulations in the United States, we will be subject to a number of significant regulations in other jurisdictions regarding clinical trials, approval, manufacturing, marketing and promotion and safety reporting. These requirements and restrictions vary from country to country, but in many instances are similar to the United States requirements, and failure to comply with them could have the same negative effects as noncompliance in the United States.

Sales and Marketing

We do not currently have the sales and marketing infrastructure in place that would be necessary to sell and market products. As our drug candidates progress in clinical trials, we may build the commercial infrastructure that would be needed to successfully market and sell any successful drug candidate. For drug candidates that may require larger clinical trials or sales efforts, we intend to establish strategic alliances and partnerships with large pharmaceutical companies during the development process.

Research Technologies

Our research technologies are focused on our proprietary multi-target aimed ligands platform and nano-based drug delivery, which are described further below. For a discussion of collaboration arrangements pursuant to which we obtain research and development services from universities, research institutions and other organizations, see "Collaboration and License Agreements" in this Item 1.

The Inhibitors of Multi-Expression Signals (TIMES)

TIMES is our platform for discovering ligands, which are molecules coordinated to a central atom or molecule in a larger chemical complex, that target multi-expression signals. Because cancer is a complex disease caused by multiple factors as well as genetic modifications, cancer treatment involves a combination of drugs with different mechanisms of action, which may result in compounding the degree and extent of toxicities to which a patient is exposed. TIMES permits us to control multiple targets important for cancer proliferation with a single agent. In doing so, we utilize a proprietary, genomics-based integrated, gene expression system to identify potentially important targets that control multiple genes or signaling events in cancer cells.

3-D Gateway of Ligand Discovery (3-D GOLD)

3-D GOLD is a drug discovery platform that integrates three-dimensional ("3D") molecular modeling, databases of chemicals and proteins and ligand filtering and generation. The chemical database contains 3D structures of approximately seven million compounds. Our proprietary docking tools quantitative structure-activity relationship tool for innovative discovery are parts of the platform. Ligand filtering highlights similarities in pharmacophore and 3D fingerprinting, while ligand generation helps optimize the identification of such similarities.

Nano-medicine Drug Delivery

We have developed unique proprietary drug delivery nano-systems that we believe may increase the availability of a drug at the disease site, minimize adverse reactions, and provide longer duration of action. We are currently testing multiple nanoliposomal- and nanopolymer-based anti-cancer drugs. RX-21101 is an investigational nanoliposomal-based drug.

Manufacturing and Distribution

We have no experience in drug formulation or manufacturing, and we lack the resources and expertise to formulate or manufacture our own drug candidates internally. Therefore, we rely on third-party expertise to support us in this area. We have entered into contracts with third-party manufacturers to manufacture, supply, store and distribute supplies of our drug candidates for our clinical trials. If any of our drug candidates receive FDA approval, we expect to rely on third-party contractors to manufacture our drugs. We have no current plans to build internal manufacturing capacity for any product, and we have no long-term supply arrangements.

Intellectual Property

We generally seek proprietary patent and intellectual property ("IP") protection for our drug candidates, processes, and other know-how. In addition to patent protection, we rely upon trade secrets, know-how, continuing technological innovation and licensing opportunities to develop and safeguard and maintain our IP.

We hold U.S. and foreign patents for our drug candidates that expire from 2023 to 2036. We hold U.S., European and Japanese patents for RX-3117, Supinoxin and Archexin. In addition to these patents, we have issued or pending patents in other jurisdictions.

The patent portfolios for our most advanced programs are summarized below:

RX-3117:

The RX-3117 patent portfolio consists of three patent families. The first family consists of patents that have been issued in the United States, Europe, Japan and other jurisdictions. The patents in this family include composition of matter, use, and process claims of varying scope, including picture claims to RX-3117 or a pharmaceutically acceptable salt thereof. The patents in this first family expire in 2025, but may be extended by patent term extension and orphan and market exclusivity. The second family consists of patents that have been issued in the United States, and are pending in Europe, Japan and other jurisdictions. The patents in the second family include process claims that cover RX-3117. The patents in this second family expire in 2034. The third family consists of a patent that is pending in the United States. This patent would include use and process claims that generically cover RX-3117. This patent would expire in 2036.

Supinoxin:

The Supinoxin patent portfolio consists of three patent families. The first family consists of patents that have been issued in the United States and Europe, and are pending in Japan and other jurisdictions. The patents in the first family include composition of matter, use, and process claims of varying scope, including picture claims to Supinoxin or a pharmaceutically acceptable salt thereof. The patents in this first family expire in 2025 and may be extended up to five years in the United States. We also expect Supinoxin will be protected with market exclusivity in Europe for a minimum of ten years post-approval. The second family consists of patents that are pending in the United States, Europe, Japan and other jurisdictions. The patents in the second family include composition of matter, process and use claims that cover Supinoxin. The patents in this second family would expire in 2034. The third family consists of a patent that is pending in the United States. The patent in the third family would include use and process claims that cover Supinoxin. This patent would expire in 2036.

Archexin:

The Archexin patent portfolio consists of a patent family that includes patents that have been issued in the United States, Europe, Japan and other jurisdictions. The patents in this family include composition of matter and use claims of varying scope, including picture claims to Archexin or a pharmaceutically acceptable salt thereof. The expiration date of these patents ranges from 2023 to 2025, and may be extended by up to five years in certain countries including the United States. In addition, it is expected that Archexin will be protected from generic launches by market and orphan designations for up to seven years in the United States, and ten years in Europe and Japan.

Collaboration and License Arrangements

We have numerous collaborative research and development relationships with universities, research institutions pharmaceutical companies and other organizations.

Rexgene Biotech Co., Ltd. ("Rexgene")

In February 2003, we entered into a research collaboration agreement with Rexgene, which is engaged in the development of pharmaceutical products in Asia. Rexgene has agreed to assist us with the research, development and clinical trials necessary for registration of Archexin in Asia. Under the agreement, we have granted Rexgene an exclusive license, with right to sublicense, to make, have made, use, sell and import Archexin in Asia. In accordance with the agreement, Rexgene paid us a one-time fee of $1,500,000 in 2003. Rexgene also agreed to pay us a royalty fee of 3% of net sales of licensed products related to Archexin on a country-by-country basis in all countries in Asia by Rexgene or any sublicensee of Rexgene.

The agreement expires upon the last to expire of all U.S. and foreign patents presently or in the future issued that cover Archexin, which we currently expect to occur in 2025. The agreement is terminable by either party for the other party's material breach, subject to a 90 day cure period. To date, the only amounts we have received under the agreement are from the initial one-time fee of $1,500,000 paid in 2003.

Korea Research Institute of Chemical Technology ("KRICT")

In June 2009, we entered into a license agreement with KRICT to acquire rights to all of KRICT's intellectual property related to quinoxaline-piperazine derivatives, which includes Supinoxin. We paid an initial license fee of $100,000 in July 2009, and will pay a one-time milestone payment of $1,000,000 to KRICT upon marketing approval from FDA for the first commercial product stemming from intellectual property (the "Milestone Payment"). Upon payment of the Milestone Payment all of the rights previously licensed to us will be transferred to us and the agreement will terminate. The agreement is terminable by either party for the other party's material breach, subject to a 60 day cure period. To date, we have paid only the $100,000 initial license fee pursuant to this agreement.

The University of Maryland Baltimore ("UMB")

In July 2013, we entered into an exclusive license agreement with UMB for a novel drug delivery platform, Nano-Polymer-Drug Conjugate Systems. This platform combines existing chemotherapeutic agents with a proprietary polymer carrier that contains a signaling moiety to direct the agents into a tumor. RX-21101 is our first drug candidate utilizing this platform and is a conjugated form of docetaxel, a common chemotherapy agent. This agreement requires us to make payments to UMB if

RX-21101 or any other products developed from the licensed delivery platform achieve development milestones.

The Ohio State University

In October 2013, we entered into an exclusive license agreement with the Ohio State Innovation Foundation, an affiliate of The Ohio State University, for a novel oligonucleotide drug delivery platform, Lipid-Coated Albumin Nanoparticle ("LCAN"). The LCAN platform incorporates both cationic lipid and cationized albumin that can form an electrostatic complex with oligonucleotides and be co-encapsulated by lipids. The agreement requires us to make payments to the Ohio State Innovation Foundation if any products from the licensed delivery platform achieve development milestones.

Total Research and Development Costs

We have incurred research and development costs of $10,089,149, $12,148,226 and $7,015,901 for the years ended December 31, 2016, 2015 and 2014 respectively. Research and development costs primarily consist of clinical trials and pre-clinical development costs, as well as payroll costs for research and development personnel.

Employees

We currently have 20 full-time employees, all of whom are based either at our Rockville, Maryland office or our Gaithersburg, Maryland lab facility. Our employees are not covered by any collective bargaining agreement and we have never experienced a work stoppage. We believe our relationships with our employees are satisfactory.

Available Information

Under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), we are required to file annual, quarterly and current reports, proxy statements and other information with the SEC. Any document we file with the SEC may be read and copied at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at (800) SEC-0330 for further information about the public reference room. The SEC maintains a website at www.sec.gov that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC.

We make available, free of charge, on our website at www.rexahn.com our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K and all amendments thereto, as soon as reasonably practicable after they are filed with or furnished to the SEC. Investors are encouraged to access these reports and the other information about our business on our website. Information found on our website is not part of this Annual Report on Form 10-K (this "Annual Report"). We will also provide copies of this Annual Report, free of charge, upon written request to the Investor Relations Department at our main address, 15245 Shady Grove Road, Suite 455, Rockville MD, 20850.

Also posted on our website, and available in print upon written request of any shareholder to our Investor Relations Department, are the charters of the standing committees of our Board

Item 1A. Risk Factors.

You should carefully consider the risks described below together with the other information included in this Form 10-K. Our business, financial condition or results of operations could be adversely affected by any of these risks. If any of these risks occur, the value of our common stock could decline.

Risks Related to Our Financial Position and Capital Needs

We currently have no product revenues, have incurred negative cash flows from operations since inception and will need to raise additional capital to operate our business.

To date, we have generated no product revenues and have incurred negative cash flow from operations. Until we receive approval from the FDA or other regulatory authorities for our drug candidates, we cannot sell our drugs and will not have product revenues. We expect to continue to incur significant development and other expenses related to our ongoing operations. Therefore, for the foreseeable future, we will have to fund all of our operations and capital expenditures from the net proceeds of equity or debt offerings, cash on hand, licensing fees and grants, if any. If we are not able to raise sufficient funds, we will have to reduce our research and development activities. We will first reduce research and development activities associated with our pre-clinical compounds. To the extent necessary, we will then reduce our research and development activities related to some or all of our clinical stage product candidates.

Unforeseen events, difficulties, complications and delays may occur that could cause us to utilize our existing capital at a faster rate than projected, including the progress of our research and development efforts, the cost and timing of regulatory approvals and the costs of protecting our intellectual property rights. We may seek additional financing to implement and fund other drug candidate development, clinical trial and research and development efforts, including clinical trials for other new drug candidates, as well as other research and development projects.

We will need additional financing to continue to develop our drug candidates, which may not be available on favorable terms, if at all. If we are unable to secure additional financing in the future on acceptable terms, or at all, we may be unable to complete our planned pre-clinical and clinical trials or obtain approval of our drug candidates from the FDA and other regulatory authorities. In addition, we may be forced to reduce or discontinue product development or product licensing, reduce or forego sales and marketing efforts and forego attractive business opportunities in order to improve our liquidity to enable us to continue operations. Any additional sources of financing will likely involve the sale of our equity securities or securities convertible into our equity securities, which may have a dilutive effect on our stockholders.

We are not currently profitable and may never become profitable.

To date, we have generated no product revenues and have incurred negative cash flow from operations. Our accumulated deficit as of December 31, 2016 and 2015 was $115,024,209 and $105,716,864, respectively. For the years ended December 31, 2016, 2015 and 2014, we had net losses of $9,307,345, $14,384,556, and $18,521,601, respectively. Even if we succeed in developing and commercializing one or more of our drug candidates, we expect to incur substantial losses for the foreseeable future and may never become profitable. We also expect to continue to incur significant operating and capital expenditures and anticipate that our expenses will increase substantially in the foreseeable future, based on the following considerations:

- continued pre-clinical development and clinical trials for our current and new drug candidates;
- finding suitable partners to help us research, develop and commercialize new drug candidates;
- efforts to seek regulatory approvals for our drug candidates;
- implementing additional internal systems and infrastructure;
- in-licensing additional technologies to develop; and
- hiring additional personnel or entering into relationships with third parties to perform functions that we are unable to perform on our own.

We also expect to continue to experience negative cash flow for the foreseeable future as we fund our operations and capital expenditures. Until we have the capacity to generate revenues, we are relying upon outside funding resources to fund our cash flow requirements. If these resources are depleted or unavailable, we may be unable to continue to expand our operations or otherwise capitalize on our business opportunities, and our business, financial condition and results of operations would be materially adversely affected.

We have a limited operating history, and we have not demonstrated an ability to commercialize drug candidates.

We are a clinical-stage company with a limited number of drug candidates. We currently do not have any products that have gained regulatory approval, and we have not demonstrated an ability to perform the functions necessary for the successful commercialization of any of our drug candidates. The successful commercialization of our drug candidates will require us to first perform a variety of functions, including:

- conducting pre-clinical and clinical trials;
- participating in regulatory approval processes;
- formulating and manufacturing products; and
- conducting sales and marketing activities.

To date, our operations have been limited to organizing and staffing the Company, acquiring, developing and securing our proprietary technology, and undertaking drug candidate research and development, including pre-clinical trials and clinical trials of our principal drug candidates. These operations provide a limited basis for assessing our ability to commercialize drug candidates.

Our common stock could be at risk for delisting from the NYSE MKT if the NYSE MKT notifies us that the stock has sold for a substantial period of time at a low price per share and thereafter, our stock price does not increase. If it is delisted, our common stock and the liquidity of our common stock would be impacted.

Our common stock is listed on the NYSE MKT. Section 1003(f)(v) of the NYSE Company Guide provides that a company's common stock may be delisted from the NYSE MKT if it sells for a substantial period of time at a low price per share and the Company fails to effect a reverse stock split or

otherwise demonstrate sustained price improvement within a reasonable time after being notified that the NYSE MKT deems such action to be appropriate under all the circumstances. While the NYSE MKT has not provided notice that the NYSE MKT deems it appropriate for us to effect a reverse stock split, given the Company's recent trading prices, the NYSE MKT may deliver such a letter if the price of our common stock does not increase.

Delisting from the NYSE MKT may adversely affect our ability to raise additional financing through the public or private sale of equity securities, may significantly affect the ability of investors to trade our securities and may negatively affect the value and liquidity of our common stock. Delisting also could have other negative results, including the potential loss of employee confidence, the loss of institutional investors or interest in business development opportunities. Moreover, we committed in connection with the sale of securities to use commercially reasonably efforts to maintain the listing of our common stock during such time that certain warrants are outstanding.

If our common stock was to be delisted from the NYSE MKT and we were not able to list our common stock on another exchange, our common stock could be quoted on the OTC Bulletin Board or in the "pink sheets." As a result, we could face significant adverse consequences including, among others:

- a limited availability of market quotations for our securities;
- a determination that the Common Stock is a "penny stock," which will require brokers trading in the Common Stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of news and little or no analyst coverage for the Company;
- the Company would no longer qualify for exemptions from state securities registration requirements, which may require us to comply with applicable state securities laws; and
- a decreased ability to issue additional securities (including pursuant to short-form registration statements on Form S-3) or obtain additional financing in the future.

Risks Related to Our Business

Several of our drug candidates are in clinical trials, which are very expensive, time-consuming and difficult to design and implement.

Our drug candidates are in various stages of development and require extensive clinical testing. Such testing is expensive and time-consuming and requires specialized knowledge and expertise. Archexin entered a Phase IIa clinical trial in January 2014, RX-3117 entered a Phase IIa clinical trial in March 2016 and another Phase IIa trial in September 2016, and Supinoxin entered a Phase IIa clinical trial in February 2017.

Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time-consuming, and the outcome is not certain; the results of pre-clinical studies and early clinical trials may not be predictive of the results of later-stage clinical trials. We estimate that clinical trials of our current drug candidates will take multiple years to complete. Furthermore, failure can occur at any stage of a clinical trial, and we could encounter problems that cause us to abandon or repeat clinical trials. The commencement and completion of clinical trials may be delayed or precluded by a number of factors, including:

- delay or failure in reaching agreement with the FDA or a foreign regulatory authority on the design of a given trial, or in obtaining authorization to commence a trial;
- delay or failure in reaching agreement on acceptable terms with prospective contract research organizations and clinical trial sites;
- delay or failure in obtaining approval of an IRB to conduct a clinical trial at a given site;
- withdrawal of clinical trial sites from our clinical trials as a result of changing standards of care of the ineligibility of a site to participate;
- delay or failure in recruiting and enrolling study subjects;
- delay or failure in having subjects complete a clinical trial or return for post-treatment follow up;
- clinical sites or investigators deviating from trial protocol, failing to conduct the trial in accordance with applicable regulatory requirements, or dropping out of a trial;
- inability to identify and maintain a sufficient number of trial sites;
- failure of third-party clinical trial managers to meet their contractual obligations or deadlines;
- the need to modify a study protocol;
- unforeseen safety issues;
- emergence of dosing issues;
- lack of effectiveness during clinical trials;
- change in the standard of care of the indication being studied;
- reliance on third-party suppliers for the clinical trial supply of drug candidates;
- inability to monitor patients adequately during or after treatment;
- lack of sufficient funding to finance the clinical trials; and
- changes in governmental regulations or administrative action.

We, the FDA or an IRB may suspend a clinical trial at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in our IND applications or the conduct of these trials. Additionally, we may have difficulty enrolling patients in our clinical trials. If we experience such difficulties, we may not be able to complete a clinical trial or we may experience significant delays in completing a clinical trial.

If the results of our clinical trials fail to support the approval of any of our drug candidates, the completion of development of that candidate may be significantly delayed, or we may be forced to abandon development altogether, which will significantly impair our ability to generate product revenues.

Even if our clinical trials are completed as planned, we cannot be certain that clinical results will support approval of our drug candidates. Success in pre-clinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and pre-clinical testing. The clinical trial process may fail to demonstrate that one or more of our drug candidates is safe and effective for indicated uses. As a result, we may have to conduct additional clinical trials or may decide to abandon a drug candidate, in which case we may never recognize any revenue related to such candidate. Standard of care treatments may change, which may require additional clinical trials. Repeating clinical trials or conducting additional clinical trials will increase our development costs and delay the filing of an NDA and, ultimately, delay our ability to commercialize our drug candidates and generate product revenues.

We may not obtain the necessary U.S. or worldwide regulatory approvals to commercialize our drug candidates, and we cannot guarantee how long it will take the FDA or other comparable regulatory agencies to review applications for our drug candidates.

We will need the FDA approval to commercialize our drug candidates in the United States and approvals from the comparable regulatory authorities to commercialize our drug candidates in foreign jurisdictions.

The time it takes to obtain approval, either in the United States or foreign jurisdictions, is unpredictable, but typically takes many years, depending upon a variety of factors, including the type, complexity and novelty of the drug candidate. Obtaining approval requires substantial resources and is subject to regulatory authorities' substantial discretion. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's development and may vary among jurisdictions. We cannot guarantee that any of our drug candidates will ultimately be approved by the FDA or any other regulatory authority, or the length of time obtaining approval will take. One of our drug candidates, Archexin, is an ASO compound. To date, the FDA has approved very few ASO compounds. In addition, Archexin is in the drug class known as Akt-1 inhibitors that to date have not been approved by the FDA, nor have we submitted an NDA for an Akt-1 inhibitor.

Our product candidates could fail to receive regulatory approval from the FDA or a comparable foreign authority for a variety of reasons, including:

- disagreement with the design or implementation of our clinical trials;
- failure to demonstrate to the authority's satisfaction that the product candidate is safe and effective for the proposed indication;
- failure of clinical trials to meet the level of statistical significance required for approval;
- failure to demonstrate that the product's benefits outweigh its risks;
- disagreement with our interpretation of pre-clinical or clinical data; and
- inadequacies in the manufacturing facilities or processes of third-party manufacturers.

The FDA or a comparable foreign authority may require us to conduct additional pre-clinical and clinical testing, which may delay or prevent approval and our commercialization plans or cause us to abandon the development program. Further, any approval we receive may be for fewer or more limited indications than we request, may not include labeling claims necessary for successful commercialization of the product candidate, or may be contingent upon our conducting costly post-marketing clinical trials. Any of these scenarios could materially harm the commercial prospects of a product candidate.

Even if our product candidates obtain approval, they may face future development and regulatory difficulties that can negatively affect commercial prospects.

Even if we obtain approval for a product candidate, it would be subject to ongoing regulatory requirements and restrictions of the FDA and comparable regulatory authorities regarding manufacturing, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting. Failure by us or any of the third parties on which we rely to meet those requirements can lead to enforcement action, among other consequences, that could significantly impair our ability to successfully commercialize a given product. If the FDA or a comparable regulatory authority becomes aware of new safety information, it can impose additional restrictions on how the product is marketed or may seek to withdraw marketing approval altogether.

There is no assurance that any of our products that has received or will receive orphan drug designation will subsequently obtain orphan drug exclusivity, or that any such exclusivity will provide the desired benefit.

Although we have obtained orphan drug designation for several uses of Archexin and one use of RX-3117 and may obtain additional orphan drug designation for these or other product candidates, we are not assured of being awarded orphan drug exclusivity or realizing the benefits of such exclusivity, even if any of these products is approved for its orphan-designated use. If another company also holding orphan drug designation for a product containing the same active moiety intended for the same rare disease or condition receives approval before our orphan-designated product, approval of our product could be precluded for seven years because of that product's orphan drug exclusivity, unless we could demonstrate our product to be clinically superior to the earlier-approved product. Similarly, even if our orphan designated drug were approved first and awarded seven-year orphan drug exclusivity, it would not block approval of the other product if that product were shown to be clinically superior, or if we fail to assure a sufficient quantity of our orphan drug. Additionally, because orphan drug exclusivity is product- and indication-specific, it does not prevent approval of another drug for the same orphan indication or the same drug for a different use.

If physicians and patients do not accept and use our drugs, our ability to generate revenue from sales of our products will be materially impaired.

Even if the FDA approves our drug candidates, physicians and patients may not accept and use them. Future acceptance and use of our products will depend upon a number of factors including, but not limited to:

- awareness of a drug's availability and benefits;
- perceptions by members of the health care community, including physicians, about the safety and effectiveness of our drugs;

- pharmacological benefit and cost-effectiveness of our products relative to competing products;
- availability of reimbursement for our products from government or other third-party payors;
- effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any; and
- the price at which we sell our products.

Because we expect sales of our current drug candidates, if approved, to generate substantially all of our product revenues for the foreseeable future, the failure of any of these drugs to find market acceptance would harm our business and could require us to seek additional financing.

Even if we are able to commercialize any of our product candidates, these products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which could harm our business.

The regulations that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenues we are able to generate from the sale of the product in that particular country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates even if our product candidates obtain marketing approval.

Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available in a timely manner from government third-party payors, including governmental healthcare programs such as Medicare and Medicaid, commercial health insurers and managed care organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, determine which medications they will cover and establish reimbursement levels. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA approved products for a particular indication. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government healthcare programs and other third-party payors are increasingly challenging the prices charged for medical products and services and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy, and have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that coverage and reimbursement will be available promptly or at all for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Moreover, eligibility for coverage and reimbursement does not imply that any drug will be paid for in all cases. Limited coverage may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and

reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval.

Payors also are increasingly considering new metrics as the basis for reimbursement rates, such as ASP, AMP and actual acquisition cost. The existing data for reimbursement based on these metrics is relatively limited, although certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates. CMS, surveys and publishes retail community pharmacy acquisition cost information in the form of NADAC files to provide state Medicaid agencies with a basis of comparison for their own reimbursement and pricing methodologies and rates. It may be difficult to project the impact of these evolving reimbursement mechanics on the willingness of payors to cover our products for which we receive regulatory approval.

If we successfully commercialize any of our products, we may participate in the Medicaid Drug Rebate program. Participation is required for federal funds to be available for our products under Medicaid and Medicare Part B. Under the Medicaid Drug Rebate Program, we would be required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and Part B of the Medicare program.

Federal law requires that any company that participates in the Medicaid Drug Rebate Program also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B drug pricing program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients.

In addition, in order to be eligible to have its products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, a manufacturer also must participate in the FSS, pricing program, established by Section 603 of the VHCA. Under this program, the manufacturer is obligated to make its innovator and single source products available for procurement on an FSS contract and charge a price to four federal agencies, Department of Veterans Affairs, DoD, Public Health Service, and Coast Guard, that is no higher than the statutory Federal Ceiling Price. Moreover, pursuant to regulations issued by the DoD TMA, now the DHA, to implement Section 703 of the National Defense Authorization Act for Fiscal Year 2008, manufacturers are required to provide rebates on utilization of their innovator and single source products that are dispensed to TRICARE beneficiaries by TRICARE network retail pharmacies. The formula for determining the rebate is established in the regulations and is based on the difference between the annual non-federal average manufacturer price and the Federal Ceiling Price (these price points are required to be calculated by us under the VHCA). The requirements under the 340B, FSS, and TRICARE programs could reduce the revenue we may generate from any products that are commercialized in the future and could adversely affect our business and operating results.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare

programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Limited coverage may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. Third-party payors also may seek additional clinical evidence, including expensive pharmacoeconomic studies beyond the data required to obtain marketing approval, demonstrating clinical benefits and value in specific patient populations, before covering our products for those patients. If reimbursement is available only for limited indications, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Changes in healthcare law and implementing regulations, including those based on recently enacted and future legislation, as well as changes in healthcare policy, may increase the difficulty and cost for us to commercialize our product candidates and affect the prices we may obtain.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidate for which we obtain marketing approval. The United States government, state legislatures and foreign governments also have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs.

In recent years, Congress has considered reductions in Medicare reimbursement levels for drugs administered by physicians. CMS also has authority to revise reimbursement rates and to implement coverage restrictions for some drugs. Cost reduction initiatives and changes in coverage implemented through legislation or regulation could decrease utilization of and reimbursement for any approved products, which in turn would affect the price we can receive for those products. While Medicare regulations apply only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from federal legislation or regulation may result in a similar reduction in payments from private payors.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "Affordable Care Act"). This law substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The Affordable Care Act is intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers, and impose additional health policy reforms. Among other things, the Affordable Care Act expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum Medicaid rebate for both branded and generic drugs, expanded the 340B program, and revised the definition of AMP. The legislation also extended Medicaid drug rebates, previously due only on fee-for-service Medicaid utilization, to include the utilization of Medicaid managed care organizations as well and created an alternative rebate formula for certain new formulations of certain existing products that is intended to increase the amount of rebates due on those drugs. On February 1, 2016, CMS issued final regulations to implement the changes to the Medicaid Drug Rebate program under the Affordable Care Act. These regulations became effective on April 1, 2016. Moreover, legislative changes to the Affordable Care Act remain possible and appear likely in the 115th United States Congress and under the Trump

Administration, which could include changes that, among other things, decrease the number of individuals with health coverage. We expect that the Affordable Care Act, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future could have a material adverse effect on our industry generally and on our ability to successfully commercialize our product candidates, if approved.

The Affordable Care Act requires pharmaceutical manufacturers of branded prescription drugs to pay a branded prescription drug fee to the federal government. Each individual pharmaceutical manufacturer pays a prorated share of the branded prescription drug fee of $3.0 billion in 2016, based on the dollar value of its branded prescription drug sales to certain federal programs identified in the law. Furthermore, the new law requires manufacturers to provide a 50% discount off the negotiated price of prescriptions filled by beneficiaries in the Medicare Part D coverage gap, referred to as the "donut hole."

The Affordable Care Act also expanded the Public Health Service's 340B drug pricing discount program. The 340B drug pricing program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. The Affordable Care Act expanded the 340B program to include additional types of covered entities: certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, each as defined by the Affordable Care Act. The Affordable Care Act exempts "orphan drugs"—those designated under section 526 of the Food, Drug, and Cosmetic Act—from the ceiling price requirements for these newly-eligible entities. Because the 340B ceiling price is determined based on AMP and Medicaid drug rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discounts to increase.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, recent legislative enactments have resulted in Medicare payments being subject to a two percent reduction, referred to as sequestration, until 2025. Continuation of sequestration or enactment of other reductions in Medicare reimbursement for drugs could affect our ability to achieve a profit on any candidate products that are approved for marketing.

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

If we are able to successfully commercialize any of our products and if we participate in the Medicaid drug rebate program or other governmental pricing programs, failure to comply with reporting and payment obligations under these programs could result in additional reimbursement requirements, penalties, sanctions and fines which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

The Medicaid Drug Rebate Program and other governmental pricing programs require participating manufacturers to report pricing data to the government. Pricing calculations vary among products and programs and include average manufacturer price and best price for the Medicaid Drug Rebate Program, average sales price for certain categories of drugs that are paid under Part B of the Medicare program, and non-federal average manufacturer price for the FSS pricing program. If we successfully commercialize any of our products and participate in such governmental pricing programs, we will be liable for errors associated with our submission of pricing data. That liability could be significant. For example, if we are found to have knowingly submitted false average manufacturer price,

average sales price, best price, or non-federal average manufacturer price information to the government, we may be liable for civil monetary penalties in the amount of $178,156 per item of false information. If we are found to have made a misrepresentation in the reporting of average sales price, the statute provides for civil monetary penalties of up to $12,856 for each misrepresentation for each day in which the misrepresentation was applied. Our failure to submit monthly/quarterly average manufacturer price, average sales price, and best price, and quarterly/annual non-federal average manufacturer price data on a timely basis could result in a civil monetary penalty of $17,816 per day for each day the information is late beyond the due date. Such failure also could be grounds for other sanctions, such as termination from the Medicaid Drug Rebate Program.

If we fail to comply with data protection laws and regulations, we could be subject to government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity, which could negatively affect our operating results and business.

We are subject to data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the U.S., numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), govern the collection, use, disclosure, and protection of health-related and other personal information. Failure to comply with data protection laws and regulations could result in government enforcement actions and create liability for us (which could include civil and/or criminal penalties), private litigation and/or adverse publicity that could negatively affect our operating results and business. In addition, we may obtain health information from third parties (e.g., healthcare providers who prescribe our products) that are subject to privacy and security requirements under HIPAA. Although we are not directly subject to HIPAA—other than potentially with respect to providing certain employee benefits—we could be subject to criminal penalties if we knowingly obtain or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. HIPAA generally requires that healthcare providers and other covered entities obtain written authorizations from patients prior to disclosing protected health information of the patient (unless an exception to the authorization requirement applies). If authorization is required and the patient fails to execute an authorization or the authorization fails to contain all required provisions, then we may not be allowed access to and use of the patient's information and our research efforts could be impaired or delayed. Furthermore, use of protected health information that is provided to us pursuant to a valid patient authorization is subject to the limits set forth in the authorization (e.g., for use in research and in submissions to regulatory authorities for product approvals). In addition, HIPAA does not replace federal, state, international or other laws that may grant individuals even greater privacy protections.

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

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

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

- the federal civil False Claims Act imposes penalties, including through 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, claims for payment that are false or fraudulent or making a false statement material to an obligation to pay money to the government or knowingly concealing or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal liability for knowingly and willfully executing a scheme to defraud any healthcare benefit program, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense, or knowingly and willfully making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and its implementing regulations, also imposes obligations on certain covered entity health care providers, health plans and health care clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal Open Payments program, created under Section 6002 of the Affordable Care Act and its implementing regulations, requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the CMS information related to "payments or other transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually CMS ownership and investment interests held by physicians (as defined above) and their immediate family members; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to certain healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws that govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, that person or entity may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. For a fuller discussion of the applicable anti-kickback fraud and abuse, transparency and other healthcare laws and regulations applicable to our business, see Item 1, 'Description of Business – Government Regulation"

Developments by competitors may render our products or technologies obsolete or non-competitive.

We compete against fully integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies as well as academic institutions, government agencies and other public and private research organizations. Many of these competitors, either alone or together with their collaborative partners, operate larger research and development programs or have substantially greater financial resources than we do, as well as more experience in:

- developing drugs;
- undertaking pre-clinical testing and human clinical trials;
- obtaining FDA and other regulatory approvals of drugs;
- formulating and manufacturing drugs; and
- launching, marketing and selling drugs.

Large pharmaceutical companies currently sell both generic and proprietary compounds for the treatment of cancer. In addition, companies developing oncology therapies represent substantial competition. Many of these organizations have substantially greater capital resources, larger research and development staff and facilities, longer drug development history in obtaining regulatory approvals and greater manufacturing and marketing capabilities than we do. These organizations also compete with us to attract qualified personnel, parties for acquisitions, joint ventures or other collaborations. Our competitors may succeed in developing products that are more effective and/or safe than ours, which could render our product candidates less competitive prior to recovery by us of expenses incurred with respect to their development.

If we are unable to successfully manage our growth, our business may be harmed.

In addition to our own internally developed drug candidates, we are actively seeking opportunities to in-license compounds in oncology and other therapeutic areas that are strategic additions to our product pipeline. Such additional drug candidates could significantly increase our capital requirements and place further strain on our resources, including on the time of our existing personnel, which may delay or otherwise adversely affect the development of our existing drug candidates. As of December 31, 2016, we had 20 full-time employees. We may need to hire more employees as our product

pipeline and operations expand, further increasing the size of our organization and related expenses. If we are unable to manage our growth effectively, we may not efficiently use our resources, which may delay the development of our drug candidates and negatively impact our business, results of operations and financial condition.

We may not be able to attract and retain qualified personnel necessary for the development and commercialization of our drug candidates. Our success may be negatively impacted if key personnel leave.

Attracting and retaining qualified personnel is critical to our future success. We compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions. Competition for such individuals is intense, and we cannot assure you that we will be successful in engaging personnel with the skills and experience to support our business and research and development activities.

Our key personnel, especially Dr. Chang H. Ahn, our Chairman Emeritus and Chief Scientist, Dr. Peter Suzdak, our Chief Executive Officer, Dr. Ely Benaim, our Chief Medical Officer, Dr. Lisa Nolan, our Chief Business Officer, and Dr. Tae Heum Jeong, our Chief Financial Officer, provide critical technical knowledge and expertise. The loss of Dr. Ahn, Dr. Suzdak, Dr. Benaim, Dr. Nolan, Dr. Jeong, or any of the other members of our management team, could result in delays in product development and diversion of management resources, which could adversely affect our operating results. We do not have "key person" life insurance policies for any of our executive officers.

We may incur substantial liabilities and may be required to limit commercialization of our products in response to product liability lawsuits.

The testing and marketing of medical products entail an inherent risk of product liability. Product liability claims may be brought against us by subjects enrolled in our clinical trials, patients, healthcare providers or others using, administering or selling our products. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of pharmaceutical products we develop, alone or with collaborators. Although we currently carry clinical trial insurance and product liability insurance we, or any collaborators, may not be able to maintain such insurance at a reasonable cost. Even if our agreements with any future collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claims arise.

Risks Related to Reliance on Third Parties

Much of our drug development program depends upon third-party researchers, and thus the conduct and completion of our clinical trials are, to some extent, beyond our control.

We have engaged third-party contract research organizations and other investigators and collaborators, such as universities and medical institutions, to conduct our pre-clinical studies, toxicology studies and clinical trials. Engaging third-party contract research organizations is typical practice in our industry. However, relying on such organizations means that the clinical trials and other studies described above are being conducted at external locations and that the completion of these trials and studies is not within our direct control. Trials and studies may be delayed due to circumstances outside our control, and such delays may result in additional expenses for us.

While we make every effort internally to oversee the work of third-party contractors, these collaborators are not our employees, and we cannot control the effort, time or other resources that they devote to our programs. Third parties may not assign priority to our programs or pursue them as diligently as we would if we were undertaking them ourselves. If outside collaborators fail to devote sufficient time and resources to our drug-development programs, or if their performance is substandard, the approval of our FDA applications and introduction of new drugs to the market may be delayed. These collaborators may also have relationships with other commercial entities, some of which may compete with us. If our collaborators assist our competitors at our expense, our competitive position would be harmed.

We rely exclusively on third parties to formulate and manufacture our drug candidates, which exposes us to a number of risks that may delay development, regulatory approval and commercialization of our products or result in higher product costs.

We have no experience in drug formulation or manufacturing and we lack the resources and expertise to formulate or manufacture our own drug candidates internally. Therefore, we rely on third-party expertise to support us in this area. We have entered into contracts with third-party manufacturers to manufacture, supply, store and distribute supplies of our drug candidates for our clinical trials. If any of our drug candidates receives FDA approval, we expect to rely on third-party contractors to manufacture our drugs. We have no current plans to build internal manufacturing capacity for any product, and we have no long-term supply arrangements.

Our reliance on third-party manufacturers exposes us to the following potential risks:

- We may be unable to contract with third-party manufacturers on acceptable terms, or at all, because the number of potential manufacturers is limited and potential manufacturers are subject to FDA approval. FDA approval requires testing and compliance inspections. In addition, any new manufacturer would have to be qualified and approved to produce our products after receipt of FDA approval, if any;

- Our third-party manufacturers might be unable to formulate and manufacture our drugs in the volume and of the quality required to meet our clinical and commercial needs, if any;

- Our third-party manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials through completion or to successfully produce, store and distribute our commercial products, if approved;

- Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA and other government agencies to ensure compliance with cGMP and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards, but we may ultimately be responsible for any of their failures;

- If any third-party manufacturer makes improvements in the manufacturing process for our products, we may not own, or may have to share, the intellectual property rights to such improvements; and

- A third-party manufacturer may gain knowledge from working with us that could be used to supply one of our competitors with a product that competes with ours.

Each of these risks could delay or have other adverse impacts on our clinical trials and the approval and commercialization of our drug candidates, potentially resulting in higher costs, reduced revenues or both.

We have no experience selling, marketing or distributing products and currently no internal capability to do so.

We currently have no sales, marketing or distribution capabilities. While we intend to have a role in the commercialization of our products, we do not anticipate having the resources in the foreseeable future to develop global sales and marketing capabilities for all of our proposed products. Our future success depends, in part, on our ability to enter into and maintain collaborative relationships with other companies that have sales, marketing and distribution capabilities, a strategic interest in the products under development, and the ability to successfully market and sell our products. To the extent that we decide not to, or are unable to, enter into collaborative arrangements with respect to the sales and marketing of our proposed products, significant capital expenditures, management resources and time will be required to establish and develop an in-house marketing and sales force with the necessary expertise. We cannot assure you that we will be able to establish or maintain relationships with third-party collaborators or develop in-house sales and distribution capabilities. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, as well as the terms of our agreements with such third parties, which cannot be predicted at this early stage of our development. We cannot assure you that such efforts will be successful. In addition, we cannot assure you that we will be able to market and sell our products in the United States or overseas.

Risks Related to Our Intellectual Property

If we fail to adequately protect or enforce our intellectual property rights or secure rights to patents of others, the value of our intellectual property rights would diminish, and our business and competitive position would suffer.

Our success, competitive position and future revenues will depend in part on our ability and the abilities of our licensors and licensees to obtain and maintain patent protection for our products, methods, processes and other technologies, to preserve our trade secrets, to prevent third parties from infringing on our proprietary rights and to operate without infringing the proprietary rights of third parties. We have an active patent protection program that includes filing patent applications on new compounds, formulations, delivery systems and methods of making and using products and prosecuting these patent applications in the United States and abroad. As patents issue, we also file continuation applications as appropriate. Although we have taken steps to build a strong patent portfolio, we cannot predict:

- the degree and range of protection any patents will afford us against competitors, including whether third parties find ways to invalidate or otherwise circumvent our licensed patents;
- if and when patents will issue in the United States or any other country;
- whether or not others will obtain patents claiming aspects similar to those covered by our licensed patents and patent applications;
- whether we will need to initiate litigation or administrative proceedings to protect our intellectual property rights, which may be costly whether we win or lose;
- whether any of our patents will be challenged by our competitors alleging invalidity or

unenforceability and, if opposed or litigated, the outcome of any administrative or court action as to patent validity, enforceability or scope;

- whether a competitor will develop a similar compound that is outside the scope of protection afforded by a patent or whether the patent scope is inherent in the claims modified due to interpretation of claim scope by a court;

- whether there were activities previously undertaken by a licensor that could limit the scope, validity or enforceability of licensed patents and intellectual property; or

- whether a competitor will assert infringement of its patents or intellectual property, whether or not meritorious, and what the outcome of any related litigation or challenge may be.

Our success also depends upon the skills, knowledge and experience of our scientific and technical personnel, our consultants and advisors as well as our licensors, sublicensees and contractors. To help protect our proprietary know-how and our inventions for which patents may be unobtainable or difficult to obtain, we rely on trade secret protection and confidentiality agreements. To this end, we require all employees to enter into agreements that prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business. These agreements may not provide adequate protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure or the lawful development by others of such information. If any of our trade secrets, know-how or other proprietary information is disclosed, the value of our trade secrets, know-how and other proprietary rights would be significantly impaired, and our business and competitive position would suffer.

Due to legal and factual uncertainties regarding the scope and protection afforded by patents and other proprietary rights, we may not have meaningful protection from competition.

Our long-term success will substantially depend upon our ability to protect our proprietary technologies from infringement, misappropriation, discovery and duplication and avoid infringing the proprietary rights of others. Our patent rights, and the patent rights of biopharmaceutical companies in general, are highly uncertain and include complex legal and factual issues. These uncertainties also mean that any patents that we own or may obtain in the future could be subject to challenge, and even if not challenged, may not provide us with meaningful protection from competition. Patents already issued to us or our pending applications may become subject to dispute, and any dispute could be resolved against us.

In connection with the process of seeking patent protection for Supinoxin in Japan, we filed a patent application including claims covering Supinoxin with the Japanese Patent Office ("JPO") for examination. The JPO initially agreed that the claims covering the compound for Supinoxin were allowable, but as a result of a mistake in the patent application filing as prepared and submitted by our Japanese patent attorney and incomplete review by the JPO's patent examiner, the JPO issued a decision to grant a patent with claims that did not include Supinoxin's chemical structure. We appealed this decision with the JPO and requested withdrawal of the 'decision to grant' so that the correct claims would be allowed, but the JPO refused to withdraw its decision. As a result, and in accordance with Japanese law and procedure for appealing patent application decisions, we have filed a lawsuit against the JPO in Tokyo District Court to cause the JPO to reverse its decision to grant the errant patent and to allow a patent that includes claims covering Supinoxin. The patent application at issue remains pending subject to the outcome of this action. However, there can be no guarantee that we will be successful in winning the appeal to correct the error in the patent registration that would exclude the compound for Supinoxin. While the composition of matter patent on Supinoxin's structure remains pending in Japan, we have also filed, or intend to file, additional patents covering method of use and manufacturing process that would

extend to 2035/2036 if approved. We also expect that Supinoxin will be covered by regulatory exclusivity up to ten years post approval.

If we infringe the rights of third parties, we could be prevented from selling products and be forced to defend against litigation and pay damages.

If our products, methods, processes and other technologies infringe the proprietary rights of other parties, we could incur substantial costs and may have to:

- obtain licenses, which may not be available on commercially reasonable terms, if at all;
- redesign our products or processes to avoid infringement;
- stop using the subject matter claimed in patents held by others, which could cause us to lose the use of one or more of our drug candidates;
- pay damages; or
- defend litigation or administrative proceedings that may be costly whether we win or lose and that could result in a substantial diversion of our management resources.

Although we have not received any claims of infringement by any third parties to date, we expect that as our drug candidates move further into clinical trials and commercialization and our public profile is raised, we may be subject to such claims.

Risks Related to Ownership of Our Common Stock

An investment in shares of our common stock is very speculative and involves a very high degree of risk.

To date, we have generated no revenues from product sales and only minimal revenues from a research agreement with a minority shareholder and interest on bank account balances and short-term investments. Our accumulated deficit as of December 31, 2016 and 2015 was $115,024,209 and $105,716,864 respectively. For the years ended December 31, 2016, 2015 and 2014, we had net losses of $9,307,345, $14,384,556 and $18,521,601, respectively, partially as a result of expenses incurred through a combination of research and development activities related to the various technologies under our control and expenses supporting those activities. Until we receive approval from the FDA and other regulatory authorities for our drug candidates, we cannot sell our drugs and will not have product revenues.

The market price of our common stock may fluctuate significantly.

The market price of our common stock may fluctuate significantly in response to factors, some of which are beyond our control, such as:

- the announcement of new products or product enhancements by us or our competitors;
- changes in our relationships with our licensors or other strategic partners;
- developments concerning intellectual property rights and regulatory approvals;

- variations in our and our competitors' results of operations;
- changes in earnings estimates or recommendations by securities analysts;
- changes in the structure of healthcare payment systems; and
- developments and market conditions in the pharmaceutical and biotechnology industries.

Further, the stock market, in general, and the market for biotechnology companies, in particular, have experienced extreme price and volume fluctuations. Continued market fluctuations could result in extreme volatility in the price of our common stock, which may be unrelated or disproportionate to our operating performance and which could cause a decline in the value of our common stock. You should also be aware that price volatility might be worse if the trading volume of our common stock is low.

We will require additional capital funding the receipt of which may impair the value of our common stock.

Our future capital requirements depend on many factors, including our research, development, sales and marketing activities. We will need to raise additional capital through public or private equity or debt offerings or through arrangements with strategic partners or other sources in order to continue to develop our drug candidates. There can be no assurance that additional capital will be available when needed or on terms satisfactory to us, if at all. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution and the new equity securities may have greater rights, preferences or privileges than our existing common stock.

We have not paid dividends to our stockholders in the past, and we do not anticipate paying dividends to our stockholders in the foreseeable future.

We have not declared or paid cash dividends on our common stock. We currently intend to retain all future earnings, if any, to fund the continuing operation of our business, and therefore we do not anticipate paying dividends on our common stock in the foreseeable future. As a result, you will not realize any income from an investment in our common stock until and unless you sell your shares at a profit.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock may be volatile, and in the past companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and direct our management's attention from other business concerns, which could seriously harm our business.

Item 1B. Unresolved Staff Comments.

None

Item 2. Description of Property.

We lease approximately 7,103 square feet of office space in Rockville, Maryland. We also lease approximately 1,100 square feet of laboratory space in Gaithersburg, Maryland. The laboratory space is equipped with the requisite laboratory services required to conduct our business and we believe our existing facilities are adequate to meet our needs for the foreseeable future. The office lease, which commenced on June 29, 2009, expires in June 2019. The laboratory lease, which commenced on July 1, 2015 expires in June 2020. We do not own any real property.

Item 3. Legal Proceedings.

None

Item 4. Mine Safety Disclosures.

Not Applicable

PART II

Item 5. Market for Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Our common stock is traded on the NYSE MKT, under the ticker symbol "RNN". As of February 24, 2017, there were approximately 65 stockholders of record of our common stock. The following table sets forth the high and low sales prices of our common shares as reported on the NYSE MKT during the periods indicated.

Period	High ($)	Low ($)
2015		
First Quarter	0.96	0.69
Second Quarter	0.81	0.60
Third Quarter	0.66	0.48
Fourth Quarter	0.53	0.35
2016		
First Quarter	0.42	0.26
Second Quarter	0.34	0.24
Third Quarter	0.28	0.20
Fourth Quarter	0.23	0.13

Dividends

We have not paid any cash dividends on common stock and do not expect to do so in the foreseeable future. We anticipate that any earnings generated from future operations will be used to finance our operations. No restrictions exist upon our ability to pay dividends.

Purchase of Equity Securities by the Issuer and Affiliated Purchasers

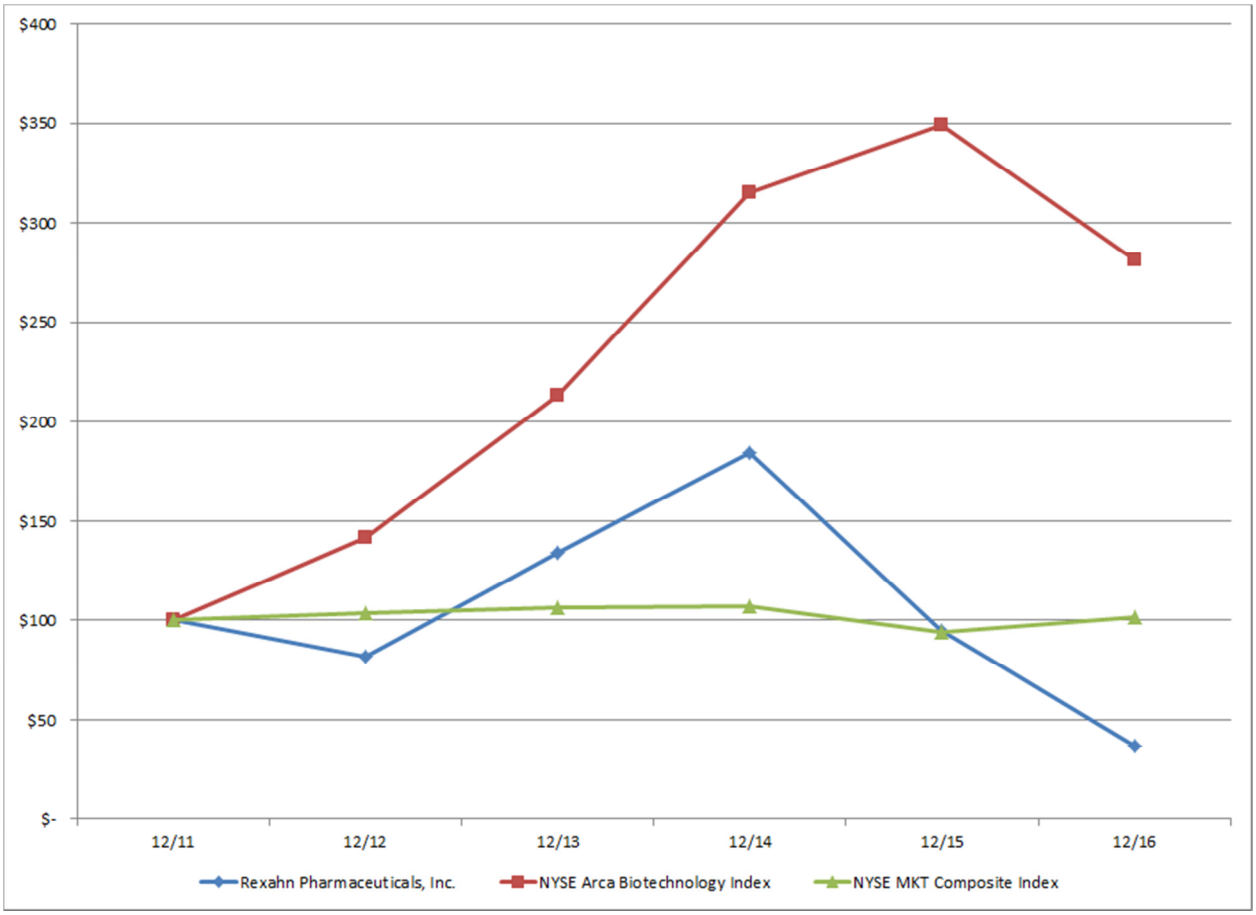
There were no repurchases of equity securities in 2016.

Recent Sales of Unregistered Equity Securities

None

Performance Graph

The following graph compares the cumulative total stockholder return on $100 of our common stock for the period beginning December 31, 2011 through December 31, 2016, with the cumulative total return over such period for an identical investment in i) the NYSE Arca Biotechnology Index or ii) the NYSE MKT Composite Index. This graph is not deemed to be "filed" with the SEC or subject to the liabilities of Section 18 of the Exchange Act, and the graph shall not be deemed to be incorporated by reference into any prior or subsequent filing by us under the Securities Act or the Exchange Act.



Item 6. Selected Financial Data.

The following selected data should be read in conjunction with "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements included elsewhere in this Annual Report.

	For the Year Ended December 31,				
Statement of Operations Data:	2016	2015	2014	2013	2012
Revenues	$ -	$ -	$ -	$ -	$ -
Expenses:					
General and administrative	6,324,236	6,115,210	6,253,328	4,725,699	3,186,634
Research and development	10,089,149	12,148,226	7,015,901	3,253,139	3,392,896
Total expenses	16,413,385	18,263,436	13,269,229	7,978,838	6,579,530
Loss from operations	(16,413,385)	(18,263,436)	(13,269,229)	(7,978,838)	(6,579,530)
Other Income (Expense), net	7,106,040	3,878,880	(5,252,372)	(1,520,586)	352,860
Net Loss	$ (9,307,345)	$ (14,384,556)	$ (18,521,601)	$ (9,499,424)	$ (6,226,670)
Net Loss per share, basic and	$ (0.04)	$ (0.08)	$ (0.11)	$ (0.07)	$ (0.06)
Weighted average shares outstanding, basic and diluted	217,447,405	182,388,226	176,106,981	128,649,303	97,138,233

	As of December 31,				
Balance Sheet Data:	2016	2015	2014	2013	2012
Cash, Cash Equivalents, and Marketable Securities	$ 20,315,580	$ 23,439,526	$ 32,698,296	$ 18,788,031	$ 13,586,543
Working Capital	$ 19,041,597	$ 22,000,046	$ 30,970,020	$ 18,361,438	$ 12,923,514
Total Assets	$ 21,043,532	$ 24,805,029	$ 33,533,060	$ 19,556,498	$ 14,919,308
Warrant Liabilities	$ 1,573,366	$ 2,739,163	$ 3,768,351	$ 5,034,058	$ 2,842,065
Accumulated Deficit	$(115,024,209)	$(105,716,864)	$ (91,332,308)	$ (72,810,707)	$ (63,311,283)
Total Stockholders' Equity	$ 17,058,462	$ 18,775,548	$ 26,580,491	$ 12,625,488	$ 9,533,989
Common shares outstanding	237,368,785	197,413,785	178,253,318	146,717,795	119,428,989

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our results of operations, financial condition and liquidity in conjunction with our financial statements and the related notes, which are included in this Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategies for our business, statements regarding the industry outlook, our expectations regarding the future performance of our business, and the other non-historical statements contained herein are forward-looking statements. See "Cautionary Statement Regarding Forward-Looking Statements." You should also review the "Risk Factors" section under this Item 1A of this Annual Report for a discussion of important factors that could cause actual results to differ materially from the results described herein or implied by such forward-looking statements.

OVERVIEW

We are a clinical stage biopharmaceutical company dedicated to the discovery, development and commercialization of innovative treatments for cancer. Our mission is to improve the lives of cancer patients by developing next-generation cancer therapies that are designed to maximize efficacy while minimizing the toxicity and side effects traditionally associated with cancer treatment. Our clinical pipeline features three product candidates in Phase II clinical development and additional compounds in pre-clinical development. Our strategy is to continue building a significant pipeline of innovative oncology product candidates that we will commercialize alone or with partners.

Since our inception, our efforts and resources have been focused primarily on developing our pharmaceutical technologies, raising capital and recruiting personnel. We have no product sales to date, and we will not generate any product sales until we receive approval from the FDA or equivalent foreign regulatory bodies to begin selling our pharmaceutical candidates. Our major sources of working capital have been proceeds from various private and public financings, and licensing and collaboration agreements with our strategic investors and partners.

Critical Accounting Policies

A "critical accounting policy" is one which is both important to the portrayal of our financial condition and results and requires our management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Our accounting policies are in accordance with U.S. generally accepted accounting principles and their basis of application is consistent with that of the previous year. Our significant estimates include assumptions made in estimating the fair values of stock-based compensation, warrant liabilities, marketable securities, and our assessment relating to costs incurred on research and development contracts.

Research and Development

Research and development costs are expensed as incurred. Research and development expenses consist primarily of third party service costs under research and development agreements, salaries and related personnel costs, as well as stock-based compensation related to these costs, costs to acquire pharmaceutical products and product rights for development and amounts paid to contract research organizations, hospitals and laboratories for the provision of services and materials for drug development and clinical trials.

Costs incurred in obtaining the license rights to technology in the research and development stage that have no alternative future uses and are for unapproved product compounds are expensed as incurred

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. Examples of estimated accrued research and development expenses include fees paid to:

- Contract Research Organizations ("CROs") and investigative sites in connection with clinical studies;
- Vendors related to product manufacturing, development, and distribution of clinical supplies; and
- Vendors in connection with preclinical development activities.

We record expenses related to clinical studies and manufacturing development activities based on our estimates of the services received and efforts expended pursuant to contracts with multiple CROs and manufacturing vendors that conduct and manage these activities on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract, and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. Payments under some of these contracts depend on factors such as the successful enrollment of subjects and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed, enrollment of subjects, number of sites activated and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrued or prepaid expense balance accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, we may report amounts that are too high or too low in any particular period. To date, there have been no material differences from our estimates to the amounts actually incurred.

Fair Value of Financial Instruments

The carrying amounts reported in the accompanying financial statements for cash and cash equivalents, prepaid expenses and other current assets and accounts payable and accrued expenses approximate fair value because of the short-term maturity of these financial instruments. The fair value methodology for our warrant liabilities and marketable securities is described in detail in Item 8 of this Annual Report on Form 10-K.

Income Taxes

We account for income taxes in accordance with Accounting Standards Codification ("ASC") 740, "Income Taxes." Deferred tax assets and liabilities are recorded for differences between the financial statement and tax basis of the assets and liabilities that will result in taxable or deductible amounts in the future based on enacted tax laws and rates. ASC 740 requires that a valuation allowance be established when it is more likely than not that all portions of a deferred tax asset will not be realized. A review of all positive and negative evidence needs to be considered, including a company's current and past performance, the market environment in which the company operates, length of carryback and

carryforward periods and existing contracts that will result in future profits. Income tax expense is recorded for the amount of income tax payable or refundable for the period, increased or decreased by the change in deferred tax assets and liabilities during the period.

As a result of our significant cumulative losses, we determined that it was appropriate to establish a valuation allowance for the full amount of our deferred tax assets.

The calculation of our tax liabilities involves the inherent uncertainty associated with the application of complex tax laws. We are subject to examination by various taxing authorities. We believe that as a result of our losses sustained to date, any examination would result in a reduction of our net operating loss carryforward rather than a tax liability. As such, we have not provided for additional taxes estimated under ASC 740.

Warrant Liabilities

In accordance with ASC 480, "Distinguishing Liabilities from Equity," we record warrant liabilities at fair value due to provisions in our warrant agreements, as discussed further in Note 12, Warrants, in the Notes to the Financial Statements of Item 8 of this Annual Report. We reevaluate the fair value of our warrants at each reporting period, and changes in the fair value between reporting periods is recorded as "unrealized gain (loss) on fair value of warrants" in the statement of operations.

Stock-Based Compensation

In accordance with ASC 718, "Stock Compensation" compensation costs related to share-based payment transactions, including employee stock options, are to be recognized in the financial statements. In addition, we adhere to the guidance set forth within SEC Staff Accounting Bulletin No. 107 ("SAB 107"), which provides the Staff's views regarding the interaction between ASC 718 and certain SEC rules and regulations, and provides interpretations with respect to the valuation of share-based payments for public companies.

We estimate the fair value of stock options using the Black-Scholes valuation model. The Black-Scholes model requires the input of highly subjective assumptions. These assumptions include:

Expected Term-the expected term was estimated using the simplified method whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option.

Volatility-historical trading volatility of our stock on the date of grant for a period consistent with the expected term

Risk-Free Interest Rate-the risk-free interest rate is based on the zero-coupon U.S. Treasury instruments on the date of grant with a maturity date consistent with the expected term of our stock option grants.

Expected Dividend -to date, we have not declared or paid any cash dividends and do not have any plans to do so in the future. Therefore, we used an expected dividend yield of zero.

As required, we review our valuation assumptions at each grant date and, as a result, we may change our valuation assumptions used to value employee stock-based awards granted in future periods. Employee and director stock-based compensation costs are to be recognized over the vesting period of the award.

Concentration of Credit Risk

ASC 825, "Financial Instruments," requires disclosure of any significant off-balance sheet risk and credit risk concentration. We do not have significant off-balance sheet risk or credit concentration. We maintain cash and short-term investments with major financial institutions. From time to time we have funds on deposit with commercial banks that exceed federally insured limits. The balances are insured by the Federal Deposit Insurance Corporation up to $250,000. At December 31, 2016, our uninsured cash balance was $11,078,473. Management does not consider this to be a significant credit risk as the banks are large, established financial institutions.

Recently Issued Accounting Standards

See Note 2, "Summary of Significant Accounting Policies in the Notes to the Financial Statements", in the Notes to Financial Statements of this Annual Report for a discussion of recent accounting pronouncements.

Results of Operations

Comparison of the Years Ended December 31, 2016 and December 31, 2015

Total Revenues

We had no revenues for the years ended December 31, 2016 or 2015.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related expenses for executive, finance and other administrative personnel, recruitment expenses, professional fees and other corporate expenses, including business development, investor relations, and general legal activities.

General and administrative expenses increased approximately $209,000, or 3.4%, to $6,324,000 for the year ended December 31, 2016 from $6,115,000 for the year ended December 31, 2015. The year over year increase is primarily attributable to an increase in personnel expenses.

Research and Development Expenses

Research and development expenses decreased approximately $2,059,000, or 16.9%, to $10,089,000 for the year ended December 31, 2016, from $12,148,000 for the year ended December 31, 2015. Decreased research and development costs for the year ended December 31, 2016 were primarily attributable to lower manufacturing costs for our drug candidates due to a significant supply of our drug candidates already being available to us from earlier manufacturing campaigns. During the year ended December 31, 2016, we incurred approximately $2,564,000 of drug manufacturing costs, compared to approximately $5,614,000 during the year ended December 31, 2015. Because the volume and timing of drug manufacturing does not correlate directly with the level and timing of clinical trial activity, we expect expenses related to drug manufacturing costs to vary from period to period based not only on the progress of clinical trials, but also when we engage in manufacturing activities. The decreases to drug manufacturing costs were partially offset by increases in clinical costs related to patient and site enrollment and personnel costs. We expect expenses to increase in the year ending December 31, 2017 compared to the year ended December 31, 2016 due to increased patient enrollments in, and further progress of, our clinical trials.

The table below summarizes the approximate amounts incurred on each of our research and development projects for the years ended December 31, 2016 and 2015:

	For the Year Ended December 31, 2016	2015
Clinical Candidates:		
RX-3117	$ 2,290,000	$ 4,062,000
Supinoxin	2,230,800	2,839,000
Archexin	1,573,800	1,547,000
Preclinical, Personnel and Overhead	3,994,549	3,700,226
Total Research and Development Expenses	$ 10,089,149	$ 12,148,226

Interest Income

Interest income increased approximately $15,000 or 14.8% to $118,000 for the year ended December 31, 2016 from $103,000 for the year ended December 31, 2015. The increase is primarily attributable to higher interest rates on cash and cash equivalents, and marketable securities for the year ended December 31, 2016 compared to the year ended December 31, 2015.

Mediation Settlement

During the year ended December 31, 2016, we received approximately $1,771,000 from a binding, one-time settlement agreement with one of our Japanese patent attorneys in exchange for our agreement not to bring any future claims related to a patent filing in Japan.

Unrealized Gain on Fair Value of Warrants

Our warrants are recorded as liabilities at fair value, and the warrants are valued using a lattice model. Changes in the fair value of warrants are recorded as an unrealized gain or loss in our statement of operations. During the years ended December 31, 2016 and 2015, we recorded unrealized gains on the fair value of our warrants of approximately $5,530,000 and $3,987,000 respectively. Estimating fair values of warrants requires the development of significant and subjective estimates that may, and are likely to, change over the duration of the warrant with related changes to external market factors. The unrealized gains for the years ended December 31, 2016 and 2015 primarily resulted from a decreased stock price underlying the common stock at December 31, 2016 and 2015, and from the greater number of warrants outstanding in 2016 compared to 2015.

Financing Expense

We incurred approximately $313,000 and $211,000 of financing expenses during the years ended December 31, 2016 and 2015, respectively, related to our registered direct offerings in September 2016, March 2016, and November 2015.

Net Loss

As a result of the above, net loss for the years ended December 31, 2016 and 2015 was approximately $9,307,000 and $14,385,000 or $0.04 and $0.08 per share, respectively.

Comparison of the Years Ended December 31, 2015 and December 31, 2014

Total Revenues

We had no revenues for the years ended December 31, 2015 or 2014.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related expenses for executive, finance and other administrative personnel, recruitment expenses, professional fees and other corporate expenses, including business development, investor relations, and general legal activities.

General and administrative expenses decreased approximately $138,000, or 2.2%, to $6,115,000 for the year ended December 31, 2015 from $6,253,000 for the year ended December 31, 2014. The year over year decrease is primarily attributable to a decrease in professional fees.

Research and Development Expenses

Research and development expenses increased approximately $5,132,000, or 73.2%, to $12,148,000 for the year ended December 31, 2015, from $7,016,000 for the year ended December 31, 2014. The increase is primarily attributable to the advancement of our drug candidates. During the year ended December 31, 2015, we incurred additional clinical trial and drug manufacturing costs as we have advanced our clinical trials for RX-3117, Supinoxin and Archexin. The increase is also partially attributable to an increase in personnel expenses.

The table below summarizes the approximate amounts incurred on each of our research and development projects for the years ended December 31, 2015 and 2014:

	For the Year Ended December 31, 2015	2014
Clinical Candidates:		
RX-3117	$ 4,062,000	$ 1,897,000
Supinoxin	2,839,000	1,351,000
Archexin	1,547,000	1,215,000
Preclinical, Personnel and Overhead	3,700,226	2,552,901
Total Research and Development Expenses	$ 12,148,226	$ 7,015,901

Interest Income

Interest income decreased approximately $31,000 or 22.9% to $103,000 for the year ended December 31, 2015 from $134,000 for the year ended December 31, 2014. The decrease is primarily attributable to lower aggregate balances of cash, cash equivalents, and marketable securities for the year ended December 31, 2015 compared to the year ended December 31, 2014.

Unrealized Gain (Loss) on Fair Value of Warrants

Our warrants are recorded as liabilities at fair value, and the warrants are valued using a lattice model. Changes in the fair value of warrants are recorded as an unrealized gain or loss in our statement of operations. During the years ended December 31, 2015 and 2014, we recorded unrealized gains (losses) on the fair value of our warrants of approximately $3,987,000 and $(5,180,000) respectively. Estimating fair values of warrants requires the development of significant and subjective estimates that may, and are likely to, change over the duration of the warrant with related changes to external market factors. The unrealized gain for the year ended December 31, 2015 primarily resulted from a decreased stock price underlying the common stock at December 31, 2015, while the unrealized loss for the year ended December 31, 2014 primarily resulted from an increased price of the underlying common stock at December 31, 2014 and on the dates during the year when warrant holders exercised their warrants.

Financing Expense

We incurred approximately $211,000 and $206,000 of financing expenses during the years ended December 31, 2015 and 2014, respectively, related to our registered direct offerings in November 2015 and January 2014, respectively.

Net Loss

As a result of the above, net loss for the years ended December 31, 2015 and 2014 was approximately $14,385,000 and $18,522,000 or $0.08 and $0.11 per share, respectively.

Research and Development Projects

Research and development costs are expensed as incurred. These costs consist primarily of salaries and related personnel costs, costs to acquire pharmaceutical products and product rights for development and amounts paid to contract research organizations, hospitals and laboratories for the provision of services and materials for drug development and clinical trials. Costs incurred in obtaining the license rights to technology in the research and development stage that have no alternative future uses are expensed as incurred. Our research and development programs are related to our oncology clinical stage drug candidates, RX-3117, Supinoxin and Archexin, and our pre-clinical stage drug candidate, RX-21101. As we expand our clinical studies, we expect to enter into additional development agreements. Significant additional expenditures will be required if we complete our clinical trials, start new trials, apply for regulatory approvals, continue development of our technologies, expand our operations and bring our products to market. The eventual total cost of each clinical trial is dependent on a number of uncertainties such as trial design, the length of the trial, the number of clinical sites and the number of patients. The process of obtaining and maintaining regulatory approvals for new therapeutic products is lengthy, expensive and uncertain. Because the successful development of our most advanced drug candidates, RX-3117, Supinoxin, and Archexin is uncertain, and because RX-21101 is in early-stage development, we are unable to estimate the costs of completing our research and development programs, the timing of bringing such programs to market and, therefore, when material cash inflows could commence from the sale of these drug candidates, if any. If these projects are not completed as planned, our results of operations and financial condition would be negatively affected.

RX-3117

RX-3117 is a novel, investigational oral small molecule nucleoside compound. We believe RX-3117 has therapeutic potential in a broad range of cancers including pancreatic, bladder, lung, cervical, non-small cell lung cancer and colon cancer. Additional information about RX-3117, including about the current Phase IIa clinical, can be found in Item 1 of this Annual Report. We expect that expenses related to RX-3117 will increase in 2017 compared to 2016 as we continue patient enrollment for our pancreatic and advanced bladder cancer clinical trials.

Supinoxin (RX-5902)

Supinoxin is a potential first-in-class small molecule inhibitor of phosphorylated-p68, a protein that we believe plays a key role in cancer growth, progression and metastasis. Phosphorylated p68 results in up-regulation of cancer-related genes and a subsequent proliferation of cancer cells and tumor growth. Additional information about Supinoxin, including about the Phase I dose-escalation clinical trial in cancer patients with solid tumors designed to evaluate the safety, tolerability, dose-limiting toxicities and recommended Phase II dose, can be found in Item 1 of this Annual Report. We expect that expenses related to Supinoxin will remain flat in 2017 compared to 2016 as we initiated a Phase IIa study in patients with triple negative breast cancer.

Archexin

Archexin is a potential best-in-class, potent inhibitor of the protein kinase Akt-1, which we believe plays a critical role in cancer cell proliferation, survival, angiogenesis, metastasis and drug resistance. Additional information about Archexin, including about the ongoing two-stage Phase IIa proof-of-concept clinical trial of Archexin in patients with metastatic renal cell carcinoma to evaluate its safety and efficacy, can be found in Item 1 to this Annual Report. We expect that expenses related to Archexin will remain flat in 2017 compared to 2016 as we continue in Stage 2 of the trial.

Pre-clinical Pipeline

We expect that expenses related to our pre-clinical pipeline, including RX-21101, will remain flat in 2017 compared to 2016 as we continue testing and development.

Research and Development Process

We have engaged third-party contract research organizations and other investigators and collaborators, such as universities and medical institutions, to conduct our pre-clinical studies, toxicology studies and clinical trials. Engaging third-party contract research organizations is typical practice in our industry. However, relying on such organizations means that the clinical trials and other studies described above are being conducted at external locations and that the completion of these trials and studies is not within our direct control. Trials and studies may be delayed due to circumstances outside our control, and such delays may result in additional expenses for us.

Liquidity and Capital Resources

Cash Flows

The table below summarizes our net cash flow activity:

	For the Year Ended December 31,		
	2016	2015	2014
Net Cash Used in Operating Activities	$ (13,227,101)	$ (17,351,950)	$ (11,041,211)
Net Cash Provided by (Used In) Investing Activities	4,483,911	9,554,394	(22,661,045)
Net Cash Provided by Financing Activities	10,122,223	8,170,751	24,840,470
Net Increase (Decrease) in Cash and Cash Equivalents	$ 1,379,033	$ 373,195	$ (8,861,786)

Cash used in operating activities was approximately $13,227,000 for the year ended December 31, 2016. The operating cash flows during the year ended December 31, 2016 reflect our net loss of $9,307,000, an unrealized gain on the fair value of warrants of $5,530,000 and a net increase of cash components of working capital and non-cash charges totaling $1,610,000. Cash used in operating activities was approximately $17,352,000 for the year ended December 31, 2015. The operating cash flows during the year ended December 31, 2015 reflect our net loss of $14,385,000, an unrealized gain on the fair value of warrants of $3,987,000 and a net increase of cash components of working capital and non-cash charges totaling $1,020,000. Cash used in operating activities was approximately $11,041,000 for the year ended December 31, 2014. The operating cash flows during the year ended December 31, 2014 reflect our net loss of $18,522,000, which includes an unrealized loss on fair value of warrants of $5,180,000 and a net increase of cash components of working capital and other non-cash charges totaling $2,301,000.

Cash provided by investing activities was approximately $4,484,000 for the year ended December 31, 2016, which consisted of $13,240,000 from the redemption of marketable securities, offset by $8,747,000 and $9,000 for the purchases of marketable securities and equipment, respectively. Cash provided by investing activities was approximately $9,554,000 for the year ended December 31, 2015, which consisted of $17,525,000 from the redemption of marketable securities, offset by $7,909,000 and $62,000 for the purchases of marketable securities and equipment, respectively. Cash used in investing activities was approximately $22,661,000 for the year ended December 31, 2014, which consisted of $26,076,000 and $41,000 for the purchases of marketable securities and equipment, respectively, offset by a decrease in restricted cash equivalents of $196,000 and $3,260,000 from the redemption of marketable securities.

Cash provided by financing activities was approximately $10,122,000 for the year ended December 31, 2016 which consisted of net proceeds from our registered direct public offerings in March 2016 and September 2016. Cash provided by financing activities was approximately $8,171,000 for the year ended December 31, 2015, which consisted of net proceeds of $7,440,000 from our registered direct public offering in November 2015 and sales from our at market issuance agreement, and proceeds of $709,000 and $22,000 received from the exercise of stock options and stock warrants, respectively. Cash provided by financing activities was approximately $24,840,000 for the year ended December 31, 2014, which consisted of net proceeds of $18,634,000 from our registered direct public offering in January 2014, $259,000 from the exercise of stock options and $5,947,000 from the exercise of warrants.

Financings

On January 21, 2014 we closed a registered direct public offering of 19,047,620 shares of common stock and warrants to purchase up to 4,761,905 shares of common stock. The common stock and warrants were sold in units consisting of one share of common stock and a warrant to purchase 0.25 shares of common stock, at a price of $1.05 per unit, and the warrants have an exercise price of $1.28 per share. The total gross proceeds of the offering were $20,000,001. The warrants issued are exercisable beginning six months and one day after the closing date until the five-year anniversary of the closing date.

On November 12, 2015 we closed a registered direct public offering of 16,666,667 shares of common stock and warrants to purchase up to 12,500,000 shares of common stock. The common stock and warrants were sold in units consisting of one share of common stock and a warrant to purchase 0.75 shares of common stock at a price of $0.42 per unit, and the warrants have an exercise price of $0.53 per share. The total gross proceeds of the offering were $7,000,000. The warrants issued are exercisable beginning six months after the closing date until the five-year anniversary of the initial exercise date.

On March 2, 2016 we closed a registered direct public offering of 15,625,000 shares of common stock and warrants to purchase up to 11,718,750 shares of common stock. The common stock and warrants were sold in units consisting of one share of common stock and a warrant to purchase 0.75 shares of common stock at a price of $0.32 per unit, and the warrants have an exercise price of $0.42 per share. The total gross proceeds of the offering were $5,000,000. The warrants are exercisable beginning six months after the closing date until the five-year anniversary of the initial exercise date.

On September 19, 2016 we closed a registered direct public offering of 24,000,000 shares of common stock and warrants to purchase up to 18,000,000 shares of common stock. The common stock and warrants were sold in units consisting of one share of common stock and a warrant to purchase 0.75 shares of common stock at a price of $0.25 per unit, and the warrants have an exercise price of $0.30 per share. The total gross proceeds of the offering were $6,000,000. The warrants are exercisable beginning six months after the closing date until the five-year anniversary of the initial exercise date.

We will need to raise additional capital through public or private equity or debt offerings or through arrangements with strategic partners or other sources in order to continue to develop our drug candidates. There can be no assurance that additional capital will be available when needed or on terms satisfactory to us, if at all. If we are not able to raise sufficient additional capital, we will have to reduce our research and development activities. We will first reduce research and development activities associated with our pre-clinical compounds. To the extent necessary, we will then reduce our research and development activities related to some or all of our clinical drugs.

At Market Issuance Sales Agreement

On March 16, 2015, we entered into an at market issuance sales agreement (the "Sales Agreement") with MLV & Co. LLC ("MLV"), pursuant to which we may issue and sell shares of our common stock having an aggregate offering price of up to $40 million from time to time, at our option, through MLV as our sales agent, subject to certain terms and conditions. Any shares sold will be sold pursuant to our effective shelf registration statement on Form S-3 (File No. 333-196255), as supplemented by a prospectus supplement dated March 16, 2015. We will pay MLV a commission of 3.0% of the gross proceeds of the sale of any shares sold through MLV. There were no sales under the Sales Agreement in 2016. As of December 31, 2016, we have sold 1,407,072 shares of common stock pursuant to the Sales Agreement for $1,042,573 in gross proceeds at a weighted average price of $0.7410 per share. Net proceeds to us were $1,005,715 after deducting commissions and other transaction costs. We are not obligated to make any further sales under the Sales Agreement and no assurance can be given

that we will sell any further shares under the Sales Agreement, or, if we do, as to the price or amount of shares that we will sell, or the dates on which any such sales will take place. Pursuant to the securities purchase agreement entered into in connection with our registered direct offering, which closed on September 19, 2016, we are prohibited from selling any additional shares under the Sales Agreement.

Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2016:

	Total	Less than 1 year	1 -3 Years	3-5 Years	More than 5 years
Operating Leases	$ 677,077	$ 255,731	$ 386,878	$ 34,468	$ -

We also have obligations under various license agreements that become due and payable on the achievement of certain development, regulatory, or commercial milestones. We have not included these commitments on our balance sheet or in the above table of contractual obligations because the achievement and timing of these events is neither fixed nor determinable.

We have contracted with various vendors for research and development services, the terms of which require payments over the term of the agreements, usually ranging from two to 36 months. The costs to be incurred are estimated and are subject to revision. As of December 31, 2016, the total estimated cost to complete these agreements was approximately $4,960,000. All of these agreements may be terminated by either party upon appropriate notice as stipulated in the respective agreements, and therefore, are not included in the above table of contractual obligations.

Current and Future Financing Needs

We have incurred negative cash flow from operations since we started our business. We have spent, and expect to continue to spend, substantial amounts in connection with implementing our business strategy, including our planned product development efforts, our clinical trials and our research and development efforts. We will need to raise additional capital through public or private equity or debt offerings or through arrangements with strategic partners or other sources in order to continue to develop our drug candidates. There can be no assurance that additional capital will be available when needed or on terms satisfactory to us, if at all. If we are not able to raise sufficient additional capital, we will have to reduce our research and development activities. We believe our cash, cash equivalents, and marketable securities will be sufficient to cover our cash flow requirements for our current activities for at least the next 12 months from the date our financial statements are issued.

The actual amount of funds we will need to operate is subject to many factors, some of which are beyond our control. These factors include the following:

- the progress of our product development activities;
- the number and scope of our product development programs;
- the progress of our pre-clinical and clinical trial activities;

- the progress of the development efforts of parties with whom we have entered into collaboration agreements;

- our ability to maintain current collaboration programs and to establish new collaboration arrangements;

- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights; and

- the costs and timing of regulatory approvals.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements or holdings in variable interest entities.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

For the year ended December 31, 2016, we are exposed to the following market risks:

Interest Rate Risk

We invest our cash in a variety of financial instruments. At December 31, 2016, our cash and cash equivalents was invested primarily in short term bank deposits and municipal obligations, all of which were denominated in U.S. dollars. Due to the conservative nature of these investments, which primarily bear interest at fixed rates, we do not believe we have material exposure to interest rate risk.

Foreign Currency Risk

We are exposed to risks associated with foreign currency transactions on contracts with vendors associated outside of the United States. Accordingly changes in the value of the U.S. dollar, relative to other currencies, may have an impact on our financial statements and earnings. The number and dollar amount of contracts denominated in foreign currency is immaterial; therefore, we believe we do not have material exposure to foreign currency risk.

Item 8. Financial Statements and Supplementary Data.

Our financial statements and the Report of the Independent Registered Public Accounting Firm thereon filed pursuant to this Item 8 and are included in this Annual Report on Form 10-K beginning on page F-1.

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. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this report. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of the end of the period covered by this report were effective such that the information required to be disclosed by us in reports filed under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding disclosure. A controls system cannot provide absolute assurance, however, that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

Changes in Internal Control Over Financial Reporting. During the most recent quarter ended December 31, 2016, there has been no change in our internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act) that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act). Our internal control over financial reporting is a process designed 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 and includes those policies and procedures that:

- Pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and the dispositions of our assets;

- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorization of our management and the board of directors; and

- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

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

Our management, with the participation of the Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2016. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in the Internal Control-Integrated Framework (2013).

Based on this evaluation, our management, with the participation of the Chief Executive Officer and Chief Financial Officer, concluded that, as of December 31, 2016, our internal control over financial reporting was effective.

Management's assessment of the effectiveness of the Company's internal control over financial reporting has been audited by Baker Tilly Virchow Krause, LLP, an independent registered public accounting firm. Baker Tilly Virchow Krause, LLP has issued an attestation report on the effectiveness of the Company's internal control over financial reporting, which appears herein.

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Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
Rexahn Pharmaceuticals, Inc.

We have audited Rexahn Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2016, based on criteria established in Internal Control—Integrated Framework (2013 framework) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Rexahn Pharmaceuticals, Inc.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the entity's internal control over financial reporting based on our audit.

We conducted our audit 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 effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

An entity's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. An entity's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the entity; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the entity are being made only in accordance with authorizations of management and directors of the entity; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the entity's assets that could have a material effect on the financial statements.

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

In our opinion, Rexahn Pharmaceuticals, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2016, based on criteria established in Internal Control—Integrated Framework (2013 framework) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheet and the related statements of operations, comprehensive loss, stockholders' equity, and cash flows of Rexahn Pharmaceuticals, Inc., and our report dated February 24, 2017 expressed an unqualified opinion.

/s/ Baker Tilly Virchow Krause, LLP

Wyomissing, Pennsylvania
February 24, 2017

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item is set forth in our 2017 Proxy Statement to be filed with the SEC within 120 days of December 31, 2016 and is incorporated into this Annual Report by reference.

Item 11. Executive Compensation.

The information required by this Item is set forth in our 2017 Proxy Statement to be filed with the SEC within 120 days of December 31, 2016 and is incorporated into this Annual Report by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item is set forth in our 2017 Proxy Statement to be filed with the SEC within 120 days of December 31, 2016 and is incorporated into this Annual Report by reference.

Item 13. Certain Relationships and Related Transactions; and Director Independence.

The information required by this Item is set forth in our 2017 Proxy Statement to be filed with the SEC within 120 days of December 31, 2016 and is incorporated into this Annual Report by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this Item is set forth in our 2017 Proxy Statement to be filed with the SEC within 120 days of December 31, 2016 and is incorporated into this Annual Report by reference.

Item 15. Exhibits, Financial Statement Schedules.

(a) The following documents are filed as a part of this Annual Report:

(1) The following documents are filed as a part of this Annual Report:

(2) All financial statement schedules have been omitted because they are not applicable or not required or because the information is included elsewhere in the financial statements or the Notes thereto.

(3) See the accompanying Index to Exhibits filed as a part of this Annual Report, which list is incorporated by reference in this Item.

(b) See the accompanying Index to Exhibits filed as a part of this Annual Report.

(c) Other schedules are not applicable.

SIGNATURES

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

REXAHN PHARMACEUTICALS, INC.

By: /s/ Peter D. Suzdak
Peter D. Suzdak
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, 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	Title	Date
/s/ Peter D. Suzdak* Peter Suzdak	Chief Executive Officer and Director (Principal Executive Officer)	February 24, 2017
/s/ Tae Heum Jeong* Tae Heum Jeong	Chief Financial Officer, and Secretary (Principal Financial and Accounting Officer)	February 24, 2017
/s/ Peter Brandt* Peter Brandt	Chairman	February 24, 2017
/s/ Chang H. Ahn* Chang H. Ahn	Director	February 24, 2017
/s/ Charles Beever* Charles Beever	Director	February 24, 2017
/s/ Kwang Soo Cheong* Kwang Soo Cheong	Director	February 24, 2017
/s/ Mark Carthy* Mark Carthy	Director	February 24, 2017
/s/ Richard J. Rodgers* Richard J. Rodgers	Director	February 24, 2017

* By: /s/ Tae Heum Jeong, Attorney-in Fact
Tae Heum Jeong, Attorney-in-Fact**

** By authority of the power of attorney filed as Exhibit 24 hereto

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Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
Rexahn Pharmaceuticals, Inc.

We have audited the accompanying balance sheet of Rexahn Pharmaceuticals, Inc. as of December 31, 2016 and 2015, and the related statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2016. These financial statements are the responsibility of the entity'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. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Rexahn Pharmaceuticals, Inc. as of December 31, 2016 and 2015, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2016, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Rexahn Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2016, based on criteria established in Internal Control—Integrated Framework (2013 framework) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated February 24, 2017 expressed an unqualified opinion.

/s/ Baker Tilly Virchow Krause, LLP

Wyomissing, Pennsylvania
February 24, 2017

REXAHN PHARMACEUTICALS, INC.
Balance Sheet

	December 31, 2016	December 31, 2015
ASSETS		
Current Assets:		
Cash and cash equivalents	**$ 11,578,473**	$ 10,199,440
Marketable securities	**8,737,107**	13,240,086
Prepaid expenses and other current assets	**608,517**	1,221,818
Total Current Assets	**20,924,097**	24,661,344
Security Deposits	**30,785**	30,785
Equipment, Net	**88,650**	112,900
Total Assets	**$ 21,043,532**	$ 24,805,029
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	**$ 1,882,500**	$ 2,661,298
Deferred Research and Development Arrangement	**450,000**	525,000
Other Liabilities	**79,204**	104,020
Warrant Liabilities	**1,573,366**	2,739,163
Total Liabilities	**3,985,070**	6,029,481
Commitments and Contingencies (note 15)		
Stockholders' Equity:		
Preferred stock, par value $0.0001, 100,000,000 authorized shares, none issued and outstanding	**-**	-
Common stock, par value $0.0001, 500,000,000 authorized shares, 237,368,785 and 197,413,785 issued and outstanding	**23,737**	19,741
Additional paid-in capital	**132,065,056**	124,490,712
Accumulated other comprehensive loss	**(6,122)**	(18,041)
Accumulated deficit	**(115,024,209)**	(105,716,864)
Total Stockholders' Equity	**17,058,462**	18,775,548
Total Liabilities and Stockholders' Equity	**$ 21,043,532**	$ 24,805,029

(See accompanying notes to the financial statements)

REXAHN PHARMACEUTICALS, INC.
Statement of Operations

	For the Year Ended December 31,		
	2016	2015	2014
Revenues:	**$ -**	$ -	**$** -
Expenses:			
General and administrative	**6,324,236**	6,115,210	6,253,328
Research and development	**10,089,149**	12,148,226	7,015,901
Total Expenses	**16,413,385**	18,263,436	13,269,229
Loss from Operations	**(16,413,385)**	(18,263,436)	(13,269,229)
Other Income (Expense)			
Interest income	**118,565**	103,269	133,907
Mediation settlement	**1,770,658**	-	-
Unrealized gain (loss) on fair value of warrants	**5,529,907**	3,986,727	(5,180,107)
Financing expense	**(313,090)**	(211,116)	(206,172)
Total Other Income (Expense)	**7,106,040**	3,878,880	(5,252,372)
Net Loss Before Provision for Income Taxes	**(9,307,345)**	(14,384,556)	(18,521,601)
Provision for income taxes	**-**	-	-
Net Loss	**$ (9,307,345)**	$ (14,384,556)	**$** (18,521,601)
Net loss per share, basic and diluted	**$ (0.04)**	$ (0.08)	**$** (0.11)
Weighted average number of shares outstanding, basic and diluted	**217,447,405**	182,388,226	176,106,981

(See accompanying notes to the financial statements)

REXAHN PHARMACEUTICALS, INC.
Statement of Comprehensive Loss

	For the Year Ended December 31,		
	2016	2015	2014
Net Loss	**$ (9,307,345)**	$ (14,384,556)	**$** (18,521,601)
Unrealized gain (loss) on available-for-sale securities	**11,919**	15,606	(33,647)
Comprehensive Loss	**$ (9,295,426)**	$ (14,368,950)	**$** (18,555,248)

(See accompanying notes to the financial statements)

REXAHN PHARMACEUTICALS, INC.
Statement of Stockholders' Equity
For the Year Ended December 31, 2016, 2015 and 2014

	Common Stock				Treasury Stock			
	Number of Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Number of Shares	Amount	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
Balances at January 1, 2014	146,732,000 $	14,673 $	85,449,932 $	(72,810,707)	14,205 $	(28,410)$	-$	12,625,488
Issuance of common stock and units	19,047,620	1,905	16,306,667	-	-	- -	-	16,308,572
Stock issuance costs	-	-	(1,159,582)	-	-	-	-	(1,159,582)
Common stock issued in exchange for services	400,000	40	408,960	-	-	-	-	409,000
Stock options exercised	448,693	45	358,910	-	-	-	-	358,955
Shares surrendered for net stock option exercise	-	-	-	-	99,010	(100,000)	-	(100,000)
Stock warrants exercised	11,738,220	1,174	16,083,337	-	-	-	-	16,084,511
Stock-based compensation	-	-	608,795	-	-	-	-	608,795
Net loss	-	-	-	(18,521,601)	-	-	-	(18,521,601)
Other comprehensive loss	-	-	-	-	-	-	(33,647)	(33,647)
Balances at December 31, 2014	178,366,533 $	17,837 $	118,057,019 $	(91,332,308)	113,215 $	(128,410)$	(33,647)$	26,580,491
Issuance of common stock and units	18,073,739	1,807	5,248,266	-	-	-	-	5,250,073
Stock issuance costs	-	-	(566,065)	-	-	-	-	(566,065)
Common stock issued in exchange for services	150,000	15	101,985	-	-	-	-	102,000
Stock options exercised	889,428	89	708,528	-	-	-	-	708,617
Stock warrants exercised	47,300	4	31,699	-	-	-	-	31,703
Stock-based compensation	-	-	1,037,679	-	-	-	-	1,037,679
Retirement of treasury stock	(113,215)	(11)	(128,399)		(113,215)	128,410	-	-
Net loss	-	-	-	(14,384,556)	-	-	-	(14,384,556)
Other comprehensive income	-	-	-	-	-	-	15,606	15,606
Balances at December 31, 2015	197,413,785 $	19,741 $	124,490,712 $	(105,716,864)	-$	-$	(18,041)$	18,775,548
Issuance of common stock and units	39,625,000	3,963	6,904,995	-	-	-	-	6,908,958
Stock issuance costs	-	-	(837,755)	-	-	-	-	(837,755)
Common stock issued in exchange for services	330,000	33	97,616	-	-	-	-	97,649
Stock-based compensation	-	-	1,409,488	-	-	-	-	1,409,488
Net loss	-	-	-	(9,307,345)	-	-	-	(9,307,345)
Other comprehensive income	-	-	-	-	-	-	11,919	11,919
Balances at December 31, 2016	**237,368,785 $**	**23,737 $**	**132,065,056 $**	**(115,024,209)**	**-$**	**-$**	**(6,122)$**	**17,058,462**

(See accompanying notes to the financial statements)

REXAHN PHARMACEUTICALS, INC.
Statement of Cash Flows

	For the Year Ended December 31,		
	2016	2015	2014
Cash Flows from Operating Activities:			
Net loss	**$ (9,307,345)**	$ (14,384,556)	(18,521,601)
Adjustments to reconcile net loss to net cash used in operating activities:			
Compensatory stock	**97,649**	102,000	409,000
Depreciation and amortization	**32,916**	27,498	28,325
Amortization of premiums and discounts on marketable securities, net	**22,321**	30,875	10,228
Stock-based compensation	**1,409,488**	1,037,679	608,795
Amortization of deferred research and development arrangements	**(75,000)**	(75,000)	(233,630)
Unrealized (gain) loss on fair value of warrants	**(5,529,907)**	(3,986,727)	5,180,107
Financing expense	**313,090**	211,116	206,172
Amortization of deferred lease incentive	**(12,443)**	(12,443)	(12,443)
Deferred lease expenses	**(12,373)**	(8,492)	7,834
Changes in assets and liabilities:			
Prepaid expenses and other assets	**613,301**	(495,935)	(249,503)
Accounts payable and accrued expenses	**(778,798)**	202,035	1,525,505
Net Cash Used in Operating Activities	**(13,227,101)**	(17,351,950)	(11,041,211)
Cash Flows from Investing Activities:			
Restricted cash equivalents	**-**	-	196,130
Purchase of equipment	**(8,666)**	(62,302)	(41,249)
Purchase of marketable securities	**(8,747,423)**	(7,908,304)	(26,075,926)
Redemption of marketable securities	**13,240,000**	17,525,000	3,260,000
Net Cash Provided by (Used in) Investing Activities	**4,483,911**	9,554,394	(22,661,045)
Cash Flows from Financing Activities:			
Issuance of common stock and units, net of issuance costs	**10,122,223**	7,439,809	18,634,247
Proceeds from exercise of stock options	**-**	708,617	258,955
Proceeds from exercise of stock warrants	**-**	22,325	5,947,268
Net Cash Provided by Financing Activities	**10,122,223**	8,170,751	24,840,470
Net Increase (Decrease) in Cash and Cash Equivalents	**1,379,033**	373,195	(8,861,786)
Cash and Cash Equivalents – beginning of period	**10,199,440**	9,826,245	18,688,031
Cash and Cash Equivalents - end of period	**$ 11,578,473**	$ 10,199,440	9,826,245
Supplemental Cash Flow Information			
Non-cash financing and investing activities:			
Warrants issued	**$ 4,364,110**	$ 2,966,917	3,691,429
Warrant liability extinguishment from exercise of warrants	**$ -**	$ 9,378	10,137,243
Shares withheld for net stock option exercise	**$ -**	$ -	100,000
Retirement of treasury stock	**$ -**	$ 128,410	-

(See accompanying notes to the financial statements)

1. Operations and Organization

Operations

Rexahn Pharmaceuticals, Inc. (the "Company,"), a Delaware corporation, is a biopharmaceutical company whose principal operations are the discovery, development and commercialization of innovative treatments for cancer. The Company had an accumulated deficit of $115,024,209 at December 31, 2016 and anticipates incurring losses through fiscal year 2017 and beyond. The Company has not yet generated commercial revenues and has funded its operating losses to date through the sale of shares of its common stock and warrants to purchase shares of its common stock, convertible debt, financings, interest income from cash, cash equivalents and marketable securities, and proceeds from reimbursed research and development costs. The Company believes that its cash, cash equivalents, and marketable securities, will be sufficient to cover its cash flow requirements for its current activities at least for the next 12 months from the date these financial statements were issued. Management believes it has the capability of managing the Company's operations within existing cash available by focusing on select research and development activities, selecting projects in conjunction with potential financings and milestones, and efficiently managing its general and administrative affairs.

2. Summary of Significant Accounting Policies

a) Cash and Cash Equivalents

Cash and cash equivalents include cash on hand and short-term investments purchased with remaining maturities of three months or less at acquisition.

b) Marketable Securities

Marketable securities are considered "available-for-sale" in accordance with Financial Statement Accounting Board ("FASB") Accounting Standards Codification ("ASC") 320, "Debt and Equity Securities", and thus are reported at fair value in the Company's accompanying balance sheet, with unrealized gains and losses excluded from earnings and reported as a separate component of stockholders' equity. Amounts reclassified out of accumulated other comprehensive loss into realized gains and losses are accounted for on the basis of specific identification and are included in other income or expense in the statement of operations. The Company classifies such investments as current on the balance sheet as the investments are readily marketable and available for use in the Company's current operations.

c) Equipment

Equipment is stated at cost less accumulated depreciation. Depreciation, based on the lesser of the term of the lease or the estimated useful life of the assets, is provided as follows:

	Life	Depreciation Method
Furniture and fixtures	7 years	straight line
Office equipment	5 years	straight line
Lab equipment	5-7 years	straight line
Computer equipment	3-5 years	straight line
Leasehold improvements	3-5 years	straight line

d) Research and Development

Research and development costs are expensed as incurred. Research and development expenses consist primarily of third party service costs under research and development agreements, salaries and related personnel costs, including stock-based compensation, costs to acquire pharmaceutical products and product rights for development and amounts paid to contract research organizations, hospitals and laboratories for the provision of services and materials for drug development and clinical trials.

Costs incurred in obtaining the licensing rights to technology in the research and development stage that have no alternative future uses and are for unapproved product compounds are expensed as incurred.

e) Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. These estimates are based on management's best knowledge of current events and actions the Company may undertake in the future. Actual results may ultimately differ from these estimates. These estimates are reviewed periodically and as adjustments become necessary, they are reported in earnings in the period in which they become available.

f) Fair Value of Financial Instruments

The carrying amounts reported in the accompanying financial statements for cash and cash equivalents, prepaid expenses and other assets, and accounts payable and accrued expenses approximate fair value because of the short-term maturity of these financial instruments. The fair value of warrant liabilities is discussed in Note 12, the fair value of marketable securities and certain other assets and liabilities is discussed in Note 16.

g) Income Taxes

The Company accounts for income taxes in accordance with ASC 740, "Income Taxes". Deferred tax assets and liabilities are recorded for differences between the financial statement and tax basis of the assets and liabilities that will result in taxable or deductible amounts in the future based on enacted tax laws and rates. ASC 740 requires that a valuation allowance be established when it is more likely than not that all portions of a deferred tax asset will not be realized. A review of all positive and negative evidence needs to be considered, including a company's current and past performance, the market environment in which the company operates, length of carryback and carryforward periods and existing contracts that will result in future profits. Income tax expense is recorded for the amount of income tax payable or refundable for the period, increased or decreased by the change in deferred tax assets and liabilities during the period.

As a result of the Company's significant cumulative losses, the Company determined that it was appropriate to establish a valuation allowance for the full amount of deferred tax assets.

The calculation of the Company's tax liabilities involves the inherent uncertainty associated with the application of complex tax laws. The Company is subject to examination by various taxing authorities. The Company believes that, as a result of its loss carryforward sustained to date, any examination would result in a reduction of its net operating losses rather than a tax liability. As such, the Company has not provided for any additional taxes that would be estimated under ASC 740.

h) Stock-Based Compensation

In accordance with ASC 718, "Stock Compensation," compensation costs related to share-based payment transactions, including employee stock options, are to be recognized in the financial statements. In addition, the Company adheres to the guidance set forth within Securities and Exchange Commission ("SEC") Staff Accounting Bulletin ("SAB") No. 107, which provides the Staff's views regarding the interaction between ASC 718 and certain SEC rules and regulations, and provides interpretations with respect to the valuation of share-based payments for public companies.

i) Concentration of Credit Risk

ASC 825, "Financial Instruments," requires disclosure of any significant off balance sheet risk and credit risk concentration. The Company does not have significant off-balance sheet risk or credit concentration. The Company maintains cash and cash equivalents with major financial institutions. From time to time the Company has funds on deposit with commercial banks that exceed federally insured limits. The balances are insured by the Federal Deposit Insurance Corporation up to $250,000. At December 31, 2016, the Company's uninsured cash balance was $11,078,473. Management does not consider this to be a significant credit risk as the banks are large, established financial institutions.

j) Reclassification

Certain amounts in the prior year's financial statements have been reclassified to conform to the current year presentation with no material effect on the financial statements.

k) Recent Accounting Pronouncements Affecting the Company

Revenue from Contracts with Customers

In May 2014, the FASB issued Accounting Standards Update ("ASU") 2014-09, "Revenue from Contracts with Customers," a comprehensive new revenue recognition standard that will supersede nearly all existing revenue recognition guidance under U.S. GAAP. The standard's core principle is that a company should recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods and services, and provides a revenue recognition framework in accordance with this principle. On August 12, 2015, the FASB issued ASU 2015-14, which defers the effective date of ASU 2014-09 by one year to December 15, 2017 for annual reporting periods beginning after that date and interim periods therein. Early adoption of the standard is permitted, but not before the original effective date of December 15, 2016. The Company is currently evaluating the impact that the adoption of this guidance will have on its financial statements and future operating results.

Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern

In August 2014, the FASB issued ASU 2014-15, "Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern," which requires management to perform interim and annual assessments as to the entity's ability to continue as a going concern and provides related disclosure guidance. ASU 2014-15 is effective for reporting periods ending after December 15, 2016, with early adoption permitted. The Company adopted this pronouncement for the year ended December 31, 2016. This pronouncement did not have a material impact on its financial statements.

Leases

In February 2016, the FASB issued ASU 2016-02, "Leases," which requires an entity to recognize assets and liabilities arising from leases on the balance sheet and to provide additional disclosures about leasing arrangements. ASU 2016-02 will be effective for reporting periods beginning after December 15, 2018, with early adoption permitted. The Company is currently evaluating the impact the adoption of this guidance will have on its financial statements.

Compensation-Stock Compensation

In March 2016, the FASB issued ASU 2016-09, "Compensation-Stock Compensation: Improvements to Employee Share Based Payment Accounting," which includes multiple provisions intended to simplify various aspects of accounting for share-based payments. The guidance is effective for reporting periods beginning after December 15, 2016, with early adoption permitted. The Company is currently evaluating the impact the adoption of this guidance will have on its financial statements.

3. Marketable Securities

The following table shows the Company's marketable securities' adjusted cost, gross unrealized gains and losses, and fair value by significant investment category as of December 31, 2016 and 2015:

	December 31, 2016			
	Cost Basis	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Certificates of Deposit	$ 720,000	$ 197	$ -	$ 720,197
Commercial Paper	3,987,424	-	(1,684)	3,985,740
Corporate Bonds	4,035,805	-	(4,635)	4,031,170
Total Marketable Securities	$ 8,743,229	$ 197	$ (6,319)	$ 8,737,107

	December 31, 2015			
	Cost Basis	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Certificates of Deposit	$ 6,240,000	$ 571	$ (5,575)	$ 6,234,996
Commercial Paper	2,981,307	-	(3,737)	2,977,570
Corporate Bonds	4,036,820	-	(9,300)	4,027,520
Total Marketable Securities	$ 13,258,127	$ 571	$ (18,612)	$ 13,240,086

The Company typically invests in highly-rated securities, with the primary objective of minimizing the potential risk of principal loss. As of December 31, 2016, the Company had four investments of commercial paper with a fair value of $3,985,740 and unrealized losses of $1,684, and four corporate bonds with a fair value of $4,031,170 and unrealized losses of $4,635, all of which have been unrealized losses for less than 12 months. The Company does not intend to sell its marketable securities in an unrealized loss position. Based upon the Company's securities' fair value relative to the cost, high ratings, and volatility of fair value, the Company considers the declines in market value of its marketable securities to be temporary in nature and does not consider any of its investments other-than-temporarily impaired, and anticipates that it will recover the entire amortized cost basis.

As of December 31, 2016, all of the Company's marketable securities are expected to mature in less than one year.

4. Prepaid Expenses and Other Current Assets

	December 31, 2016	December 31, 2015
Deposits on contracts	**$ 179,476**	$ 501,170
Prepaid expenses and other current assets	**429,041**	720,648
	$ 608,517	$ 1,221,818

Deposits on contracts consist of deposits on research and development contracts for services that had not been incurred as of the balance sheet date. Prepaid expenses and other assets include prepaid general and administrative expenses, such as insurance, rent, investor relations fees and compensatory stock issued for services not yet incurred as of the balance sheet date.

5. Equipment, Net

	December 31, 2016	December 31, 2015
Furniture and fixtures	**$ 78,794**	$ 78,794
Office and computer equipment	**113,932**	105,266
Lab equipment	**431,650**	431,650
Leasehold improvements	**133,762**	133,762
Total equipment	**758,138**	749,472
Less: Accumulated depreciation and amortization	**(669,488)**	(636,572)
Net carrying amount	**$ 88,650**	$ 112,900

6. Accounts Payable and Accrued Expenses

	December 31, 2016	December 31, 2015
Trade payables	**$ 430,013**	$ 774,543
Accrued expenses	**141,190**	92,752
Accrued research and development contract costs	**499,889**	1,515,151
Payroll liabilities	**811,408**	278,852
	$ 1,882,500	$ 2,661,298

7. Deferred Research and Development Arrangements

Rexgene Biotech Co., Ltd.

In 2003, the Company entered into a collaborative research agreement with Rexgene Biotech Co., Ltd. ("Rexgene"), a shareholder. Rexgene is engaged in the development of pharmaceutical products in Asia and has agreed to assist the Company with the research, development and clinical trials necessary for registration of the Company's drug candidate Archexin in Asia. This agreement provides Rexgene with exclusive rights to license, sublicense, make, have made, use, sell and import Archexin in Asia. In accordance with the agreement, Rexgene paid the Company a one-time fee of $1,500,000 in 2003. The agreement terminates at the later of 20 years or the term of the patent. The amortization reduces research and development expenses for the periods presented.

The Company is using 20 years as its basis for recognition and accordingly research and development expenses were reduced by $75,000 for each of the years ended December 31, 2016, 2015 and 2014. The remaining $450,000 and $525,000 to be amortized at December 31, 2016 and 2015, respectively, are reflected as a deferred research and development arrangement on the balance sheet. The payment from Rexgene is being used in the cooperative funding of the costs of development of Archexin. Royalties of 3% of net sales of licensed products will become payable by Rexgene to the Company on a quarterly basis once commercial sales of Archexin begin in Asia. The product is still under development and commercial sales in Asia are not expected to begin until at least 2018. Under the terms of the agreement, Rexgene does not pay royalties on the Company's net sales outside of Asia.

Teva Pharmaceutical Industries, Ltd.

The Company previously had an arrangement with Teva Pharmaceutical Industries Limited ("Teva") where Teva provided funds for the pre-clinical development of RX-3117. The proceeds received from Teva were recorded as restricted cash and as a deferred research and development arrangement on the balance sheet. Costs paid for the development of RX-3117 reduced the deferred research and development arrangement and therefore were not an expense in the Company's statement of operations. During the year ended December 31, 2014, $158,630 was reduced from deferred research and development arrangements. As of December 31, 2014, there were no proceeds remaining, and therefore, no deferred research and development liability relating to Teva.

8. Other Liabilities

Deferred Lease Incentive

In accordance with the Company's office lease agreement, as amended and further discussed in Note 15, the Company has been granted leasehold improvement allowances from the lessor to be used for the construction cost of improvements to the leased property, which included architectural and engineering fees, government agency plan check, permit and other fees, sales and use taxes, testing and inspection costs and telephone and data cabling and wiring in the premises. The Company accounted for the benefit of the leasehold improvement allowance as a reduction of rental expense over the term of the office lease.

The following table sets forth the cumulative deferred lease incentive:

	December 31, 2016	December 31, 2015
Deferred lease incentive	**$ 154,660**	$ 154,660
Less accumulated amortization	**(123,551)**	(111,108)
Balance	**$ 31,109**	$ 43,552

Deferred Office Lease Expense

The lease agreement, as amended, provided for an initial annual base rent with annual increases over the following six years. The Company recognizes rental expense on a straight-line basis over the term of the lease, which resulted in a deferred rent liability of $48,095 and $60,468 as of December 31, 2016 and 2015, respectively.

9. Net Loss per Common Share

Basic loss per common share is computed by dividing net loss by the weighted average number of shares of common stock outstanding for the period. Diluted loss per common share is computed by dividing net loss by the weighted average number of shares of common stock outstanding, plus the number of common share equivalents that would be dilutive. As of December 31, 2016, 2015 and 2014, there were stock options and warrants to acquire, in the aggregate, 71,427,262, 39,082,886, and 24,606,677 shares of the Company's common stock, respectively, that are potentially dilutive. However, diluted loss per share for all periods presented is the same as basic loss per share because the inclusion of common share equivalents would be anti-dilutive.

10. Common Stock

The following transactions occurred during the years ended December 31, 2016, 2015 and 2014:

Public Offerings

January 2014

On January 21, 2014, the Company closed on a registered direct public offering of 19,047,620 shares of common stock and warrants to purchase up to 4,761,905 shares of common stock. The common stock and warrants were sold in units, consisting of a share of common stock and a warrant to purchase 0.25 shares of common stock, at a price of $1.05 per unit, and the warrants have an exercise price of $1.28 per share. The total gross proceeds of the offering were $20,000,001. The warrants issued became exercisable beginning six months and one day after the closing date, will remain exercisable until the five-year anniversary of the closing date, and were recorded as liabilities at fair value.

A summary of the allocation of the proceeds of the offering is shown below:

Gross Proceeds:	$	20,000,001
Allocated to warrant liabilities:		3,691,429
Allocated to common stock and additional paid-in capital		16,308,572
Total allocated gross proceeds:	$	20,000,001

The closing costs of $1,365,754 consisted of placement agent and other professional fees. Based upon the estimated fair value of the stock and warrants in the units, the Company allocated $206,172 to financing expense and $1,159,582 as stock issuance costs.

November 2015

On November 12, 2015, the Company closed on a registered direct public offering of 16,666,667 shares of common stock and warrants to purchase up to 12,500,000 shares of common stock. The common stock and warrants were sold in units, consisting of a share of common stock and a warrant to purchase 0.75 shares of common stock, at a price of $0.42 per unit, and the warrants have an exercise price of $0.53 per share. The total gross proceeds of the offering were $7,000,000. The warrants issued became exercisable beginning six months after the closing date, will remain exercisable until the five-year anniversary of the initial exercise date, and were recorded as liabilities at fair value.

A summary of the allocation of the proceeds of the offering is shown below:

Gross Proceeds:	$	7,000,000
Allocated to warrant liabilities:		2,792,500
Allocated to common stock and additional paid-in capital		4,207,500
Total allocated gross proceeds:	$	7,000,000

The closing costs of $740,323 included 833,333 warrants valued at $174,417 and $565,906 for placement agent and other fees. Based upon the estimated fair value of the stock and warrants in the units, the Company allocated $211,116 to financing expense and $529,207 as stock issuance costs.

March 2016

On March 2, 2016, the Company closed on a registered direct public offering of 15,625,000 shares of common stock and warrants to purchase up to 11,718,750 shares of common stock. The common stock and warrants were sold in units, consisting of a share of common stock and a warrant to purchase 0.75 shares of common stock, at a price of $0.32 per unit, with an exercise price for the warrants of $0.42 per share. The total gross proceeds of the offering were $5,000,000. The issued warrants issued became exercisable beginning six months after the closing date, will remain exercisable until the five-year anniversary of the initial exercise date, and were recorded as liabilities at fair value.

A summary of the allocation of the proceeds of the offering is shown below:

Gross Proceeds:	$	5,000,000
Allocated to warrant liabilities:		2,419,922
Allocated to common stock and additional paid-in capital		2,580,078
Total allocated gross proceeds:	$	5,000,000

The closing costs of $575,751 included 781,250 warrants valued at $155,938 and $419,813 for placement agent and other fees. Based upon the estimated fair value of the stock and warrants in the units, the Company allocated $169,887 to financing expense and $405,864 as stock issuance costs.

September 2016

On September 19, 2016, the Company closed on a registered direct public offering of 24,000,000 shares of common stock and warrants to purchase up to 18,000,000 shares of common stock. The common stock and warrants were sold in units, consisting of a share of common stock and a warrant to purchase 0.75 shares of common stock, at a price of $0.25 per unit, with an exercise price for the warrants of $0.30 per share. The total gross proceeds of the offering were $6,000,000. The warrants issued will become exercisable beginning six months after the closing date, and will remain exercisable until the five-year anniversary of the initial exercise date, and were recorded as liabilities at fair value.

A summary of the allocation of the proceeds of the offering is shown below:

Gross Proceeds:	$	6,000,000
Allocated to warrant liabilities:		1,671,120
Allocated to common stock and additional paid-in capital		4,328,880
Total allocated gross proceeds:	$	6,000,000

The closing costs of $575,094 included 1,440,000 warrants valued at $117,130 and $457,964 for placement agent and other fees. Based upon the estimated fair value of the stock and warrants in the units, the Company allocated $143,203 to financing expense and $431,891 as stock issuance costs.

At Market Offering

On March 16, 2015, the Company entered into an at market issuance sales agreement (the "Sales Agreement") with MLV & Co. LLC ("MLV") pursuant to which the Company may issue and sell shares of its common stock having an aggregate offering price of up to $40 million from time to time, at its option, through MLV as its sales agent, subject to certain terms and conditions. Any shares sold will be sold pursuant to the Company's effective shelf registration statement on Form S-3 (File No. 333-196255), as supplemented by a prospectus supplement dated March 16, 2015. The Company will pay MLV a commission of 3.0% of the gross proceeds of the sale of any shares sold through MLV. For the year ended December 31, 2015, the Company sold 1,407,072 shares of common stock pursuant to the Sales Agreement for $1,042,573 in gross proceeds at a weighted average price of $0.7410 per share. Net proceeds to the Company were $1,005,715 after deducting commissions and other transaction costs. Pursuant to the securities purchase agreement entered into in connection with the Company's registered direct offering that closed on September 19, 2016, the Company is prohibited from selling any additional shares under the Sales Agreement.

Compensatory Shares

The Company has issued restricted shares to vendors in exchange for services. The table below summarizes the shares issued and the related market value:

	For the Year Ended December 31,		
	2016	2015	2014
Compensatory shares issued	**330,000**	150,000	400,000
Aggregate market value	**$ 97,649**	$ 102,000	$ 409,000

Stock Option and Stock Warrant Exercises

The table below summarizes stock options and stock warrants exercised:

	For the Year Ended December 31,		
	2016	2015	2014
Stock Option Exercises			
Number of shares issued	**-**	889,428	448,693
Total cash received	**$ -**	$ 708,617	$ 258,955
Stock Warrant Exercises			
Number of shares issued	**-**	47,300	11,738,220
Total cash received	**$ -**	$ 22,325	$ 5,947,268

Treasury Stock Transactions

On April 14, 2014, an option holder exercised stock options by a net exercise. The Company withheld 99,010 shares in treasury as payment for the $100,000 aggregate exercise price.

On December 3, 2015, the Company retired 113,215 shares of treasury stock with an aggregate purchase price of $128,410.

11. Stock-Based Compensation

As of December 31, 2016, the Company had 16,900,415 options outstanding.

At the Company's Annual Meeting of the Stockholders held on June 10, 2013, the Company's stockholders voted to approve the Rexahn Pharmaceuticals, Inc. 2013 Stock Option Plan (the "2013 Plan"). Under the 2013 Plan, the Company grants stock options to key employees, directors and consultants of the Company. A total of 17,000,000 shares of common stock have been reserved for issuance pursuant to the 2013 Plan. As of December 31, 2016, there were 12,461,915 options outstanding under the 2013 Plan, and 4,530,585 shares were available for issuance.

On August 5, 2003, the Company established a stock option plan (the "2003 Plan"). Under the 2003 Plan, the Company granted stock options to key employees, directors and consultants of the Company. With the adoption of the 2013 Plan, no new stock options may be issued under the 2003 Plan, but previously issued options under the 2003 Plan remain outstanding until their expiration. As of December 31, 2016, there were 4,318,500 outstanding options under the 2003 Plan.

In March 2016, the Company granted to a third party an option to purchase up to 120,000 shares of the Company's common stock. Of the Company's outstanding options as of December 31, 2016, these were the only options that were not issued pursuant to the 2013 Plan or the 2003 Plan.

At the Company's Annual Meeting of the Stockholders held on June 9, 2016, the Company's stockholders voted to approve an amendment to the 2013 Plan, including to provide for awards of restricted stock and restricted stock units. As of December 31, 2016, no awards of restricted stock or restricted stock units had been granted

For the majority of the grants to employees, the vesting period is either i) 30%, 30% and 40% on the first, second and third anniversaries, of the grant date, respectively, or ii) 25% each on the first four anniversaries. Options expire between five and ten years from the date of grant. For grants to non-employee consultants of the Company, the vesting period is between one and three years, subject to the fulfillment of certain conditions in the individual stock agreements, or 100% upon the occurrence of certain events specified in the individual stock agreements.

Accounting for Awards

Stock option compensation expense is the estimated fair value of options granted amortized on a straight-line basis over the requisite vesting service period for the entire portion of the award. Total stock-based compensation recognized by the Company for the years ended December 31, 2016, 2015 and 2014 is as follows:

	For the Year Ended December 31,		
	2016	2015	2014
Statement of operations line item:			
General and administrative	$ **905,911**	$ 665,063	$ 457,128
Research and development	**503,577**	372,616	151,667
Total	$ **1,409,488**	$ 1,037,679	$ 608,795

Summary of Stock Option Transactions

There were 5,926,391 stock options granted at exercise prices ranging from $0.18 to $0.37 with an aggregate fair value of $1,156,273 during the year ended December 31, 2016. There were 4,201,316 stock options granted at exercise prices ranging from $0.54 to $0.89 with an aggregate fair value of $1,994,893 during the year ended December 31, 2015. There were 2,528,499 stock options granted at exercise prices ranging from $0.68 to $1.35 with an aggregate fair value of $1,737,087 during the year ended December 31, 2014.

The fair value of options at the date of grant was estimated using the Black-Scholes option pricing model. The Company took into consideration guidance under ASC 718, "Compensation-Stock Compensation" and Staff Accounting Bulletin No. 107 ("SAB 107") when reviewing and updating assumptions.

Significant assumptions are determined as follows:

Expected Term-the expected term was estimated using the simplified method whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option.

Volatility-historical trading volatility of the Company's stock on the date of grant for a period consistent with the expected term.

Risk-Free Interest Rate-the risk-free interest rate is based on the zero-coupon U.S. Treasury instruments on the date of grant with a maturity date consistent with the expected term of the Company's stock option grants.

Expected Dividend -to date, the Company has not declared or paid any cash dividends and do not have any plans to do so in the future. Therefore, the Company used an expected dividend yield of zero.

The assumptions made in calculating the fair values of options are as follows:

	Year Ended December 31,		
	2016	2015	2014
Black-Scholes assumptions			
Expected dividend yield	**0%**	0%	0%
Expected volatility	**31-75%**	72-80%	92-96%
Risk free interest rate	**0.8-1.4%**	1.2-1.7%	1.5-1.8%
Expected term (in years)	**2-6 years**	5-6 years	5 years

The following table summarizes share-based transactions:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding, January 1, 2016	12,590,982 $	0.83	6.8 years $	26,500
Granted	5,926,391	0.31		
Exercised	-	-		
Expired	(730,000)	1.37		
Cancelled	(886,958)	0.89		
Outstanding, December 31, 2016	16,900,415 $	0.62	7.3 years $	-
Exercisable, December 31, 2016	7,929,179 $	0.78	5.8 years $	-

There were no stock options exercised during the year ended December 31, 2016. The total intrinsic value of the options exercised was $99,895 and $115,528 for the years ended December 31, 2015 and 2014, respectively. The weighted average fair value of the options granted was $0.20, $0.47, and $0.69 for the years ended December 31, 2016, 2015 and 2014, respectively.

A summary of the Company's unvested options as of December 31, 2016 and changes during the year ended December 31, 2016 is presented below:

	2016	
	Number of Options	**Weighted Average Fair Value at Grant Date**
Unvested at January 1, 2016	5,888,432	**$** 0.51
Granted	5,926,391	**$** 0.20
Vested	(2,625,254)	**$** 0.46
Cancelled	(218,333)	**$** 0.41
Unvested at December 31, 2016	8,971,236	**$** 0.32

As of December 31, 2016 there was $1,882,605 of total unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted average vesting period of 2.0 years.

12. Warrants

As of December 31, 2016, warrants to purchase 54,526,847 shares were outstanding, having exercise prices ranging from $0.30 to $1.28 and expiration dates ranging from December 4, 2017 to March 19, 2022.

	2016		2015	
	Number of warrants	**Weighted average exercise price**	Number of warrants	Weighted average exercise price
Balance, January 1	**26,491,904**	**$ 0.80**	13,205,871	$ 1.07
Issued during the period	**31,940,000**	**$ 0.35**	13,333,333	$ 0.53
Exercised during the period	**-**	**$ -**	(47,300)	$ 0.47
Expired during the period	**(3,905,057)**	**$ 1.37**	-	$ -
Balance, December 31	**54,526,847**	**$ 0.49**	26,491,904	$ 0.80

At December 31, 2016 the weighted average remaining contractual life of the outstanding warrants was 4.3 years.

The warrants issued to investors in the December 2012, November 2015, March 2016, September 2016, and previous offerings contain a provision for net cash settlement in the event that there is a fundamental transaction (contractually defined as a merger, sale of substantially all assets, tender offer or share exchange). If a fundamental transaction occurs in which the consideration issued consists principally of cash or stock in a non-public company, then the warrant holder has the option to receive cash, equal to the fair value of the remaining unexercised portion of the warrant. Due to this contingent redemption provision, the warrants require liability classification in accordance with ASC 480 and are recorded at fair value. The warrants issued to investors in the July 2013, October 2013 and January 2014 offerings contain a fundamental transaction provision, but the warrant holders only have an option as to the type of consideration received if the holders of common stock receive an option as to their consideration. In addition, the warrants issued in the December 2012, July 2013, October 2013, January 2014, November 2015, March 2016, September 2016 and previous offerings contain a cashless exercise provision that is exercisable only in the event that a registration statement is not effective. That provision may not be operative if an effective registration statement is not available because an exemption under the U.S. securities laws may not be available to issue unregistered shares. As a result, net cash settlement may be required, and the warrants require liability classification.

ASC 820 provides requirements for disclosure of liabilities that are measured at fair value on a recurring basis in periods subsequent to the initial recognition. Fair values for warrants were determined using the Binomial Lattice ("Lattice") valuation technique. The Lattice model provides for dynamic assumptions regarding volatility and risk-free interest rates within the total period to maturity. Accordingly, within the contractual term, the Company provided multiple date intervals over which multiple volatilities and risk free interest rates were used. These intervals allow the Lattice model to project outcomes along specific paths that consider volatilities and risk free rates that would be more likely in an early exercise scenario.

Significant assumptions are determined as follows:
Trading market values—Published trading market values;
Exercise price—Stated exercise price;
Term—Remaining contractual term of the warrant;
Volatility—Historical trading volatility for periods consistent with the remaining terms; and
Risk-free rate—Yields on zero coupon government securities with remaining terms consistent with the remaining terms of the warrants.

Due to the fundamental transaction provision, which could provide for early redemption of the warrants, the model also considered the probability the Company would enter into a fundamental transaction during the remaining term of the warrant. Because the Company is not yet achieving positive cash flow, management believes the probability of a fundamental transaction occurring over the term of the warrant is unlikely and therefore estimates the probability of entering into a fundamental transaction to be 5%. For valuation purposes, the Company also assumed that if such a transaction did occur, it was more likely to occur towards the end of the term of the warrants.

The significant unobservable inputs used in the fair value measurement of the warrants include management's estimate of the probability that a fundamental transaction may occur in the future. Significant increases (decreases) in the probability of occurrence would result in a significantly higher (lower) fair value measurement.

The following table summarizes the fair value of the warrants as of the respective balance sheet dates:

	Fair Value as of:	
Warrant Issuance:	**December 31, 2016**	December 31, 2015
Expired Warrants	**$ -**	$ 2,590
December 2012 Investor Warrants	**49**	9,818
July 2013 Investor Warrants	**2,060**	121,420
October 2013 Investor Warrants	**3,708**	169,349
January 2014 Investor Warrants	**714**	131,476
November 2015 Investor Warrants	**260,500**	2,169,375
November 2015 Placement Agent Warrants	**13,542**	135,135
March 2016 Investor Warrants	**358,945**	-
March 2016 Placement Agent Warrants	**21,320**	-
September 2016 Investor Warrants	**854,640**	-
September 2016 Placement Agent Warrants	**57,888**	-
Total:	**$ 1,573,366**	$ 2,739,163

The following table summarizes the number of shares indexed to the warrants as of the respective balance sheet dates:

	Number of Shares indexed as of:	
Warrant Issuance	**December 31, 2016**	December 31, 2015
Expired Warrants	**-**	3,905,057
December 2012 Investor Warrants	**174,300**	174,300
July 2013 Investor Warrants	**2,000,000**	2,000,000
October 2013 Investor Warrants	**2,317,309**	2,317,309
January 2014 Investor Warrants	**4,761,905**	4,761,905
November 2015 Investor Warrants	**12,500,000**	12,500,000
November 2015 Placement Agent Warrants	**833,333**	833,333
March 2016 Investor Warrants	**11,718,750**	-
March 2016 Placement Agent Warrants	**781,250**	-
September 2016 Investor Warrants	**18,000,000**	-
September 2016 Placement Agent Warrants	**1,440,000**	-
Total:	**54,526,847**	26,491,904

The assumptions used in calculating the fair values of the warrants are as follows:

	December 31, 2016	December 31, 2015
Trading market prices	**$ 0.14**	$ 0.36
Estimated future volatility	**104 %**	105 %
Dividend	**-**	-
Estimated future risk-free rate	**1.06-2.44%**	0.82-2.38%
Equivalent volatility	**51-60%**	44-65%
Equivalent risk-free rate	**0.59-1.25%**	0.22-1.11%

Changes in the fair value of the warrant liabilities, carried at fair value, as reported as "unrealized gain (loss) on fair value of warrants" in the statement of operations:

	For the Year Ended December 31,		
	2016	2015	2014
Expired Warrants	**$ 2,590**	$ 458,439	**$** (1,059,400)
December 2012 Investor Warrants	**9,769**	70,856	(4,120,103)
July 2013 Investor Warrants	**119,360**	666,894	(1,272,731)
October 2013 Investor Warrants	**165,641**	780,407	(940,100)
January 2014 Investor Warrants	**130,762**	1,347,724	2,212,227
November 2015 Investor Warrants	**1,908,875**	623,125	-
November 2015 Placement Agent	**121,593**	39,282	-
March 2016 Investor Warrants	**2,060,977**	**-**	-
March 2016 Placement Agent	**134,617**	**-**	-
September 2016 Investor Warrants	**816,480**	**-**	-
September 2016 Placement Agent	**59,243**	**-**	-
Total:	**$ 5,529,907**	$ 3,986,727	**$** (5,180,107)

13. Mediation Settlement

In connection with the process of seeking patent protection for Supinoxin in Japan, the Company had filed a patent application including claims covering Supinoxin with the Japanese Patent Office ("JPO") for examination. The JPO initially agreed that the claims covering the compound for Supinoxin were allowable, but as a result of a mistake in the patent application filing as prepared and submitted by the Company's Japanese patent attorney and incomplete review by the JPO's patent examiner, the JPO issued a decision to grant a patent with claims that did not include Supinoxin's chemical structure. The Company appealed this decision with the JPO to request withdrawal of the decision to grant so that the correct claims would be allowed, but the JPO refused to withdraw its decision. As a result, and in accordance with Japanese law and procedure for appealing patent application decisions, the Company has filed a lawsuit against the JPO in Tokyo District Court to cause the JPO to reverse its decision to grant the errant patent and to allow a patent that includes claims covering Supinoxin. The patent application at issue remains pending subject to the outcome of this action. While the composition of matter patent on Supinoxin structure remains pending in Japan, the Company either has already or will have protection in Japan from its issued and pending patents on formulation, method of use, and method of manufacturing as well as from market exclusivity period.

On December 19, 2016, the Company entered into a binding settlement arrangement with the Company's Japanese patent attorney in which the Japanese patent attorney agreed to pay a one-time settlement JPY 210,000,000, or $1,770,658, in exchange for the Company agreeing not to bring any future claims on account of this patent filing. The settlement payment was received by the Company by December 31, 2016.

14. Income Taxes

No provision for federal and state income taxes was required for the years ended December 31, 2016, 2015 and 2014 due to the Company's operating losses and increased deferred tax asset valuation allowance. At December 31, 2016 and 2015, the Company had unused net operating loss carry-forwards of approximately $111,605,000 and $98,954,000, respectively, which expire at various dates through 2036. Some of this amount may be subject to annual limitations under certain provisions of the Internal Revenue Code related to "changes in ownership."

As of December 31, 2016 and 2015, the deferred tax assets related to the aforementioned carry-forwards have been fully offset by valuation allowances, because significant utilization of such amounts is not presently expected in the foreseeable future.

Deferred tax assets and valuation allowances consist of:

	December 31, 2016	December 31, 2015
Net Operating Loss Carryforwards	**$ 43,526,000**	$ 38,592,000
Stock Compensation Expense	**1,968,000**	1,891,000
Book tax differences on assets and liabilities	**547,000**	380,000
Valuation Allowance	**(46,041,000)**	(40,863,000)
Net Deferred Tax Assets	**$ -**	$ -

The Company files income tax returns in the U.S. federal and Maryland state jurisdictions. Tax years for fiscal 2013 through 2016 are open and potentially subject to examination by the federal and Maryland state taxing authorities.

15. Commitments and Contingencies

a) The Company has contracted with various vendors for research and development services, the terms which require payments over the term of the agreements, usually ranging from two to 36 months. The costs to be incurred are estimated and are subject to revision. As of December 31, 2016, the total estimated cost to complete these agreements was approximately $4,960,000. All of these agreements may be terminated by either party upon appropriate notice as stipulated in the respective agreements.

b) On June 22, 2009, the Company entered into a License Agreement with Korea Research Institute of Chemical Technology ("KRICT") to acquire the rights to all intellectual property related to quinoxaline-piperazine derivatives that were synthesized under a Joint Research Agreement. The initial license fee was $100,000, all of which was paid as of December 31, 2009. The agreement with KRICT calls for a one-time milestone payment of $1,000,000 within 30 days after the first achievement of marketing approval of the first commercial product arising out of or in connection with the use of KRICT's intellectual properties. As of December 31, 2016, the milestone has not occurred.

c) *Office Space Lease*

On June 7, 2013, the Company signed the first amendment to its commercial lease agreement for 5,466 square feet of office space in Rockville, Maryland. Under the lease agreement, the Company pays its allocable portion of real estate taxes and common area operating charges.

On July 26, 2014 the Company entered into the second amendment to the lease agreement. According to the terms of this amendment, the Company leased an additional 1,637 square feet of office space, beginning on September 1, 2014 and ending on August 31, 2015. The Company subsequently renewed the lease for this space for additional one-year terms, beginning on September 1, 2015 and 2016.

Rent paid under the Company's lease during the years ended December 31, 2016, 2015, and 2014 was $205,324, $202,529 and $155,057, respectively.

Prior Laboratory Lease

On August 26, 2014 and June 24, 2013, the Company signed one-year renewals to use laboratory space commencing on July 1, 2014 and 2013, respectively. The lease required monthly rental payments of $4,554. Rent paid under the Company's lease during the years ended December 31, 2015, and 2014 was $27,324 and $54,648, respectively.

Current Laboratory Lease

On April 20, 2015, the Company signed a five-year lease agreement for 2,552 square feet of laboratory space commencing on July 1, 2015 and ending on June 30, 2020. Under the lease agreement, the Company pays its allocable portion of real estate taxes and common area operating charges. Rent paid under this lease during the years ended December 31, 2016 and 2015 was $62,167 and $30,624, respectively.

Future rental payments over the next five years for all leases are as follows:

For the year ending December 31:	2017	255,731
	2018	233,923
	2019	152,955
	2020	34,468
	Total	**$ 677,077**

d) The Company has established a 401(k) plan for its employees. The Company has elected to match 100% of the first 3% of an employee's compensation plus 50% of an additional 2% of the employee's deferral. Expense related to this matching contribution aggregated to $113,204, $121,519 and $91,241 for the years ended December 31, 2016, 2015 and 2014 respectively.

e) In July 2013, the Company entered into an exclusive license agreement with the University of Maryland, Baltimore for a novel drug delivery platform, Nano-Polymer Drug Conjugate Systems. RX-21101 is the Company's first drug candidate utilizing this platform. The agreement requires the Company to make payments to the University of Maryland if RX-21101 or any products from the licensed delivery platform achieve development milestones. As of December 31, 2016, no development milestones have occurred.

f) In October 2013, the Company signed an exclusive license agreement with the Ohio State Innovation Foundation, for a novel oligonucleotide drug delivery platform, Lipid-Coated Albumin Nanoparticle. The agreement requires the Company to make payments to the Ohio State Innovation Foundation or any products from the licensed delivery platform achieve development milestones. As of December 31, 2016, no development milestones have occurred.

16. Fair Value Measurements

ASC 820 defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date, not adjusted for transaction costs. ASC 820 also establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three broad levels giving the highest priority to quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3).

The three levels are described below:

Level 1 Inputs — Unadjusted quoted prices in active markets for identical assets or liabilities that are accessible by the Company;

Level 2 Inputs — Quoted prices in markets that are not active or financial instruments for which all significant inputs are observable, either directly or indirectly;

Level 3 Inputs — Unobservable inputs for the asset or liability including significant assumptions of the Company and other market participants.

The following tables present assets and liabilities that are measured at fair value on a recurring basis and are categorized using the fair value hierarchy. There have been no changes in the methodologies used at December 31, 2016 and 2015.

	Fair Value Measurements at December 31, 2016			
	Total	Level 1	Level 2	Level 3
Assets:				
Certificates of Deposit	$ **720,197**	$ **-**	$ **720,197**	$ **-**
Commercial Paper	**3,985,740**	**-**	**3,985,740**	**-**
Corporate Bonds	**4,031,170**	**-**	**4,031,170**	**-**
Total Assets:	**$ 8,737,107**	**$ -**	**$ 8,737,107**	**$ -**
Liabilities:				
Warrant Liabilities	**$ 1,573,366**	**-**	**- $**	**1,573,366**

	Fair Value Measurements at December 31, 2015			
	Total	Level 1	Level 2	Level 3
Assets:				
Certificates of Deposit	$ 6,234,996	$ -	$ 6,234,996	$ -
Commercial Paper	2,977,570	-	2,977,570	-
Corporate Bonds	4,027,520	-	4,027,520	-
Total Assets:	$ 13,240,086	$ -	$ 13,240,086	$ -
Liabilities:				
Warrant Liabilities	$ 2,739,163	-	- $	2,739,163

The fair value of the Company's Level 2 marketable securities is determined by using quoted prices from independent pricing services that use market data for comparable securities in active or inactive markets. A variety of data inputs, including benchmark yields, interest rates, known historical trades and broker dealer quotes are using with pricing models to determine the quoted prices.

The fair value methodology for the warrant liabilities is disclosed in Note 12.

The carrying amounts reported in the financial statements for cash and cash equivalents (Level 1), prepaid expenses and other assets, and accounts payable and accrued expenses approximate fair value because of the short term maturity of these financial instruments.

The following table sets forth a reconciliation of changes in the years ended December 31, 2016 and 2015 in the fair value of the liabilities classified as Level 3 in the fair value hierarchy:

	Warrant Liabilities
Balance at January 1, 2016	$ 2,739,163
Additions	4,364,110
Unrealized gains, net	(5,529,907)
Transfers out of level 3	-
Balance at December 31, 2016	$ 1,573,366

	Warrant Liabilities
Balance at January 1, 2015	$ 3,768,351
Additions	2,966,917
Unrealized gains, net	(3,986,727)
Transfers out of level 3	(9,378)
Balance at December 31, 2015	$ 2,739,163

Additions consist of the fair value of warrant liabilities upon issuance. Transfers out of Level 3 for warrant liabilities consist of warrant exercises, where the liability is converted to additional paid-in capital upon exercise. The Company's policy is to recognize transfers in and transfers out as of the actual date of the event or change in circumstance that caused the transfer.

17. Select Quarterly Data (Unaudited)

	2016			
	For the Quarter Ended			
	March 31	June 30	September 30	December 31
Revenues	$ -	$ -	$ -	$ -
Expenses	4,863,981	3,912,782	3,717,575	3,919,047
Loss from Operations	(4,863,981)	(3,912,782)	(3,717,575)	(3,919,047)
Other Income, net	714,939	2,146,958	850,579	3,393,564
Net Loss	$ (4,149,042)	$ (1,765,824)	$ (2,866,996)	$ (525,483)
Net Loss per share, basic and diluted	$ (0.02)	$ (0.01)	$ (0.01)	$ (0.00)

	2015			
	For the Quarter Ended			
	March 31	June 30	September 30	December 31
Revenues	$ -	$ -	$ -	$ -
Expenses	4,417,708	4,819,940	4,658,555	4,367,233
Loss from Operations	(4,417,708)	(4,819,940)	(4,658,555)	(4,367,233)
Other Income, net	145,997	1,585,780	632,025	1,515,078
Net Loss per share	$ (4,271,711)	$ (3,234,160)	$ (4,026,530)	$ (2,852,155)
Net Loss per share, basic and diluted	$ (0.02)	$ (0.02)	$ (0.02)	$ (0.02)

18. Subsequent Events

Since December 31, 2016, the Company granted 3,905,600 stock options and restricted stock units to officers, employees and consultants.

EXHIBIT INDEX

3.1	Amended and Restated Certificate of Incorporation, filed as Appendix G to the Company's Definitive Proxy Statement on Schedule 14A (File No. 000-50590) dated April 29, 2005, is incorporated herein by reference.
3.2	Amended and Restated Bylaws, as amended, through March 21, 2014, filed as exhibit 3.2 to the Company's Annual Report on Form 10-K on March 21, 2014, is incorporated herein by reference.
4.1	Specimen Certificate for the Company's Common Stock, par value $.0001 per share, filed as Exhibit 4.3 to the Company's Registration Statement on Form S-8 (File No. 333-129294) dated October 28, 2005, is incorporated herein by reference.
4.2	Form of Warrant for the Company's Common Stock Purchase Warrants, filed as Exhibit 4.1 to the Company's Current Report on Form 8-K filed on November 30, 2012, is incorporated herein by reference.
4.3	Form of Warrant for the Company's Common Stock Purchase Warrants, filed as Exhibit 4.1 to the Company's Current Report on Form 8-K filed on July 24, 2013, is incorporated herein by reference.
4.4	Form of Warrant for the Company's Common Stock Purchase Warrants, filed as Exhibit 4.1 to the Company's Current Report on Form 8-K filed on October 16, 2013, is incorporated herein by reference.
4.5	Form of Warrant for the Company's Common Stock Purchase Warrants, filed as Exhibit 4.1 to the Company's Current Report on Form 8-K filed on January 15, 2014, is incorporated herein by reference.
4.6	Form of Warrant for the Company's Common Stock Purchase Warrants, filed as Exhibit 4.1 to the Company's Current Report on Form 8-K filed on November 6, 2015, is incorporated herein by reference.
4.7	Form of Warrant for the Company's Common Stock Purchase Warrants, filed as Exhibit 4.1 to the Company's Current Report on Form 8-K filed on February 26, 2016, is incorporated herein by reference.
4.8	Form of Warrant for the Company's Common Stock Purchase Warrants, filed as Exhibit 4.1 to the Company's Current Report on Form 8-K filed on September 14, 2016, is incorporated herein by reference.
*10.1	Rexahn Pharmaceuticals, Inc. Stock Option Plan, as amended, filed as Exhibit 4.4 to the Company's Registration Statement on Form S-8 (File No. 333-129294) dated October 28, 2005, is incorporated herein by reference.
*10.2	Form of Stock Option Grant Agreement for Employees, filed as Exhibit 4.5.1 to the Company's Registration Statement on Form S-8 (File No. 333-129294) dated October 28, 2005, is incorporated herein by reference.
*10.3	Form of Stock Option Grant Agreement for Non-Employee Directors and Consultants, filed as Exhibit 4.5.2 to the Company's Registration Statement on Form S-8 (File No. 333-129294) dated October 28, 2005, is incorporated herein by reference.
*10.4	Rexahn Pharmaceuticals, Inc. 2013 Stock Option Plan, filed as Exhibit 10.1 to the Company's Registration Statement on Form S-8 (File No. 333-189240) dated June 11, 2013, is incorporated herein by reference.
*10.5	Form of Stock Option Grant Agreement under Rexahn Pharmaceuticals, Inc. 2013 Stock Option Plan filed as Exhibit 10.5 to the Company's Annual Report on Form 10-K for the year ended December 31, 2015, filed on March 14, 2016, is incorporated herein by reference.

*10.6	Employment Agreement, dated as of September 9, 2010, by and between Rexahn Pharmaceuticals, Inc. and T. H. Jeong, filed as Exhibit 10.3 to the Company's Current Report on Form 8-K filed on September 10, 2010, is incorporated herein by reference.
*10.7	Employment Agreement, dated as of February 4, 2013, by and between Rexahn Pharmaceuticals, Inc. and Peter Suzdak, filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 22, 2013, is incorporated herein by reference.
*10.8	Employment Agreement, dated as of March 25, 2013, by and between Rexahn Pharmaceuticals, Inc. and Chang H. Ahn, filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on March 29, 2013, is incorporated herein by reference.
*10.9	Employment Agreement, dated as of February 2, 2015, by and between Rexahn Pharmaceuticals, Inc. and Ely Benaim, M.D., filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on May 8, 2015, is incorporated herein by reference.
*10.10	Bonus Letter Agreement, dated as of August 2, 2016, by and between Rexahn Pharmaceuticals, Inc. and Ely Benaim, M.D., filed as Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2016, is incorporated herein by reference.
*10.11	Employment Agreement, dated as of July 6, 2016, by and between Rexahn Pharmaceuticals, Inc. and Lisa Nolan, Ph.D., filed as Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2016, is incorporated herein by reference.
10.12	Lease Agreement, dated June 5, 2009, by and between Rexahn Pharmaceuticals, Inc. and The Realty Associates Fund V, L.P., filed as Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2009, is incorporated herein by reference.
10.13	First Amendment to Lease Agreement, dated as of June 7, 2013, by and between Rexahn Pharmaceuticals, Inc. and SG Plaza Holdings, LLC, filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2013, is incorporated herein by reference.
10.14	Second Amendment to Lease Agreement, dated as of July 26, 2014, by and between Rexahn Pharmaceuticals, Inc. and SG Plaza Holdings, LLC, filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2014, is incorporated herein by reference.
10.15	Third Amendment to Lease Agreement, dated as of May 6, 2015, by and between Rexahn Pharmaceuticals, Inc. and SG Plaza Holdings, LLC, filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2015, is incorporated herein by reference.
10.16	Fourth Amendment to Lease Agreement, dated as of April 4, 2016, by and between Rexahn Pharmaceuticals, Inc. and SG Plaza Holdings, LLC, filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2016, is incorporated herein by reference.
10.17	Research Collaboration Agreement on RX-0201 Clinical Development, dated as of February 6, 2003, filed as Exhibit 10.5 to the Company's Annual Report on Form 10-K for the year ended December 31, 2005, is incorporated herein by reference.
10.18	Form of Securities Purchase Agreement, dated as of July 23, 2013, by and between Rexahn Pharmaceuticals, Inc. and the purchasers identified on the signature pages thereto, filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 24, 2013, is incorporated herein by reference.

10.19	Form of Securities Purchase Agreement, dated as of October 10, 2013, by and between Rexahn Pharmaceuticals, Inc. and the purchasers identified on the signature pages thereto, filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on October 16, 2014, is incorporated herein by reference.
10.20	Form of Securities Purchase Agreement, dated as of January 15, 2014, by and between Rexahn Pharmaceuticals, Inc. and the purchasers identified on the signature pages thereto, filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 21, 2014, is incorporated herein by reference.
10.21	Form of Securities Purchase Agreement, dated as of November 6, 2015, by and between Rexahn Pharmaceuticals, Inc. and the purchasers identified on the signature pages thereto, filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 6, 2015, is incorporated herein by reference.
10.22	Form of Securities Purchase Agreement, dated as of February 26, 2016, by and between Rexahn Pharmaceuticals, Inc. and the purchasers identified on the signature pages thereto, filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on February 26, 2016, is incorporated herein by reference.
10.23	Form of Securities Purchase Agreement, dated as of September 14, 2016, by and between Rexahn Pharmaceuticals, Inc. and the purchasers identified on the signature pages thereto, filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on September 14, 2016, is incorporated herein by reference.
10.24	At Market Issuance Sales Agreement, dated as of March 16, 2015, by and between Rexahn Pharmaceuticals, Inc. and MLV & Co. LLC, filed as Exhibit 10.18 to the Company's Annual Report on Form 10-K for the year ended December 31, 2014, is incorporated herein by reference.
12.1	Statement Regarding the Computation of Ratio of Earnings to Combined Fixed Charges and Preferred Stock Dividends
23.1	Consent of Baker Tilly Virchow Krause, LLP, independent registered public accounting firm
24.1	Power of Attorney
31.1	Certification of Chief Executive Officer Pursuant to Rule 13a-14(a) or Rule 15d-14(a)
31.2	Certification of Chief Financial Officer Pursuant to Rule 13a-14(a) or Rule 15d-14(a)
32.1	Certification of Chief Executive Officer of Periodic Report Pursuant to 18 U.S.C. Section 1350
32.2	Certification of Chief Financial Officer of Periodic Report Pursuant to 18 U.S.C. Section 1350
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Calculation Linkbase
101.DEF	XBRL Taxonomy Definition Linkbase
101.LAB	XBRL Taxonomy Label Linkbase
101.PRE	XBRL Taxonomy Presentation Linkbase

*Indicates management contract or compensatory plan or arrangement

CORPORATE INFORMATION

BOARD OF DIRECTORS

Peter Brandt, Chairman
Former President and Chief Executive Officer,
Noven Pharmaceuticals

Chang H. Ahn, Ph.D. Chairman Emeritus
Chief Scientist,
Rexahn Pharmaceuticals

Charles Beever, Director
Former Vice President,
PwC Strategy&

Mark Carthy, Director
Managing Partner,
Orion Equity Partners

Kwang Soo Cheong, Ph.D. Director
Associate Professor,
Johns Hopkins University

Richard J. Rodgers, Director
Former Executive Vice President and Chief Financial Officer, TESARO

Peter D. Suzdak, Ph.D. Director
Chief Executive Officer,
Rexahn Pharmaceuticals, Inc.

EXECUTIVE OFFICERS

Peter D. Suzdak, Ph.D.
Chief Executive Officer

Tae Heum (Ted) Jeong, D. Mgt.
Sr. Vice President, Chief Financial Officer and Secretary

Ely Benaim, M.D.
Chief Medical Officer

Lisa Nolan, Ph.D.
Chief Business Officer

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SECURITIES INFORMATION

TRADING MARKET: NYSE MKT
SYMBOL: RNN

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Stockholders may obtain a copy of any exhibit to our Form 10-K free of charge by writing to the company at our corporate headquarters address above.

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