



2015

ANNUAL REPORT

REVOLUTIONIZING  
THE TREATMENT  
OF CANCER

**rexahn**  
PHARMACEUTICALS

# CEO Letter to Stockholders

Dear Rexahn Stockholders,

Our mission at Rexahn is to improve the lives of cancer patients by discovering and developing novel, highly targeted, next generation cancer therapies that are designed to maximize anti-cancer activity while minimizing the side effects and toxicity traditionally experienced with cancer treatment.

I am pleased to report that we made solid progress towards this objective in 2015 and are well positioned to continue our momentum in 2016.

Last year we made important strides advancing each of our clinical-stage oncology programs - RX-3117, Supinoxin™ and Archexin® and generated what we believe are promising interim clinical data which were presented at prominent medical meetings. Though preliminary, we are encouraged by the accumulating clinical data which show evidence of a potential clinical benefit of each of these novel investigational anti-cancer compounds. We were gratified and excited by the early clinical results, which suggest the potential to delay disease progression (evidenced as stable disease), and, in some cases, produce tumor shrinkage. These results fortify our confidence in the merits of our approach and strengthen our commitment to developing Rexahn's novel portfolio of potentially first-in-class or best-in-class cancer therapeutics.

In 2016 we will continue to advance each of our clinical oncology programs and plan to more comprehensively evaluate RX-3117 and Supinoxin in Phase Ib/IIa proof-of-concept clinical studies. Based on the existing high unmet medical need and promising clinical and preclinical data accumulated thus far, we plan to initially evaluate RX-3117 in patients with relapsed and refractory pancreatic cancer and advanced bladder cancer. In the case of Supinoxin, we are targeting patients with triple negative breast cancer (TNBC) and platinum resistant ovarian cancer.

Our Archexin program achieved an important milestone in 2015 following the conclusion of Stage 1 of our ongoing Phase Ib/IIa clinical trial. Not only did we achieve our intended goal - to determine a maximum tolerated dose of Archexin for further clinical evaluation, but we saw promising evidence of both a dose-dependent and duration-of-treatment-dependent reduction in the size of certain patients' kidney cancer tumors. We were very pleased to observe potential early evidence of the clinical activity of Archexin and, earlier this year, we commenced the randomized portion (Stage 2) of the Phase Ib/IIa clinical trial, which will evaluate Archexin, in combination with everolimus (a widely used cancer drug) in patients with metastatic renal cell carcinoma.

I am very encouraged by our progress, and the interim data we are generating, and look forward to continuing to advance our three clinical-stage oncology programs in 2016 in the hopes of improving the quality of life and longevity of patients living with cancer.

Moving on, our research engine continued to be very productive in 2015. Our scientists and academic and clinical collaborators generated intriguing new preclinical data supporting the anti-cancer effects of our programs. Through this research we confirmed the broad applicability of RX-3117 against a range of human solid tumors in preclinical models. We were also very excited to observe the ability of RX-3117 to achieve significant tumor inhibition in gemcitabine-resistant cancers in preclinical models. This could suggest a potential role for RX-3117 in

treating the approximately 25% to 40% of cancer patients that develop resistance to standard-of-care therapy with gemcitabine. We also presented new data for Supinoxin elucidating a unique mechanism of action that is highly cancer-specific. Further, we showed that Supinoxin dose-dependently decreased the migration of TNBC cells, potentially suggesting the utility of Supinoxin in the treatment and prevention of TNBC metastases. Additionally, new data were presented showing Supinoxin's potent tumor inhibition effects in a xenograft mouse model of TNBC, further supporting our choice of TNBC as one of the initial clinical indications for the Supinoxin program.

Finally, we were honored to have been selected by the National Cancer Institute's Nanotechnology Characterization Laboratory for funding of the further preclinical development of Rexahn's RX-21101 nanotechnology anti-cancer program.

We are fortunate to have a rich diversity of oncology assets at Rexahn and the determination to progress these programs through preclinical and clinical development with the ultimate goal of improving the lives of cancer patients. We recognize that our people are the backbone of our success and took steps to further augment our leadership structure in 2015. Notably, Dr. Ely Benaim was appointed to the newly-created position of Chief Medical Officer. In addition, Peter Brandt was appointed as our new Chairman of the Board.

On behalf of our Board of Directors and the employees at Rexahn, I wish to thank you for your continued interest and support of our Company. We look forward to continuing our progress in 2016. We thank you for joining us on this important journey as we endeavor to improve the lives of patients with cancer.

Sincerely,

A handwritten signature in black ink, appearing to read "Peter D. Suzdak". The signature is fluid and cursive, with a large initial "P" and "S".

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

## **Rexahn Pharmaceuticals - Oncology Pipeline Overview**

With a strong foundation in cancer research and discovery, Rexahn has built a diverse portfolio of novel oncology assets that includes three clinical-stage investigational anti-cancer compounds currently in human clinical trials, and a robust oncology research platform. Our mission is to develop highly targeted cancer therapies with the potential for enhanced efficacy and safety – an approach which we believe could improve the lives of cancer patients.

### ***Clinical-Stage Oncology Programs:***

**RX-3117** – An orally bioavailable, cancer cell specific nucleoside agent that has shown efficacy against a broad range of human tumor cell types, including gemcitabine resistant tumors.

**Supinoxin™** - A potent, first-in-class, orally bioavailable, small molecule that inhibits the growth of cancer cells by targeting phosphorylated-p68 (P-p68), which is highly overexpressed in cancer cells.

**Archexin®** - A unique anti-sense oncology drug candidate that specifically inhibits the cancer cell signaling protein Akt-1, which is highly overexpressed in cancer cells.

### **RX-3117 – A Novel Next Generation Nucleoside Compound**

RX-3117 is an orally bioavailable, small molecule, investigational anti-cancer therapy that targets a unique biological pathway implicated in the development and metastasis of numerous cancers.

A novel, cancer-cell specific nucleoside analogue, RX-3117 is a prodrug activated by the enzyme Uridine Cytidine Kinase, or ‘UCK2’, which is only present 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 normal 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, 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, a widely-used chemotherapy. Unfortunately, resistance to gemcitabine occurs in up to approximately 25% to 40% of cancer patients over time, reducing overall treatment efficacy and further limiting options for 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.

An exploratory Phase I clinical trial of RX-3117 showed that oral administration of a 50 mg dose of RX-3117 achieved 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.

Interim results from a separate Phase Ib clinical trial of RX-3117 in patients with advanced and metastatic solid tumors were presented in September 2015 at the European Cancer Congress. The results showed that, at the dose levels tested to date, RX-3117 appeared to show evidence of tumor reduction (9%), which was observed in one patient, and stable disease, which was observed in five patients persisting from between 112 and 276 days before disease progression occurred. In addition, RX-3117 appeared to be safe and well tolerated with a predictable pharmacokinetic profile. The most frequently reported treatment emergent adverse events in the Phase Ib trial were mild to moderate fatigue, gastrointestinal disturbances, anemia, pyrexia, decreased appetite and dehydration.

RX-3117 is currently being evaluated in a Phase Ib/IIa multi-center, open-label clinical study in patients with relapsed or refractory pancreatic cancer and advanced bladder cancer. The study has a two-stage design. In the initial stage, 10 patients with relapsed or refractory pancreatic cancer and 10 patients with advanced bladder cancer will be enrolled. If responses are observed within the first 10 response-evaluable subjects, 40 additional subjects could be enrolled. RX-3117 has received Orphan Drug designation for the treatment of pancreatic cancer – one of the reasons we have selected this indication for initial clinical study.

In the Phase Ib/IIa study, RX-3117 is being administered orally five times weekly on a three weeks on, one week off dosing schedule. The primary endpoint of the Phase Ib/IIa 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 parameters.

### **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 selectively overexpressed in cancer cells and absent in normal tissue. P-p68 is believed to increase the activity of multiple cancer related genes including, cyclin D1, c-jun and c-myc, and play a prominent role in tumor progression and metastasis. Over-expression of P-p68 has been observed in many solid tumors, including, melanoma, colon, ovarian and lung tumors.

In preclinical studies, Supinixin 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 Supinixin resulted in a significant reduction in tumor growth.

Supinixin is currently being evaluated in a Phase I multi-center, dose-finding, open-label, single agent clinical study in patients with advanced or metastatic solid tumors.

Interim results from the Phase I clinical trial were presented at the European Cancer Congress in September 2015. The results showed that, at the dose levels tested to date, clinical evidence of single-agent activity of Supinixin was observed in approximately 29% of patients (4/14 patients) who showed stable disease persisting from between 255 and 497 days (as of September 14, 2015.)

In addition, Supinixin, administered orally, appeared to be safe and well tolerated with no Grade 3 or Grade 4 adverse events and only one unrelated Grade 2 adverse event. The most frequently reported drug related adverse events were mild nausea, vomiting and fatigue. Pharmacokinetic analyses of the current data show both a predictable and desirable pharmacokinetic profile for an orally-administered route of therapy.

The Phase I study of Supinixin is currently ongoing and Rexahn anticipates commencing a Phase Ib/IIa Proof-of-Concept clinical trial in the first half of 2016 in patients with triple negative breast cancer and platinum resistant ovarian cancer to more comprehensively evaluate Supinixin's clinical activity.

### **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.

We believe the overall safety profile of Archexin may be superior to existing cytotoxic compounds and chemotherapeutic drugs that affect growth in both cancerous and non-cancerous cells. 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.

In a small Phase IIa trial, Archexin appeared to be safe and well tolerated and showed preliminary signs of efficacy in advanced pancreatic cancer patients when used in combination with gemcitabine. Median survival for patients dosed with Archexin plus

gemcitabine was 9.1 months as compared to historical survival data of 5.7 months for gemcitabine alone.

Following consultation with key opinion leaders in oncology, Rexahn initiated a Phase Ib/IIa clinical trial of Archexin in patients with metastatic renal cell carcinoma. The strong scientific evidence, high unmet clinical need, and achievement of Orphan Drug Designation for renal cell carcinoma provided a firm rationale for this approach.

In addition, resistance to the anti-cancer effects of mTOR inhibitors such as everolimus (Afinitor®), a widely used chemotherapy drug which is used as second line therapy in renal cell carcinoma patients, has been attributed to an increase in Ak-1 activity. Thus, we believe that treatment with Archexin could provide a synergistic treatment effect – inhibiting the growth of renal cell carcinoma and overcoming the resistance to mTOR inhibitors, resulting in enhanced efficacy.

Rexahn is currently conducting a Phase Ib/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. 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. The first stage of the study was completed in 2015 and a maximum tolerated dose of Archexin was identified.

Notably, the results from Stage 1 of the Phase Ib/IIa trial showed early evidence of the potential clinical activity of Archexin in combination with everolimus. Among the patients enrolled in the study, four patients had stable disease which persisted for 383 days, 191 days, 176 days and 106 days, respectively. In addition, compared to baseline CT scans, three of these patients experienced reductions in the size of their tumors which ranged from 16% to 36%. At the lowest dose level of Archexin administered (125 mg/m<sup>2</sup>/day) one patient had a 16% tumor reduction after 4 cycles of treatment. At the second dose level (200 mg/m<sup>2</sup>/day) one patient experienced a 36% tumor reduction after 2 cycles of treatment. At the highest dose level (250 mg/m<sup>2</sup>/day), which has been determined to be the maximum tolerated dose, one patient had a 32% reduction in their tumor size following 6 cycles of treatment.

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 dose expansion 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<sup>2</sup>/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.

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. Rexahn has received U.S. Food and Drug Administration (FDA) Orphan Drug Designation for Archexin for metastatic RCC as well as four other cancers.

## ***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 deliver 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. Potential indications for RX-21101 include breast, ovarian, prostate and lung cancer. In 2015, the National Cancer Institute's (NCI) Nanotechnology Characterization Laboratory selected RX-21101 for funding of the further preclinical development of this program, under NCI's preclinical characterization program.



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**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, 2015**

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**

*(State or other jurisdiction of incorporation or organization)*

**11-3516358**

*(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)*

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 | <input type="checkbox"/> | Accelerated Filer         | <input checked="" type="checkbox"/> |
| Non-Accelerated Filer   | <input type="checkbox"/> | Smaller reporting company | <input type="checkbox"/>            |

(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, 2015, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was \$105,800,912 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 March 11, 2016 |
|--|----------------------------------|
| Common Stock, \$0.0001 par value per share | 213,113,785 shares               |

#### **DOCUMENTS INCORPORATED BY REFERENCE**

Certain portions of the registrant's Definitive Proxy Statement for its 2016 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, 2015, 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 which 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 one oncology product candidate in Phase II clinical development, two oncology product candidates in Phase I 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 alone or with partners. Our three clinical stage drug candidates in active development are Archexin®, RX-3117 and Supinoxin™ (RX-5902).

- *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 U.S. Food and Drug Administration (the “FDA”) for renal cell carcinoma (“RCC”), glioblastoma, ovarian cancer, stomach cancer and 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 receives seven years of exclusivity after approval, during which the FDA generally cannot approve another product with the same active moiety for the same indication. 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 to evaluate its safety and efficacy.
- *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 with no adverse effects reported. We are currently conducting a Phase Ib clinical trial to study the safety and efficacy of RX-3117 in patients with solid tumors. RX-3117 has received orphan drug designation from the FDA for pancreatic cancer.
- *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. We are currently conducting a Phase I clinical trial of Supinoxin to evaluate its safety and efficacy in patients with solid tumors.

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 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 2014, the World Economic Forum and the Harvard School of Public Health estimated that the 13.3 million new cases of cancer diagnosed worldwide in 2010 cost \$290 billion, projected 21.5 million new cancer cases occurring in 2030 at a cost of \$458 billion; and a 2016 American Cancer Society report projected that an estimated 1.7 million new cancer cases will be diagnosed in the United States in 2016. 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.

## ***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 are favorable for commercializing new cancer drugs that may 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 can 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.
- *Focus on Specialty Markets.* The marketing of new drugs to specialty physicians can be accomplished with a specialty sales force that requires fewer personnel and lower related costs than a typical 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, signal transduction and multi-kinase inhibitors, 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. Incentives 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 can speed the approval process.

### ***Target Signal Transduction Molecules with Multiple Drug Candidates***

We plan to expand our research and development pipeline to introduce new signal inhibitor drugs into clinical trials in the future. By identifying and characterizing the genes and proteins that control the signaling pathways and gene expression of cancer cells, we seek to develop DNA/RNA-based and small-molecule drugs to treat a broad range of diseases caused by abnormal expression or functions of those genes and proteins.

### ***Establish Partnerships with Large Pharmaceutical Companies***

We seek to establish strategic alliances and partnerships with large pharmaceutical companies for the 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***

*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 have completed an open label, two-stage 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. Gemcitabine is a member of a group of chemotherapy drugs known as anti-metabolites, which prevent cells from making DNA and RNA, which in turn stops cell growth and causes cells to die. Stage 1 was the dose-finding portion of the study, and Stage 2 was the dose-expansion portion of the study using the dose identified in Stage 1 administered together with gemcitabine. The study enrolled 31 subjects aged 18 to 65 with metastatic pancreatic cancer at nine centers in the United States and India. The primary endpoint was overall survival following four cycles of therapy with a six month follow-up. For those evaluable patients, the study showed that treatment with Archexin in combination with gemcitabine provided a median survival rate of 9.1 months compared to the historical survival data of 5.7 months for standard single agent gemcitabine therapy. The most frequently reported adverse events were constipation, nausea, abdominal pain and pyrexia, regardless of relatedness.

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<sup>2</sup>/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.

We have been issued a U.S. patent for Archexin that covers composition of matter and broad claims for the nucleotide sequences of the antisense compounds that target and inhibit the expression of

Akt-1 in human tissues or cells, and for the method of using the compounds to induce cytotoxicity in cancer cells.

*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 (“UCK2”), 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, Rexahn 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.

We are currently evaluating RX-3117 in a Phase Ib clinical trial to study the safety, tolerability, dose-limiting toxicities and MTD in patients with solid tumors. Secondary endpoints include pharmacokinetic analysis and an evaluation of the preliminary anti-tumor effects of RX-3117.

Preliminary results from the Phase Ib clinical trial of RX-3117 were presented in September 2015 at the 2015 European Cancer Congress. The results showed that, at the dose levels tested to date, RX-3117 administered orally appeared to be safe and well tolerated with a predictable pharmacokinetic profile. The most frequently reported treatment emergent adverse events were mild to moderate fatigue, gastrointestinal disturbances, anemia, pyrexia, decreased appetite and dehydration.

In addition, preliminary anti-tumor activity was seen in the Phase Ib clinical trial, with evidence of tumor reduction observed in one patient and stable disease observed in five patients persisting from between 112 and 276 days before disease progression occurred.

Patient enrollment has been completed in nine dose groups (30mg, 60mg, 100mg, 150mg, 200mg, 500mg, 1,000mg, 1,500mg and 2,000 mg). Based on the favorable safety and pharmacokinetic profile seen at the highest dose levels, we initiated a dosing schedule modification to increase patients’ daily exposure of RX-3117 in the ongoing Phase Ib clinical trial. All newly enrolled patients are now receiving RX-3117 five times weekly. We anticipate that the new dosing paradigm will increase drug exposure, maximizing potential therapeutic activity and enable more rapid determination of the MTD for further clinical study.

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 is currently being 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 MTD. Secondary endpoints include pharmacokinetic analyses and an evaluation of the preliminary anti-tumor effects of Supinoxin. Patients have received doses up to 25, 50, 100, 150, 225, 300, 425, 575, and 775 mg. Based on the favorable safety and pharmacokinetic profile seen at the highest dose levels (575 mg and 775 mg), we have initiated a dosing schedule modification to increase patients' daily exposure of Supinoxin. All newly enrolled patients are now receiving Supinoxin seven times weekly as opposed to once weekly. We anticipate that the new dosing paradigm will increase drug exposure and enable more rapid determination of the MTD for further clinical study.

Preliminary results from the Phase I clinical trial of Supinoxin were presented in September 2015 at the 2015 European Cancer Congress.

The results showed that, at the dose levels tested to date, Supinoxin administered orally appeared to be safe and well tolerated with no Grade 3 or Grade 4 adverse events and several unrelated Grade 2 adverse events. The most frequently reported drug related adverse events were mild nausea, vomiting and fatigue. Pharmacokinetic analyses of the current data demonstrate both a predictable and desirable pharmacokinetic profile for an orally-administered route of therapy.

Clinical evidence of single-agent activity of Supinoxin was also observed in four patients who showed stable disease persisting from between 255 and 497 days as of September 14, 2015. At that time, three of the four patients exhibiting stable disease remained on active treatment. Those patients continue to be followed in the 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.

### ***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 the National Cancer Institute'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, such as MK-2206 and GSK-2141795, which are under development by Merck & Company, Inc. and GlaxoSmithKline, respectively. Archexin will also compete with carbozantinib, a multi-kinase inhibitor under development by Exelixis for RCC. 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. 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. Those rules and regulations are subject to change, however, and in any event, a 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.

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 ("GLP") 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") at the institution at which the trial is being conducted. The sponsor of a clinical trial, the investigators and IRBs each must comply with requirements and restrictions that govern 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 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 (i.e., 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 products 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, 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, 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 already approved product to act before approval of the follow-on product 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 the 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 in recent years. Some of the pertinent laws have not been definitively interpreted by the regulatory authorities or the courts, and their provisions 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, together 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. 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 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 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 become effective on April 1, 2016. It appears likely that the Affordable Care Act will continue the pressure on pharmaceutical pricing, especially under the Medicare and Medicaid programs, and may also increase our regulatory burdens and operating costs.

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 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.

### ***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 2020 to 2030. We hold U.S. patents for Archexin, RX-3117 and Supinoxin. We also hold multiple foreign patents for Archexin, RX-3117, and Supinoxin.

In 2015, we were granted a U.S. patent from the United States Patent and Trademark Office for claims related to the synthesis of our novel anti-cancer investigational drug candidate, RX-3117. Additional U.S. and foreign patent applications related to Archexin, RX-3117, Supinoxin, and RX-21101 are pending.

### **Collaboration and License Arrangements**

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

#### *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.

### *Korea Research Institute of Chemical Technology (“KRICT”)*

In June 2009, we entered into a license agreement with KRICT to acquire all 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 \$1,000,000 to KRICT upon marketing approval from the FDA for the first commercial product stemming from the agreement.

### *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, Rexgene has exclusive rights to license, sublicense, 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 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, or, if no licensed patent is issued, within 20 years from the date of execution of the agreement. A breach of the agreement by either party give the non-breaching party the right to terminate the agreement upon 90 days written notice of termination specifying the obligations breached, provided that within said 90 days the breaching party does not remedy the breach.

## **Total Research and Development Costs**

We have incurred research and development costs of \$12,148,226, \$7,015,901 and \$3,253,139 for the years ended December 31, 2015, 2014 and 2013 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](http://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](http://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, 2015 and 2014 was \$105,716,864 and \$91,332,308, respectively. For the years ended December 31, 2015, 2014, and 2013, we had net losses of \$14,384,556, \$18,521,601 and \$9,499,424, 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.

***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 Ib clinical trial in January 2014, and Supinoxin entered a Phase I clinical trial in August 2013.

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 or 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 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.

In the past, payors have implemented reimbursement metrics and periodically revised those metrics as well as the methodologies used 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 become effective on April 1, 2016. It appears likely that the Affordable Care Act will continue the pressure on pharmaceutical pricing, especially under the Medicare and Medicaid programs, and may also increase our regulatory burdens and operating costs.

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 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 \$100,000 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 \$10,000 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 \$10,000 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.

***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, 2015, 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, 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. 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.

#### **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.

***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 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 attorneys 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. We 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, 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. 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.

***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, 2015 and 2014 was \$105,716,864 and \$91,332,308, respectively. For the years ended December 31, 2015, 2014, and 2013, we had net losses of \$14,384,556, \$18,521,601 and \$9,499,424, 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 March 11, 2016, there were approximately 66 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.

| <u>Period</u>  | <u>High</u> | <u>Low</u> |
|----------------|-------------|------------|
| 2014           |             |            |
| First Quarter  | 1.85        | 0.50       |
| Second Quarter | 1.29        | 0.78       |
| Third Quarter  | 0.89        | 0.65       |
| Fourth Quarter | 0.82        | 0.65       |
| 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       |

#### *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 2015.

#### *Recent Sales of Unregistered Equity Securities*

As previously disclosed, pursuant to an engagement letter agreement, dated November 5, 2015, with H.C. Wainwright & Co., LLC, on November 12, 2015, we issued warrants to purchase 833,333 shares of our common stock (the “Placement Agent Warrants”) to designees of Rodman & Renshaw (“Rodman”), a unit of H.C. Wainwright & Co., LLC, as partial consideration for Rodman’s services as placement agent in connection with a registered direct offering of our common stock and warrants. The common stock issuable upon exercise of the warrants is expected to be issued and the Placement Agent Warrants were offered and sold by us in reliance on the exemption from registration provided by Section 4(a)(2) of the Securities Act as transactions not involving any public offering. The Placement Agent Warrants have an exercise price of \$0.53 per share and are exercisable at any time from May 13, 2016 to November 6, 2020.

**Performance Graph**

The following graph compares the cumulative total stockholder return on \$100 of our common stock for the period beginning December 31, 2010 through December 31, 2015, 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.

| <b>Statement of Operations Data:</b> | For the Year Ended December 31, |                 |                |                |                 |
|--------------------------------------|---------------------------------|-----------------|----------------|----------------|-----------------|
|                                      | 2015                            | 2014            | 2013           | 2012           | 2011            |
| Revenues                             | \$ -                            | \$ -            | \$ -           | \$ -           | \$ -            |
| Expenses:                            |                                 |                 |                |                |                 |
| General and administrative           | 6,115,210                       | 6,253,328       | 4,725,699      | 3,186,634      | 4,138,926       |
| Research and development             | 12,148,226                      | 7,015,901       | 3,253,139      | 3,392,896      | 11,992,087      |
| Total expenses                       | 18,263,436                      | 13,269,229      | 7,978,838      | 6,579,530      | 16,131,013      |
| Loss from operations                 | (18,263,436)                    | (13,269,229)    | (7,978,838)    | (6,579,530)    | (16,131,013)    |
| Other Income (Expense), net          | 3,878,880                       | (5,252,372)     | (1,520,586)    | 352,860        | 4,786,063       |
| Net Loss                             | \$ (14,384,556)                 | \$ (18,521,601) | \$ (9,499,424) | \$ (6,226,670) | \$ (11,344,950) |
| Net Loss per share, basic and        | \$ (0.08)                       | \$ (0.11)       | \$ (0.07)      | \$ (0.06)      | \$ (0.12)       |
| Weighted average shares              |                                 |                 |                |                |                 |
| outstanding, basic and diluted       | 182,388,226                     | 176,106,981     | 128,649,303    | 97,138,233     | 93,048,490      |

| <b>Balance Sheet Data:</b>                        | As of December 31, |                 |                 |                 |                 |
|---|--------------------|-----------------|-----------------|-----------------|-----------------|
|   | 2015               | 2014            | 2013            | 2012            | 2011            |
| Cash, Cash Equivalents, and Marketable Securities | \$ 23,439,526      | \$ 32,698,296   | \$ 18,788,031   | \$ 13,586,543   | \$ 11,811,488   |
| Working Capital                                   | \$ 22,000,046      | \$ 30,970,020   | \$ 18,361,438   | \$ 12,923,514   | \$ 10,977,936   |
| Total Assets                                      | \$ 24,805,029      | \$ 33,533,060   | \$ 19,556,498   | \$ 14,919,308   | \$ 13,689,648   |
| Warrant Liabilities                               | \$ 2,739,163       | \$ 3,768,351    | \$ 5,034,058    | \$ 2,842,065    | \$ 868,725      |
| Accumulated Deficit                               | \$ (105,716,864)   | \$ (91,332,308) | \$ (72,810,707) | \$ (63,311,283) | \$ (57,084,613) |
| Total Stockholders' Equity                        | \$ 18,775,548      | \$ 26,580,491   | \$ 12,625,488   | \$ 9,533,989    | \$ 10,706,130   |
| Common shares outstanding                         | 197,413,785        | 178,253,318     | 146,717,795     | 119,428,989     | 95,345,656      |



## **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 one product candidate in Phase II clinical development, two product candidates in Phase I 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 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.

### **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.

### **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, 2015, our uninsured cash balance was \$9,554,878. 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, 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 \$138,118, or 2.2%, to \$6,115,210 for the year ended December 31, 2015 from \$6,253,328 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 \$5,132,325, or 73.2%, to \$12,148,226 for the year ended December 31, 2015, from \$7,015,901 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 Archexin, RX-3117 and Supinoxin. 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                |
| <b>Clinical Candidates:</b>                    |                                 |                     |
| Archexin                                       | \$ 1,547,000                    | \$ 1,215,000        |
| RX-3117  | 4,062,000                       | 1,897,000           |
| Supinoxin                                      | 2,839,000                       | 1,351,000           |
| Pre-clinical, Personnel and Overhead           | 3,700,226                       | 2,552,901           |
| <b>Total Research and Development Expenses</b> | <b>\$ 12,148,226</b>            | <b>\$ 7,015,901</b> |

#### ***Interest Income***

Interest income decreased \$30,638 or 22.9% to \$103,269 for the year ended December 31, 2015 from \$133,907 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 \$3,986,727 and \$(5,180,107) 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 \$211,116 and \$206,172 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 \$14,384,556 and \$18,521,601 or \$0.08 and \$0.11 per share, respectively.

## ***Comparison of the Years Ended December 31, 2014 and December 31, 2013***

### ***Total Revenues***

We had no revenues for the years ended December 31, 2014 or 2013.

### ***General and Administrative Expenses***

General and administrative expenses increased \$1,527,629, or 32.3%, to \$6,253,328 for the year ended December 31, 2014 from \$4,725,699 for the year ended December 31, 2013. The year over year increase is primarily attributable to an increase in professional fees and personnel expenses. Professional fees increased approximately \$1,015,000 during the year ended December 31, 2014 due to increased legal and accounting fees regarding corporate organizational matters, consulting, proxy solicitation fees, and investor relations fees and compensatory stock. For the year ended December 31, 2014, general and administrative expenses also increased approximately \$175,000 due to an increase in personnel, and \$150,000 due to an increase in insurance coverage.

### ***Research and Development Expenses***

Research and development expenses increased \$3,762,762, or 115.7%, to \$7,015,901 for the year ended December 31 2014, from \$3,253,139 for the year ended December 31, 2013. The increase is primarily attributable to our drug candidates advancing further through clinical development. During the year ended December 31, 2014, one of our drug candidates, Archexin, entered a Phase IIa clinical trial to study its safety and efficacy in patients with metastatic renal cell carcinoma (“RCC”) and another drug candidate, RX-3117, entered a Phase Ib clinical trial to study its safety and efficacy in patients with solid tumors. Our Phase I trial for Supinoxin was initiated in August 2013 and continued through 2014. Research and development personnel and overhead increased due to the hiring of additional personnel.

The table below summarizes the approximate amounts spent on each of our research and development projects for the years ended December 31, 2014 and 2013:

|  | For the Year Ended December 31, |                     |
|--|---------------------------------|---------------------|
|  | 2014                            | 2013                |
| <b>Clinical Candidates:</b>                    |                                 |                     |
| Archexin                                       | \$ 1,215,000                    | \$ 144,300          |
| RX-3117  | 1,897,000                       | 402,000             |
| Supinoxin                                      | 1,351,000                       | 784,800             |
| Pre-clinical, Personnel and Overhead           | 2,552,901                       | 1,922,039           |
| <b>Total Research and Development Expenses</b> | <b>\$ 7,015,901</b>             | <b>\$ 3,253,139</b> |

### ***Interest Income***

Interest income increased \$84,627, or 171.7% to \$133,907 for the year ended December 31, 2014 from \$49,280 for the year ended December 31, 2013. The increase is primarily attributable to higher cash and cash equivalents and marketable securities balances due to our registered direct offering in January 2014 and the exercise of warrants in 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, 2014 and 2013, we recorded unrealized losses on the fair value of our warrants of \$5,180,107 and \$1,365,654, 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 large unrealized loss for the year ended December 31, 2014 primarily resulted from an increased stock price of the underlying common stock at December 31, 2014 and on the dates in 2014 when warrant holders exercised their warrants.

### ***Financing Expense***

We incurred \$206,172 and \$204,212 of financing expenses during the years ended December 31, 2014 and 2013, respectively, related to our registered direct offerings in January 2014, October, 2013 and July 2013.

### ***Net Loss***

As a result of the above, net loss for the years ended December 31, 2014 and 2013 was \$18,521,601 and \$9,499,424 or \$0.11 and \$0.07 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, Archexin, RX-3117 and Supinoxin, 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, Archexin, RX-3117 and Supinoxin, 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.

### ***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 increase slightly in 2016 compared to 2015 as we begin Stage 2 of the trial.

#### *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 Ib clinical trial to study the safety, tolerability, dose-limiting toxicities and MTD in patients with solid tumors, can be found in Item 1 of this Annual Report. We expect that expenses related to RX-3117 will increase slightly in 2016 compared to 2015 as we expect to reach the MTD/recommended Phase Ib/IIa dose in the first half of 2016 and will continue development with a two arm Phase Ib/IIa study.

#### *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 current Phase I dose-escalation clinical trial in cancer patients with solid tumors designed to evaluate the safety, tolerability, dose-limiting toxicities and MTD, can be found in Item 1 of this Annual Report. We expect that expenses related to Supinoxin will increase slightly in 2016 compared to 2015 as we expect to reach the MTD/recommended Phase Ib/IIa dose in the first half of 2016 and will continue development with a two arm Phase Ib/IIa study.

#### *Pre-clinical Pipeline*

We expect that expenses related to our pre-clinical pipeline, including RX-21101, will remain flat in 2016 compared to 2015 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, |                       |                     |
|--|---------------------------------|-----------------------|---------------------|
|  | 2015                            | 2014                  | 2013                |
| Net Cash Used in Operating Activities                | \$ (17,351,950)                 | \$ (11,041,211)       | \$ (7,984,856)      |
| Net Cash Provided by (Used In) Investing Activities  | 9,554,394                       | (22,661,045)          | 845,522             |
| Net Cash Provided by Financing Activities            | 8,170,751                       | 24,840,470            | 12,340,822          |
| Net Increase (Decrease) in Cash and Cash Equivalents | <u>\$ 373,195</u>               | <u>\$ (8,861,786)</u> | <u>\$ 5,201,488</u> |

Cash used in operating activities was \$17,351,950 for the year ended December 31, 2015. The operating cash flows during the year ended December 31, 2015 reflect our net loss of \$14,384,556, an unrealized gain on the fair value of warrants of \$3,986,727 and a net decrease of cash components of working capital and non-cash charges totaling \$1,019,333. Cash used in operating activities was \$11,041,211 for the year ended December 31, 2014. The operating cash flows during the year ended December 31, 2014 reflect our net loss of \$18,521,601, which includes an unrealized loss on fair value of warrants of \$5,180,107 and a net increase of cash components of working capital and other non-cash charges totaling \$2,300,283. Cash used in operating activities was \$7,984,856 for the year ended December 31, 2013, which reflects our net loss of \$9,499,424 and a net increase of cash components of working capital and non-cash charges totaling \$1,514,568. The significant increases in cash used in operating activities for the years ended December 31, 2015 and 2014 were primarily due to increases in research and development expenses as we continued to develop our product candidates.

Cash provided by investing activities was \$9,554,394 for the year ended December 31, 2015, which consisted of \$17,525,000 from the redemption of marketable securities, offset by \$7,908,304 and \$62,302 for the purchases of marketable securities and equipment, respectively. Cash used in investing activities was \$22,661,045 for the year ended December 31, 2014, which consisted of \$26,075,926 and \$41,249 for the purchases of marketable securities and equipment, respectively, offset by a decrease in restricted cash equivalents of \$196,130 and \$3,260,000 from the redemption of marketable securities. Cash provided by investing activities for the year ended December 31, 2013 was \$845,522, which consisted of a decrease in restricted cash equivalents of \$895,671, offset by \$50,149 for the purchase of equipment.

Cash provided by financing activities was \$8,170,751 for the year ended December 31, 2015, which consisted of net proceeds of \$7,439,809 from our registered direct public offering and our at market issuance agreement, and proceeds of \$708,617 and \$22,325 received from the exercise of stock options and stock warrants, respectively. Cash provided by financing activities was \$24,840,470 for the year ended December 31, 2014, which consisted of net proceeds of \$18,634,247 from our registered direct public offering in January 2014, \$258,955 from the exercise of stock options and \$5,947,268 from the exercise of warrants. Cash provided by financing activities was \$12,340,822 for the year ended December 31, 2013, which consisted of net proceeds of \$10,041,155 from our registered direct public offerings in July and October, 2013, \$90,000 from the exercise of stock options, and \$2,209,667 from the exercise of warrants.



## ***Financings***

On July 26, 2013 we closed a registered direct public offering of 11,400,000 shares of common stock and warrants to purchase up to 3,990,000 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 0.35 shares of common stock at a price of \$0.50 per unit, and the warrants have an exercise price of \$0.59 per share. The total gross proceeds of the offering were \$5,700,000. The warrants issued are exercisable beginning six months after the closing date until the five-year anniversary of the closing date.

On October 16, 2013 we closed a registered direct public offering of 10,192,309 shares of common stock and warrants to purchase up to 3,567,309 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 0.35 shares of common stock at a price of \$0.52 per unit, and the warrants have an exercise price of \$0.575 per share. The total gross proceeds of the offering were \$5,300,001. The warrants issued are exercisable beginning six months after the closing date until the five-year anniversary of the closing date.

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.

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. During the year ended December 31, 2015, we 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 March 2, 2016, we are prohibited from selling shares under the Sales Agreement until March 2, 2017.

### ***Contractual Obligations***

The following table summarizes our contractual obligations as of December 31, 2015:

|                  | Total      | Less than 1<br>year | 1 -3 Years | 3-5 Years  | More than 5<br>years |
|------------------|------------|---------------------|------------|------------|----------------------|
| Operating Leases | \$ 951,296 | \$ 269,733          | \$ 494,140 | \$ 187,423 | -                    |

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, 2015, the total estimated cost to complete these agreements was approximately \$9,380,000. 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.

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, 2015, we are exposed to the following market risks:

***Interest Rate Risk***

We invest our cash in a variety of financial instruments. At December 31, 2015, our cash 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, 2015, 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, 2015. 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, 2015 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, 2015, 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, 2015, based on criteria established in Internal Control—Integrated Framework (2013 framework) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).



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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 March 14, 2016 expressed an unqualified opinion.

/s/ Baker Tilly Virchow Krause, LLP

Wyomissing, Pennsylvania  
March 14, 2016



**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 2016 Proxy Statement to be filed with the SEC within 120 days of December 31, 2015 and is incorporated into this Annual Report by reference.

#### **Item 11. Executive Compensation.**

The information required by this Item is set forth in our 2016 Proxy Statement to be filed with the SEC within 120 days of December 31, 2015 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 2016 Proxy Statement to be filed with the SEC within 120 days of December 31, 2015 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 2016 Proxy Statement to be filed with the SEC within 120 days of December 31, 2015 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 2016 Proxy Statement to be filed with the SEC within 120 days of December 31, 2015 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:

|  |     |
|--|-----|
| Report of Baker Tilly Virchow Krause, LLP  | F-1 |
| Balance Sheet as of December 31, 2015 and December 31, 2014                            | F-2 |
| Statement of Operations for the years ended December 31, 2015, 2014 and 2013           | F-3 |
| Statement of Comprehensive Loss for the years ended December 31, 2015, 2014 and 2013   | F-4 |
| Statement of Stockholders' Equity for the years ended December 31, 2015, 2014 and 2013 | F-5 |
| Statement of Cash Flows for the years ended December 31, 2015, 2014 and 2013           | F-6 |
| Notes to the Financial Statements  | F-7 |

(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:

| <u>Name</u>  | <u>Title</u>  | <u>Date</u>    |
|--|---|----------------|
| <u>/s/ Peter Suzdak*</u><br>Peter Suzdak             | Chief Executive Officer and<br>Director (Principal Executive<br>Officer)                  | March 14, 2016 |
| <u>/s/ Tae Heum Jeong*</u><br>Tae Heum Jeong         | Chief Financial Officer, and<br>Secretary (Principal Financial and<br>Accounting Officer) | March 14, 2016 |
| <u>/s/ Peter Brandt*</u><br>Peter Brandt             | Chairman  | March 14, 2016 |
| <u>/s/ Chang H. Ahn*</u><br>Chang H. Ahn             | Director  | March 14, 2016 |
| <u>/s/ Charles Beever*</u><br>Charles Beever         | Director  | March 14, 2016 |
| <u>/s/ Kwang Soo Cheong*</u><br>Kwang Soo Cheong     | Director  | March 14, 2016 |
| <u>/s/ Mark Carthy*</u><br>Mark Carthy               | Director  | March 14, 2016 |
| <u>/s/ Richard J. Rodgers*</u><br>Richard J. Rodgers | Director  | March 14, 2016 |

\* 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, 2015 and 2014, 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, 2015. 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, 2015 and 2014, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2015, 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, 2015, 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 March 14, 2016 expressed an unqualified opinion.

/s/ Baker Tilly Virchow Krause, LLP

Wyomissing, Pennsylvania  
March 14, 2016

**REXAHN PHARMACEUTICALS, INC.**

## Balance Sheet

|   | <u>December 31, 2015</u> | <u>December 31, 2014</u> |
|---|--------------------------|--------------------------|
| <b>ASSETS</b>   |                          |                          |
| <b>Current Assets:</b>  |                          |                          |
| Cash and cash equivalents   | \$ 10,199,440            | \$ 9,826,245             |
| Marketable securities   | 13,240,086               | 22,872,051               |
| Prepaid expenses and other current assets   | 1,221,818                | 730,987                  |
| <b>Total Current Assets</b>   | <b>24,661,344</b>        | 33,429,283               |
| <b>Security Deposits</b>  | <b>30,785</b>            | 25,681                   |
| <b>Equipment, Net</b>   | <b>112,900</b>           | 78,096                   |
| <b>Total Assets</b>   | <b>\$ 24,805,029</b>     | \$ 33,533,060            |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>   |                          |                          |
| <b>Current Liabilities:</b>   |                          |                          |
| Accounts payable and accrued expenses   | \$ 2,661,298             | \$ 2,459,263             |
| <b>Deferred Research and Development Arrangement</b>  | <b>525,000</b>           | 600,000                  |
| <b>Other Liabilities</b>  | <b>104,020</b>           | 124,955                  |
| <b>Warrant Liabilities</b>  | <b>2,739,163</b>         | 3,768,351                |
| <b>Total Liabilities</b>  | <b>6,029,481</b>         | 6,952,569                |
| <b>Commitments and Contingencies</b> (note 14)  |                          |                          |
| <b>Stockholders' Equity:</b>  |                          |                          |
| 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, 197,413,785 and 178,366,533 issued and 197,413,785 and 178,253,318 outstanding | 19,741                   | 17,837                   |
| Additional paid-in capital  | 124,490,712              | 118,057,019              |
| Accumulated other comprehensive loss  | (18,041)                 | (33,647)                 |
| Accumulated deficit   | (105,716,864)            | (91,332,308)             |
| Treasury stock, 0 and 113,215 shares, at cost   | -                        | (128,410)                |
| <b>Total Stockholders' Equity</b>   | <b>18,775,548</b>        | 26,580,491               |
| <b>Total Liabilities and Stockholders' Equity</b>   | <b>\$ 24,805,029</b>     | \$ 33,533,060            |

(See accompanying notes to the financial statements)

**REXAHN PHARMACEUTICALS, INC.**

## Statement of Operations

|  | <b>For the Year Ended December 31,</b> |                        |                       |
|--|--|------------------------|-----------------------|
|  | <b>2015</b>                            | <b>2014</b>            | <b>2013</b>           |
| <b>Revenues:</b>                                       | <b>\$ -</b>                            | <b>\$ -</b>            | <b>\$ -</b>           |
| <b>Expenses:</b>                                       |  |                        |                       |
| General and administrative                             | <b>6,115,210</b>                       | 6,253,328              | 4,725,699             |
| Research and development                               | <b>12,148,226</b>                      | 7,015,901              | 3,253,139             |
| <b>Total Expenses</b>                                  | <b>18,263,436</b>                      | 13,269,229             | 7,978,838             |
| <b>Loss from Operations</b>                            | <b>(18,263,436)</b>                    | (13,269,229)           | (7,978,838)           |
| <b>Other Income (Expense)</b>                          |  |                        |                       |
| Interest income  | <b>103,269</b>                         | 133,907                | 49,280                |
| Unrealized gain (loss) on fair value of warrants       | <b>3,986,727</b>                       | (5,180,107)            | (1,365,654)           |
| Financing expense                                      | <b>(211,116)</b>                       | (206,172)              | (204,212)             |
| <b>Total Other Income (Expense)</b>                    | <b>3,878,880</b>                       | (5,252,372)            | (1,520,586)           |
| <b>Net Loss Before Provision for Income Taxes</b>      | <b>(14,384,556)</b>                    | (18,521,601)           | (9,499,424)           |
| <b>Provision for income taxes</b>                      | <b>-</b>                               | -                      | -                     |
| <b>Net Loss</b>  | <b>\$ (14,384,556)</b>                 | <b>\$ (18,521,601)</b> | <b>\$ (9,499,424)</b> |
| Net loss per share, basic and diluted                  | <b>\$ (0.08)</b>                       | <b>\$ (0.11)</b>       | <b>\$ (0.07)</b>      |
| Weighted average shares outstanding, basic and diluted | <b>182,388,226</b>                     | 176,106,981            | 128,649,303           |

(See accompanying notes to the financial statements)

**REXAHN PHARMACEUTICALS, INC.**  
Statement of Comprehensive Loss

|   | <b>For the Year Ended December 31,</b> |                        |                       |
|---|--|------------------------|-----------------------|
|   | <b>2015</b>                            | <b>2014</b>            | <b>2013</b>           |
| Net Loss  | \$ (14,384,556)                        | \$ (18,521,601)        | \$ (9,499,424)        |
| Unrealized gain (loss) on available-for-sale securities | 15,606                                 | (33,647)               | -                     |
| <b>Comprehensive Loss</b>                               | <b>\$ (14,368,950)</b>                 | <b>\$ (18,555,248)</b> | <b>\$ (9,499,424)</b> |

(See accompanying notes to the financial statements)



# REXAHN PHARMACEUTICALS, INC.

## Statement of Stockholders' Equity

For the Year Ended December 31, 2015, 2014 and 2013

|  | Common Stock              |                         |                                  |                                | Treasury Stock      |                     | Accumulated<br>Other<br>Comprehensive<br>Loss | Total<br>Stockholders'<br>Equity |
|--|---------------------------|-------------------------|----------------------------------|--------------------------------|---------------------|---------------------|---|----------------------------------|
|  | Number of<br>Shares       | Amount                  | Additional<br>Paid-in<br>Capital | Accumulated<br>Deficit         | Number<br>of Shares | Amount              |   |                                  |
| Balances at<br>December 31, 2012                       | 119,443,194               | 11,944                  | 72,861,738                       | (63,311,283)                   | 14,205              | (28,410)            | -   | 9,533,989                        |
| Issuance of common<br>stock and units                  | 21,592,309                | 2,159                   | 8,631,696                        | -                              | -                   | -                   | -   | 8,633,855                        |
| Stock issuance costs                                   | -                         | -                       | (952,490)                        | -                              | -                   | -                   | -   | (952,490)                        |
| Common stock issued<br>in exchange for services        | 640,000                   | 64                      | 306,736                          | -                              | -                   | -                   | -   | 306,800                          |
| Stock options exercised                                | 375,000                   | 38                      | 89,962                           | -                              | -                   | -                   | -   | 90,000                           |
| Stock warrants<br>exercised                            | 4,681,497                 | 468                     | 3,946,862                        | -                              | -                   | -                   | -   | 3,947,330                        |
| Stock based<br>compensation                            | -                         | -                       | 565,428                          | -                              | -                   | -                   | -   | 565,428                          |
| Net loss   | -                         | -                       | -                                | (9,499,424)                    | -                   | -                   | -   | (9,499,424)                      |
| Balances at<br>December 31, 2013                       | <u>146,732,000</u>        | <u>\$ 14,673</u>        | <u>\$ 85,449,932</u>             | <u>\$ (72,810,707)</u>         | <u>14,205</u>       | <u>\$ (28,410)</u>  | <u>-\$</u>                                    | <u>12,625,488</u>                |
| Issuance of common<br>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<br>in exchange for services        | 400,000                   | 40                      | 408,960                          | -                              | -                   | -                   | -   | 409,000                          |
| Stock options exercised                                | 448,693                   | 45                      | 358,910                          | -                              | -                   | -                   | -   | 358,955                          |
| Shares surrendered for<br>net stock option<br>exercise | -                         | -                       | -                                | -                              | 99,010              | (100,000)           | -   | (100,000)                        |
| Stock warrants<br>exercised                            | 11,738,220                | 1,174                   | 16,083,337                       | -                              | -                   | -                   | -   | 16,084,511                       |
| Stock based<br>compensation                            | -                         | -                       | 608,795                          | -                              | -                   | -                   | -   | 608,795                          |
| Net loss   | -                         | -                       | -                                | (18,521,601)                   | -                   | -                   | -   | (18,521,601)                     |
| Other comprehensive<br>loss                            | -                         | -                       | -                                | -                              | -                   | -                   | (33,647)                                      | (33,647)                         |
| Balances at<br>December 31, 2014                       | <u>178,366,533</u>        | <u>\$ 17,837</u>        | <u>\$ 118,057,019</u>            | <u>\$ (91,332,308)</u>         | <u>113,215</u>      | <u>\$ (128,410)</u> | <u>(33,647)</u>                               | <u>\$ 26,580,491</u>             |
| Issuance of common<br>stock and units                  | 18,073,739                | 1,807                   | 5,248,266                        | -                              | -                   | -                   | -   | 5,250,073                        |
| Stock issuance costs                                   | -                         | -                       | (566,065)                        | -                              | -                   | -                   | -   | (566,065)                        |
| Common stock issued<br>in exchange for services        | 150,000                   | 15                      | 101,985                          | -                              | -                   | -                   | -   | 102,000                          |
| Stock options exercised                                | 889,428                   | 89                      | 708,528                          | -                              | -                   | -                   | -   | 708,617                          |
| Stock warrants<br>exercised                            | 47,300                    | 4                       | 31,699                           | -                              | -                   | -                   | -   | 31,703                           |
| Stock based<br>compensation                            | -                         | -                       | 1,037,679                        | -                              | -                   | -                   | -   | 1,037,679                        |
| Retirement of treasury<br>stock                        | (113,215)                 | (11)                    | (128,399)                        | -                              | (113,215)           | 128,410             | -   | -                                |
| Net loss   | -                         | -                       | -                                | (14,384,556)                   | -                   | -                   | -   | (14,384,556)                     |
| Other comprehensive<br>loss                            | -                         | -                       | -                                | -                              | -                   | -                   | 15,606  | 15,606                           |
| <b>Balances at<br/>December 31, 2015</b>               | <u><b>197,413,785</b></u> | <u><b>\$ 19,741</b></u> | <u><b>\$ 124,490,712</b></u>     | <u><b>\$ (105,716,864)</b></u> | <u><b>-</b></u>     | <u><b>-\$</b></u>   | <u><b>(18,041)</b></u>                        | <u><b>\$ 18,775,548</b></u>      |

(See accompanying notes to the financial statements)

# REXAHN PHARMACEUTICALS, INC.

## Statement of Cash Flows

|   | <b>For the Year Ended December 31,</b> |                     |                      |
|---|--|---------------------|----------------------|
|   | <b>2015</b>                            | 2014                | 2013                 |
| <b>Cash Flows from Operating Activities:</b>                                |  |                     |                      |
| Net loss  | \$ (14,384,556)                        | \$ (18,521,601)     | \$ (9,499,424)       |
| Adjustments to reconcile net loss to net cash used in operating activities: |  |                     |                      |
| Compensatory stock  | 102,000                                | 409,000             | 306,800              |
| Depreciation and amortization   | 27,498                                 | 28,325              | 37,133               |
| Amortization of premiums and discounts on marketable securities, net        | 30,875                                 | 10,228              | -                    |
| Stock-based compensation  | 1,037,679                              | 608,795             | 565,428              |
| Amortization of deferred research and development arrangements              | (75,000)                               | (233,630)           | (792,370)            |
| Unrealized (gain) loss on fair value of warrants                            | (3,986,727)                            | 5,180,107           | 1,365,654            |
| Financing expense   | 211,116                                | 206,172             | 204,212              |
| Amortization of deferred lease incentive                                    | (12,443)                               | (12,443)            | (16,222)             |
| Deferred lease expenses   | (8,492)                                | 7,834               | 25,709               |
| Changes in assets and liabilities:  |  |                     |                      |
| Prepaid expenses and other assets   | (495,935)                              | (249,503)           | (263,697)            |
| Accounts payable and accrued expenses                                       | 202,035                                | 1,525,505           | 81,921               |
| <b>Net Cash Used in Operating Activities</b>                                | <b>(17,351,950)</b>                    | <b>(11,041,211)</b> | <b>(7,984,856)</b>   |
| <b>Cash Flows from Investing Activities:</b>                                |  |                     |                      |
| Restricted cash equivalents   | -                                      | 196,130             | 895,671              |
| Purchase of equipment   | (62,302)                               | (41,249)            | (50,149)             |
| Purchase of marketable securities   | (7,908,304)                            | (26,075,926)        | -                    |
| Redemption of marketable securities   | 17,525,000                             | 3,260,000           | -                    |
| <b>Net Cash Provided by (Used In) Investing Activities</b>                  | <b>9,554,394</b>                       | <b>(22,661,045)</b> | <b>845,522</b>       |
| <b>Cash Flows from Financing Activities:</b>                                |  |                     |                      |
| Issuance of common stock and units, net of issuance costs                   | 7,439,809                              | 18,634,247          | 10,041,155           |
| Proceeds from exercise of stock options                                     | 708,617                                | 258,955             | 90,000               |
| Proceeds from exercise of stock warrants                                    | 22,325                                 | 5,947,268           | 2,209,667            |
| <b>Net Cash Provided by Financing Activities</b>                            | <b>8,170,751</b>                       | <b>24,840,470</b>   | <b>12,340,822</b>    |
| <b>Net Increase (Decrease) in Cash and Cash Equivalents</b>                 | <b>373,195</b>                         | <b>(8,861,786)</b>  | <b>5,201,488</b>     |
| <b>Cash and Cash Equivalents – beginning of period</b>                      | <b>9,826,245</b>                       | <b>18,688,031</b>   | <b>13,486,543</b>    |
| <b>Cash and Cash Equivalents - end of period</b>                            | <b>\$ 10,199,440</b>                   | <b>\$ 9,826,245</b> | <b>\$ 18,688,031</b> |
| <b>Supplemental Cash Flow Information</b>                                   |  |                     |                      |
| Non-cash financing and investing activities:                                |  |                     |                      |
| Warrants issued   | \$ 2,966,917                           | \$ 3,691,429        | \$ 2,564,002         |
| Warrant liability extinguishment from exercise of warrants                  | \$ 9,378                               | \$ 10,137,243       | \$ 1,737,663         |
| Shares withheld for net stock option exercise                               | \$ -                                   | \$ 100,000          | \$ -                 |
| Leasehold improvement incentive   | \$ -                                   | \$ -                | \$ 54,660            |
| 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 \$105,716,864 at December 31, 2015 and anticipates incurring losses through fiscal year 2016 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 for at least the next 12 months. 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 Rexahn Pharmaceuticals’ 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:

|                        | <u>Life</u> | <u>Depreciation Method</u> |
|------------------------|-------------|----------------------------|
| 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, as well as stock 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 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 current assets, the security deposit and accounts payable and accrued expenses approximate fair value because of the short-term maturity of these financial instruments. The fair value for marketable securities, warrant liabilities, and certain other assets and liabilities is discussed in Notes 3, 12, and 15, respectively.

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, 2015, the Company's uninsured cash balance was \$9,554,878. 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 accounting principles generally accepted in the United States of America. 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 will be 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.

*Leases*

In February 2016, the FASB issued ASU 2016-02, “Leases,” which requires that lease arrangements for a period greater than 12 months result in an entity recognizing an asset and a liability. ASU 2016-02 will be effective for reporting periods beginning after December 15, 2016, with early adoption permitted. We have not evaluated the impact that the adoption of this guidance will have on our 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, 2015 and 2014:

|                                    | 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            |
| <b>Total Marketable Securities</b> | <b>\$ 13,258,127</b> | <b>\$ 571</b>          | <b>\$ (18,612)</b>      | <b>\$ 13,240,086</b> |

  

|                                    | December 31, 2014    |                        |                         |                      |
|------------------------------------|----------------------|------------------------|-------------------------|----------------------|
|                                    | Cost Basis           | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value           |
| Certificates of Deposit            | \$ 18,865,000        | \$ 60                  | \$ (26,789)             | \$ 18,838,271        |
| Commercial Paper                   | 1,998,001            | 62                     | (153)                   | 1,997,910            |
| Corporate Bonds                    | 2,042,697            | -                      | (6,827)                 | 2,035,870            |
| <b>Total Marketable Securities</b> | <b>\$ 22,905,698</b> | <b>\$ 122</b>          | <b>\$ (33,769)</b>      | <b>\$ 22,872,051</b> |

The Company typically invests in highly-rated securities, with the primary objective of minimizing the potential risk of principal loss. As of December 31, 2015, the Company had 15 certificates of deposit with a fair value of \$3,594,425 and unrealized losses of \$5,575, three commercial papers with a fair value of \$2,977,570 and unrealized losses of \$3,737, and three corporate bonds with a fair value of \$3,025,320 and unrealized losses of \$7,625, all of which have been unrealized losses for less than 12 months. The Company has one corporate bond with a fair value of \$1,002,200 and unrealized losses of \$1,675 which has been an unrealized loss for greater 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, 2015, all of the Company's marketable securities are expected to mature in less than one year.

**4. Prepaid Expenses and Other Current Assets**

|   | <b>December 31,<br/>2015</b> | December 31,<br>2014 |
|---|------------------------------|----------------------|
| Deposits on contracts                     | \$ 501,170                   | \$ 369,811           |
| Prepaid expenses and other current assets | <b>720,648</b>               | 361,176              |
|   | <b>\$ 1,221,818</b>          | <b>\$ 730,987</b>    |

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**

|   | <b>December 31,<br/>2015</b> | December 31,<br>2014 |
|---|------------------------------|----------------------|
| Furniture and fixtures                          | \$ 78,794                    | \$ 70,320            |
| Office and computer equipment                   | <b>105,266</b>               | 57,893               |
| Lab equipment                                   | <b>431,650</b>               | 425,195              |
| Leasehold improvements                          | <b>133,762</b>               | 133,762              |
| Total equipment                                 | <b>749,472</b>               | 687,170              |
| Less: Accumulated depreciation and amortization | <b>(636,572)</b>             | (609,074)            |
| Net carrying amount                             | <b>\$ 112,900</b>            | <b>\$ 78,096</b>     |

**6. Accounts Payable and Accrued Expenses**

|   | <b>December 31,<br/>2015</b> | December 31,<br>2014 |
|---|------------------------------|----------------------|
| Trade payables                                  | \$ 774,543                   | \$ 706,781           |
| Accrued expenses                                | <b>92,752</b>                | 56,884               |
| Accrued research and development contract costs | <b>1,515,151</b>             | 1,078,532            |
| Payroll liabilities                             | <b>278,852</b>               | 617,066              |
|   | <b>\$ 2,661,298</b>          | <b>\$ 2,459,263</b>  |



## **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, 2015, 2014 and 2013. The remaining \$525,000 and \$600,000 to be amortized at December 31, 2015 and 2014, respectively, are reflected as deferred research and development arrangements 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 2017. Under the terms of the agreement, Rexgene does not receive 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 years ended December 31, 2014 and 2013, \$158,630 and \$717,730 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*

On June 29, 2009, the Company entered into a five-year office lease agreement which is further discussed in Note 14. The lessor agreed to grant a leasehold improvement allowance of \$100,000 to the Company 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 five-year term of the office lease.

On June 7, 2013, the Company entered into the first amendment to the lease agreement, also discussed in Note 14. According to the terms of the amendment, the Company extended the lease term until June 30, 2019. The lessor agreed to grant an additional leasehold improvement allowance of \$54,660 to the Company to be used for further construction of the leased property, furniture and equipment. The Company accounts for this benefit, including the unamortized portion from the original lease agreement, as a reduction of rental expense over the six-year amended term of the lease.

The following table sets forth the cumulative deferred lease incentive:

|                               | <b>December 31,<br/>2015</b> | December 31,<br>2014 |
|-------------------------------|------------------------------|----------------------|
| Deferred lease incentive      | <b>\$ 154,660</b>            | \$ 154,660           |
| Less accumulated amortization | <b>(111,108)</b>             | (98,665)             |
| Balance                       | <b>\$ 43,552</b>             | \$ 55,995            |

### *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 \$60,468 and \$68,960 as of December 31, 2015 and 2014, 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, 2015, 2014 and 2013, there were stock options and warrants to acquire, in the aggregate, 39,082,886, 24,606,677 and 34,325,663 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, 2015, 2014 and 2013:

### *Public Offerings*

#### July 2013

On July 26, 2013 the Company closed on a registered direct public offering to issue and sell 11,400,000 shares of common stock and warrants to purchase up to 3,990,000 shares of common stock. The common stock and warrants were sold in units, consisting of common stock and a warrant to purchase 0.35 shares of common stock, at a price of \$0.50 per share, and the warrants have an exercise price of \$0.59 per share. The total gross proceeds of the offering were \$5,700,000. The warrants issued are exercisable beginning six months after the closing date 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:  | \$ 5,700,000        |
| Allocated to warrant liabilities:                        | 1,295,952           |
| Allocated to common stock and additional paid-in capital | 4,404,048           |
| <b>Total allocated gross proceeds:</b>                   | <b>\$ 5,700,000</b> |

The closing costs of \$637,334 included 456,000 warrants valued at \$110,489 and \$526,845 for placement agent and other fees. Based upon the estimated fair value of the stock and warrants in the units, the Company allocated \$112,559 to financing expense and \$524,775 as stock issuance costs.

#### October 2013

On October 16, 2013, the Company closed on a registered direct public offering to issue and sell 10,192,309 shares of common stock and warrants to purchase up to 3,567,309 shares of common stock. The common stock and warrants were sold in units, consisting of common stock and a warrant to purchase 0.35 shares of common stock, at a price of \$0.52 per share, and the warrants have an exercise price of \$0.575 per share. The total gross proceeds of the offering were \$5,300,001. The warrants issued are exercisable beginning six months after the closing date 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:  | \$ 5,300,001        |
| Allocated to warrant liabilities:                        | 1,070,193           |
| Allocated to common stock and additional paid-in capital | 4,229,808           |
| <b>Total allocated gross proceeds:</b>                   | <b>\$ 5,300,001</b> |

The closing costs of \$519,368 included 407,692 warrants valued at \$87,368 and \$432,000 for placement agent and other fees. Based upon the estimated fair value of the stock and warrants in the units, the Company allocated \$91,653 to financing expense and \$427,715 as stock issuance costs.

January 2014

On January 21, 2014 the Company closed on a registered direct public offering to issue and sell 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 common stock and a warrant to purchase 0.25 shares of common stock, at a price of \$1.05 per share, 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 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           |
| <b>Total allocated gross proceeds:</b>                   | <b>\$ 20,000,001</b> |

The total closing costs of the offering were \$1,365,754, which 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 to issue and sell 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 common stock and a warrant to purchase 0.75 shares of common stock, at a price of \$0.42 per share, 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 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           |
| <b>Total allocated gross proceeds:</b>                   | <b>\$ 7,000,000</b> |

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.

*At Market Offering*

On March 16, 2015, the Company entered into an at market (“ATM”) 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 March 2, 2016, the Company is prohibited from selling shares under the Sales Agreement until March 2, 2017. See Note 17, “Subsequent Events”, for information on this registered direct offering.

*Compensatory Shares*

The Company has issued shares to vendors in exchange for services. A summary of the shares issued, and the related market value is shown below:

| <b>Date of Issuance</b> | <b>Number of Shares Issued</b> | <b>Market Value Per Share</b> | <b>Total Market Value of Share Issuance</b> |
|-------------------------|--------------------------------|-------------------------------|---|
| May 10, 2013            | 120,000                        | \$ 0.31                       | \$ 37,200                                   |
| June 10, 2013           | 200,000                        | 0.50                          | 100,000                                     |
| August 1, 2013          | 120,000                        | 0.53                          | 63,600                                      |
| October 1, 2013         | 200,000                        | 0.53                          | 106,000                                     |
| <b>2013 Total</b>       | <u>640,000</u>                 |                               | <u>\$ 306,800</u>                           |
| February 10, 2014       | 300,000                        | \$ 1.12                       | \$ 336,000                                  |
| August 1, 2014          | 100,000                        | 0.73                          | 73,000                                      |
| <b>2014 Total</b>       | <u>400,000</u>                 |                               | <u>\$ 409,000</u>                           |
| February 10, 2015       | 75,000                         | \$ 0.75                       | \$ 56,250                                   |
| July 1, 2015            | 75,000                         | 0.61                          | 45,750                                      |
| <b>2015 Total</b>       | <u>150,000</u>                 |                               | <u>\$ 102,000</u>                           |

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*Stock Option and Stock Warrant Exercises*

The table below summarizes stock options and stock warrants exercised:

|                                | For the Year Ended December 31, |              |              |
|--------------------------------|---------------------------------|--------------|--------------|
|                                | 2015                            | 2014         | 2013         |
| <u>Stock Option Exercises</u>  |                                 |              |              |
| Number of shares issued        | 889,428                         | 448,693      | 375,000      |
| Total cash received            | \$ 708,617                      | \$ 258,955   | \$ 90,000    |
| <u>Stock Warrant Exercises</u> |                                 |              |              |
| Number of shares issued        | 47,300                          | 11,738,220   | 4,681,497    |
| Total cash received            | \$ 22,325                       | \$ 5,947,268 | \$ 2,209,667 |

*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, 2015, the Company had 12,590,982 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, 2015, there were 6,912,482 options outstanding under the 2013 Plan, and 10,080,018 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, 2015, there were 5,678,500 outstanding options under the 2003 Plan.

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*

The Company's results of operations for the years ended December 31, 2015, 2014 and 2013 include stock-based compensation expense totaling \$1,037,679, \$608,795 and \$565,428 respectively. Such amounts have been included in the statement of operations in general and administrative and research and development expenses. No income tax benefit has been recognized in the statement of operations for stock-based compensation arrangements as the Company has provided for a 100% valuation allowance on its deferred tax assets.

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.

*Summary of Stock Compensation Expense Recognized*

Total stock-based compensation recognized by the Company for the years ended December 31, 2015, 2014 and 2013 is as follows:

|                                    | <b><u>For the Year Ended December 31,</u></b> |            |            |
|------------------------------------|---|------------|------------|
|                                    | <b><u>2015</u></b>                            | 2014       | 2013       |
| Statement of operations line item: |   |            |            |
| General and administrative         | \$ <b>665,063</b>                             | \$ 457,128 | \$ 503,076 |
| Research and development           | <b>372,616</b>                                | 151,667    | 62,352     |
| Total                              | <b>\$ 1,037,679</b>                           | \$ 608,795 | \$ 565,428 |

*Summary of Stock Option Transactions*

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. There were 2,450,000 stock options granted at exercise prices ranging from \$0.31 to \$0.61 with an aggregate fair value of \$681,752 during the year ended December 31, 2013.

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. The expected volatility is based upon historical volatility of the Company's stock. The expected term is based upon the simplified method as allowed under SAB 107.

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

|                           | <b><u>Year Ended December 31,</u></b> |            |            |
|---------------------------|---------------------------------------|------------|------------|
|                           | <b><u>2015</u></b>                    | 2014       | 2013       |
| Black-Scholes assumptions |                                       |            |            |
| Expected dividend yield   | <b>0%</b>                             | 0%         | 0%         |
| Expected volatility       | <b>72-80%</b>                         | 92-96%     | 94-96%     |
| Risk free interest rate   | <b>1.2-1.7%</b>                       | 1.49-1.75% | 0.75-1.75% |
| Expected term (in years)  | <b>5-6 years</b>                      | 5 years    | 5 years    |



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The following table summarizes share-based transactions:

|                                | Number of<br>Options | Weighted<br>Average<br>Exercise<br>Price | Weighted Average<br>Remaining<br>Contractual Term | Aggregate<br>Intrinsic<br>Value |
|--------------------------------|----------------------|--|---|---------------------------------|
| Outstanding, January 1, 2015   | 11,400,806 \$        | 0.93                                     | 5.2 years \$                                      | 842,300                         |
| Granted                        | 4,201,316            | 0.69                                     |   |                                 |
| Exercised                      | (889,428)            | 0.80                                     |   |                                 |
| Expired                        | (1,741,879)          | 1.19                                     |   |                                 |
| Cancelled                      | (379,833)            | 0.88                                     |   |                                 |
| Outstanding, December 31, 2015 | 12,590,982 \$        | 0.83                                     | 6.8 years \$                                      | 26,500                          |
| Exercisable, December 31, 2015 | 6,702,550 \$         | 0.91                                     | 5.0 years \$                                      | 16,500                          |

The total intrinsic value of the options exercised was \$99,895, \$115,528 and \$91,300 for the years ended December 31, 2015, 2014 and 2013, respectively. The weighted average fair value of the options granted was \$0.47, \$0.69 and \$0.28 for the years ended December 31, 2015, 2014 and 2013, respectively.

A summary of the Company's unvested options as of December 31, 2015 and changes during the year ended December 31, 2015 is presented below:

|                                      | <b>2015</b>                  |  |
|--------------------------------------|------------------------------|--|
|                                      | <b>Number of<br/>Options</b> | <b>Weighted Average Fair<br/>Value at Grant Date</b> |
| Unvested at January 1, 2015          | 3,233,499                    | \$ 0.60  |
| Granted                              | 4,201,316                    | \$ 0.47  |
| Vested                               | (1,308,050)                  | \$ 0.58  |
| Cancelled                            | (238,333)                    | \$ 0.57  |
| <b>Unvested at December 31, 2015</b> | <b>5,888,432</b>             | <b>\$ 0.51</b>                                       |

As of December 31, 2015 there was \$2,233,363 of total unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted average vesting period of 2.5 years.

## 12. Warrants

As of December 31, 2015, warrants to purchase 26,491,904 shares were outstanding, having exercise prices ranging from \$0.41 to \$1.50 and expiration dates ranging from July 5, 2016 to May 13, 2021.

|                             | 2015               |                                 | 2014               |                                 |
|-----------------------------|--------------------|---------------------------------|--------------------|---------------------------------|
|                             | Number of warrants | Weighted average exercise price | Number of warrants | Weighted average exercise price |
| Balance, January 1          | 13,205,871         | \$ 1.07                         | 24,968,868         | \$ 0.86                         |
| Issued during the period    | 13,333,333         | \$ 0.53                         | 4,761,905          | \$ 1.28                         |
| Exercised during the period | (47,300)           | \$ 0.47                         | (12,058,871)       | \$ 0.52                         |
| Expired during the period   | -                  | \$ -                            | (4,466,031)        | \$ 1.59                         |
| <b>Balance, December 31</b> | <b>26,491,904</b>  | <b>\$ 0.80</b>                  | <b>13,205,871</b>  | <b>\$ 1.07</b>                  |

At December 31, 2015 the weighted average remaining contractual life of the outstanding warrants was 3.8 years.

The warrants issued to investors in the March 2011, December 2012, November 2015 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 March 2011, December 2012, July 2013, October 2013, January 2014, November 2015 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 are 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.

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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, 2015   | December 31, 2014   |
| March 31, 2011 financing:           |                     |                     |
| Warrants to institutional investors | \$ 30               | \$ 319,277          |
| December 4, 2012 financing:         |                     |                     |
| Warrants to institutional investors | 9,818               | 90,052              |
| Warrants to placement agent         | 1,206               | 14,595              |
| July 26, 2013 financing:            |                     |                     |
| Warrants to institutional investors | 121,420             | 788,314             |
| Warrants to placement agent         | 384                 | 30,594              |
| October 16, 2013 financing:         |                     |                     |
| Warrants to institutional investors | 169,349             | 949,756             |
| Warrants to placement agent         | 970                 | 96,563              |
| January 21, 2014 financing:         |                     |                     |
| Warrants to institutional investors | 131,476             | 1,479,200           |
| November 12, 2015 financing:        |                     |                     |
| Warrants to institutional investors | 2,169,375           | -                   |
| Warrants to placement agent         | 135,135             | -                   |
| <b>Total:</b>                       | <b>\$ 2,739,163</b> | <b>\$ 3,768,351</b> |

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

| Warrant Issuance                    | Number of Shares indexed as of: |                   |
|-------------------------------------|---------------------------------|-------------------|
|                                     | December 31, 2015               | December 31, 2014 |
| March 31, 2011 financing:           |                                 |                   |
| Warrants to institutional investors | 3,333,333                       | 3,333,333         |
| December 4, 2012 financing:         |                                 |                   |
| Warrants to institutional investors | 174,300                         | 221,600           |
| Warrants to placement agent         | 40,000                          | 40,000            |
| July 26, 2013 financing:            |                                 |                   |
| Warrants to institutional investors | 2,000,000                       | 2,000,000         |
| Warrants to placement agent         | 124,032                         | 124,032           |
| October 16, 2013 financing:         |                                 |                   |
| Warrants to institutional investors | 2,317,309                       | 2,317,309         |
| Warrants to placement agent         | 407,692                         | 407,692           |
| January 21, 2014 financing:         |                                 |                   |
| Warrants to institutional investors | 4,761,905                       | 4,761,905         |
| November 12, 2015 financing:        |                                 |                   |
| Warrants to institutional investors | 12,500,000                      | -                 |
| Warrants to placement agent         | 833,333                         | -                 |
| <b>Total:</b>                       | <b>26,491,904</b>               | <b>13,205,871</b> |

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

|                                 | December 31, 2015 | December 31, 2014 |
|---------------------------------|-------------------|-------------------|
| Trading market prices           | \$ 0.36           | \$ 0.70           |
| Estimated future volatility     | 105 %             | 108 %             |
| Dividend                        | -                 | -                 |
| Estimated future risk-free rate | 0.82-2.38%        | 0.74-1.90%        |
| Equivalent volatility           | 44-65%            | 65-78%            |
| Equivalent risk-free rate       | 0.22-1.11%        | 0.18-0.63%        |

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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:

|                                     | <b>Year Ended December 31,</b> |                       |             |                    |
|-------------------------------------|--------------------------------|-----------------------|-------------|--------------------|
|                                     | <b>2015</b>                    | 2014                  | 2013        |                    |
| Exercised and Expired Warrants      | \$                             | -\$                   | (277,769)\$ | 104,887            |
| March 31, 2011 financing:           |                                |                       |             |                    |
| Warrants to institutional investors | <b>319,247</b>                 | (7,917)               |             | (5,027)            |
| December 4, 2012 financing:         |                                |                       |             |                    |
| Warrants to institutional investors | <b>70,856</b>                  | (4,120,103)           |             | (1,598,195)        |
| Warrants to placement agent         | <b>13,389</b>                  | (514,881)             |             | (75,062)           |
| July 26, 2013 financing:            |                                |                       |             |                    |
| Warrants to institutional investors | <b>666,894</b>                 | (1,272,731)           |             | 147,562            |
| Warrants to placement agent         | <b>30,210</b>                  | (234,877)             |             | 26,681             |
| October 16, 2013 financing:         |                                |                       |             |                    |
| Warrants to institutional investors | <b>780,407</b>                 | (940,100)             |             | 18,739             |
| Warrants to placement agent         | <b>95,593</b>                  | (23,956)              |             | 14,761             |
| January 21, 2014 financing:         |                                |                       |             |                    |
| Warrants to institutional investors | <b>1,347,724</b>               | 2,212,227             |             | -                  |
| November 12, 2015 financing:        |                                |                       |             |                    |
| Warrants to institutional investors | <b>623,125</b>                 | -                     |             | -                  |
| Warrants to placement agent         | <b>39,282</b>                  | -                     |             | -                  |
| <b>Total:</b>                       | <b>\$ 3,986,727</b>            | <b>\$ (5,180,107)</b> | <b>\$</b>   | <b>(1,365,654)</b> |

**13. Income Taxes**

No provision for federal and state income taxes was required for the years ended December 31, 2015, 2014 and 2013 due to the Company's operating losses and increased deferred tax asset valuation allowance. At December 31, 2015 and 2014, the Company had unused net operating loss carry-forwards of approximately \$98,954,000 and \$81,619,000, respectively, which expire at various dates through 2035. 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, 2015 and 2014, 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:

|  | <b>December 31,<br/>2015</b> | December 31,<br>2014 |
|--|------------------------------|----------------------|
| Net Operating Loss Carryforwards               | <b>\$ 38,592,000</b>         | \$ 31,831,000        |
| Stock Compensation Expense                     | <b>1,891,000</b>             | 2,221,000            |
| Book tax differences on assets and liabilities | <b>380,000</b>               | 416,000              |
| Valuation Allowance                            | <b>(40,863,000)</b>          | (34,468,000)         |
|  | <hr/>                        | <hr/>                |
| Net Deferred Tax Assets                        | <b>\$ -</b>                  | -                    |

The Company files income tax returns in the U.S. federal and Maryland state jurisdictions. Tax years for fiscal 2012 through 2015 are open and potentially subject to examination by the federal and Maryland state taxing authorities.

## 14. 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, 2015, the total estimated cost to complete these agreements was approximately \$9,380,000. 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, 2015, the milestone has not occurred.

c) *Office Space Lease*

On June 29, 2009, the Company signed a five-year 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. Rent paid under the Company’s lease during the years ended December 31, 2015, 2014 and 2013 was \$202,529, \$155,057 and \$117,977, respectively.

On June 7, 2013, the Company entered into the first amendment to the lease agreement. According to the terms of this amendment, the Company extended the lease term until June 30, 2019. The amended base rent was \$100,210 and is subject to annual base rent increases the remaining term of the lease.

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. On May 6, 2015, the Company renewed the lease for this space for an additional year, beginning on September 1, 2015 and ending on August 31, 2016.

*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, 2014 and 2013 was \$27,324, \$54,648, 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 year ended December 31, 2015 was \$30,624.

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

|                                  |              |                   |
|----------------------------------|--------------|-------------------|
| For the year ending December 31: | 2016         | 269,733           |
|                                  | 2017         | 260,217           |
|                                  | 2018         | 233,923           |
|                                  | 2019         | 152,955           |
|                                  | 2020         | 34,468            |
|                                  | <b>Total</b> | <b>\$ 951,296</b> |

- 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 \$121,519, \$91,241 and \$78,487 for the years ended December 31, 2015, 2014 and 2013, 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, 2015, 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, 2015, no development milestones have occurred.



**15. 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, 2015 and 2014.

| <b>Fair Value Measurements at December 31, 2015</b> |                      |             |                      |              |
|---|----------------------|-------------|----------------------|--------------|
|   | Total                | Level 1     | Level 2              | Level 3      |
| <b>Assets:</b>                                      |                      |             |                      |              |
| 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            | -            |
| <b>Total Assets:</b>                                | <b>\$ 13,240,086</b> | <b>\$ -</b> | <b>\$ 13,240,086</b> | <b>\$ -</b>  |
| <b>Liabilities:</b>                                 |                      |             |                      |              |
| Warrant Liabilities                                 | \$ 2,739,163         | -           | -                    | \$ 2,739,163 |

| <b>Fair Value Measurements at December 31, 2014</b> |                      |             |                      |              |
|---|----------------------|-------------|----------------------|--------------|
|   | Total                | Level 1     | Level 2              | Level 3      |
| <b>Assets:</b>                                      |                      |             |                      |              |
| Certificates of Deposit                             | \$ 18,838,271        | -           | \$ 18,838,271        | -            |
| Commercial Paper                                    | 1,997,910            | -           | 1,997,910            | -            |
| Corporate Bonds                                     | 2,035,870            | -           | 2,035,870            | -            |
| <b>Total Assets:</b>                                | <b>\$ 22,872,051</b> | <b>\$ -</b> | <b>\$ 22,872,051</b> | <b>\$ -</b>  |
| <b>Liabilities:</b>                                 |                      |             |                      |              |
| Warrant Liabilities                                 | \$ 3,768,351         | -           | -                    | \$ 3,768,351 |

**REXAHN PHARMACEUTICALS, INC.**  
Notes to Financial Statements

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, 2015 and 2014 in the fair value of the liabilities classified as Level 3 in the fair value hierarchy:

|                              | 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 | <u>\$ 2,739,163</u> |

|                              | Warrant Liabilities |
|------------------------------|---------------------|
| Balance at January 1, 2014   | \$ 5,034,058        |
| Additions                    | 3,691,429           |
| Unrealized losses, net       | 5,180,107           |
| Transfers out of level 3     | (10,137,243)        |
| Balance at December 31, 2014 | <u>\$ 3,768,351</u> |

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.

**16. Select Quarterly Data (Unaudited)**

|                                       | <b>2015</b>           |                       |                       |                       |
|---------------------------------------|-----------------------|-----------------------|-----------------------|-----------------------|
|                                       | 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 (Expense)                | 145,997               | 1,585,780             | 632,025               | 1,515,078             |
| Net Loss                              | <u>\$ (4,271,711)</u> | <u>\$ (3,234,160)</u> | <u>\$ (4,026,530)</u> | <u>\$ (2,852,155)</u> |
| Net Loss per share, basic and diluted | <u>\$ (0.02)</u>      | <u>\$ (0.02)</u>      | <u>\$ (0.02)</u>      | <u>\$ (0.02)</u>      |

|  | <b>2014</b>            |                   |                       |                       |
|--|------------------------|-------------------|-----------------------|-----------------------|
|  | For the Quarter Ended  |                   |                       |                       |
|  | March 31               | June 30           | September 30          | December 31           |
| Revenues                                       | \$ -                   | \$ -              | \$ -                  | -                     |
| Expenses                                       | 2,766,094              | 3,508,936         | 3,141,706             | 3,852,493             |
| Loss from Operations                           | (2,766,094)            | (3,508,936)       | (3,141,706)           | (3,852,493)           |
| Other Income (Expense)                         | (11,834,405)           | 3,703,400         | 1,236,258             | 1,642,375             |
| Net (Loss) Income per share                    | <u>\$ (14,600,499)</u> | <u>\$ 194,464</u> | <u>\$ (1,905,448)</u> | <u>\$ (2,210,118)</u> |
| Net (Loss) Income per share, basic and diluted | <u>\$ (0.09)</u>       | <u>\$ 0.00</u>    | <u>\$ (0.01)</u>      | <u>\$ (0.01)</u>      |

**17. Subsequent Events**

Since December 31, 2015, the Company granted 3,337,090 stock options to officers, employees and consultants.

On March 2, 2016, the Company issued 15,625,000 shares of its common stock and warrants exercisable for up to 11,718,750 shares of its common stock in a registered direct offering for gross proceeds of \$5 million. The shares and warrants were sold in units, consisting of one share of common stock and a warrant to purchase 0.75 of a share of common stock, at an offering price of \$0.32 per unit. Subject to certain ownership limitations, the warrants are exercisable beginning six months after the closing date until the five-year anniversary of the initial exercise date. The warrants have an exercise price of \$0.42 per share. The Company also issued warrants to purchase 781,250 shares of the Company's common stock, at an exercise price of \$0.40 per share, to the placement agent in the offering and its designees in reliance on the exemption from registration provided by Section 4(a)(2) under the Securities Act as transactions not involving any public offering.

## 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 March 30, 2011, 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 November 30, 2012, is incorporated herein by reference.
- 4.4 Form of Warrant for the Company's Common Stock Purchase Warrants, filed as Exhibit 4.2 to the Company's Current Report on Form 8-K filed on November 30, 2012, 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 July 24, 2013, 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 October 16, 2013, 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 January 15, 2014, 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 November 6, 2015, is incorporated herein by reference.
- 4.9 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.
- \*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.
- \*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 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.
- 10.11 First Amendment to Lease Agreement, dated 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.
- 10.12 Second Amendment to Lease Agreement, dated 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.
- 10.13 Third Amendment to Lease Agreement, dated 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.
- 10.14 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.
- 10.15 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.
- 10.16 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.
- 10.17 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.   |
| 10.18   | 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, 2015, is incorporated herein by reference. |
| 10.19   | At Market Issuance Sales Agreement, dated 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

## **CORPORATE HEADQUARTERS**

Rexahn Pharmaceuticals, Inc.  
15245 Shady Grove Road, Suite 455  
Rockville, MD 20850  
Phone: 240-268-5300  
www.rexahn.com

## **TRANSFER AGENT**

Olde Monmouth Stock Transfer Co., Inc.  
Matthew J. Troster  
200 Memorial Parkway  
Atlantic Highlands, NJ 07716  
Phone: 732-872-2727

## **LEGAL COUNSEL**

Hogan Lovells US LLP  
100 International Drive, Suite 2000  
Baltimore, MD 21202

## **INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

Baker Tilly Virchow Krause, LLP  
2609 Keiser Blvd  
Wyomissing, PA 19610-3338

## **SECURITIES INFORMATION**

TRADING MARKET: NYSE MKT  
SYMBOL: RNN

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TO REQUEST ADDITIONAL COPIES OF THIS  
ANNUAL REPORT, CONTACT:

LifeSci Advisors, LLC  
Matthew P. Duffy  
(212)-915-0685  
matthew@lifesciadvisors.com

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.

**REXAHN PHARMACEUTICALS, INC.**

15245 Shady Grove Road, Suite 455  
Rockville, MD 20850

T: 240.268.5300

[ir@rexahn.com](mailto:ir@rexahn.com)  
[www.rexahn.com](http://www.rexahn.com)