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, 2018**

OR

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

For the transition period from _____to_____

Commission File No.: 001-34079

Rexahn Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**11-3516358**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*

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

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

Title of each class	**Name of each exchange on which registered**
Common Stock, $0.0001 par value per share	NYSE American

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 every Interactive Data File required to be submitted 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 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.

Large Accelerated Filer	☐	Accelerated Filer	☐
Non-Accelerated Filer	☐	Smaller reporting company	☑
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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, 2018, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was $44,699,663 based on the closing price reported on NYSE American.**

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 7, 2019**
Common Stock, $0.0001 par value per share	48,282,995 shares

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the registrant's Definitive Proxy Statement for its 2019 Annual Meeting of Shareholders, 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, 2018, 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," "may," "could," "intend" and other similar expressions, that are "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. We caution that forward-looking statements are based largely on our expectations and are subject to a number of known and unknown risks and uncertainties that are subject to change based on factors that are, in many instances, beyond our control. Actual results, performance or achievements may differ materially from those contemplated, expressed or implied by the forward-looking statements.

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

- our understandings and beliefs regarding the role of certain biological mechanisms and processes in cancer;
- our product candidates being in early stages of development, including in preclinical development;
- our ability to develop product candidates for orphan indications to take advantage of certain incentives provided by the U.S. Food and Drug Administration;
- our ability to transition from our initial focus on developing product candidates for orphan indications to candidates for more highly prevalent indications;
- our ability to successfully and timely complete clinical trials for our product candidates in clinical development;
- uncertainties related to the timing, results and analyses related to our product candidates in preclinical development;
- our ability to obtain the necessary U.S. and foreign regulatory approvals for our product 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 product candidates for our clinical trials;
- our ability to form strategic alliances and partnerships with pharmaceutical companies and other partners for sales and marketing of our product candidates, if approved;
- demand for and market acceptance of our product candidates, if approved;
- the scope and validity of our intellectual property protection for our product 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 developing innovative therapies to improve patient outcomes in cancers that are difficult to treat. 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 pipeline features two oncology product candidates in Phase 2 clinical development and additional compounds in preclinical development. Our strategy is to advance our existing product candidates and to continue building a pipeline of innovative oncology product candidates. Our clinical-stage product candidates in development are RX-3117 and RX-5902.

- RX-3117 is a novel, investigational oral small molecule nucleoside compound. Once intracellularly activated (phosphorylated) by the enzyme UCK2, it is incorporated into the DNA or RNA of cells and inhibits both DNA and RNA synthesis, which induces apoptotic cell death of tumor cells. 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, and we believe it has therapeutic potential in a broad range of cancers, including pancreatic, bladder, colon, lung and cervical cancer. In January 2018, we reported final data from a Phase 2a clinical trial of RX-3117 in patients with relapsed or refractory metastatic pancreatic cancer. In this trial evidence of tumor shrinkage was observed in some patients with metastatic pancreatic cancer that was resistant to gemcitabine and who had failed on multiple prior treatments. In this study, 31% of patients experienced progression free survival for two months or more and five patients, or 12%, had disease stabilization for greater than four months. RX-3117 is currently being evaluated in a Phase 2a clinical trial in combination with Celgene's ABRAXANE® (paclitaxel protein-bound particles for injectable suspension) as a first-line treatment in patients newly diagnosed with metastatic pancreatic cancer. Preliminary safety and efficacy data from this trial reported in January 2019 showed a 38% overall response rate in the 24 patients who had at least one scan on treatment and were included in the preliminary evaluation of overall response. The trial began dosing patients in this study in November 2017 and reached the target enrollment of 40 patients in February 2019. RX-3117 has received "orphan drug designation" from the U.S. Food and Drug Administration ("FDA") and from the European Commission ("EC") for pancreatic cancer. RX-3117 is also being evaluated in a Phase 2a clinical trial in advanced bladder cancer. We presented updated preliminary safety and efficacy data from this trial in February 2019.

- RX-5902 is a potential first-in-class small molecule modulator of the Wnt/beta-catenin pathway which plays a key role in cancer cell proliferation and tumor growth. RX-5902 modulates the pathway through inhibition of phosphorylated p68, a protein that helps to transport beta-catenin from the cytoplasm into the cell nucleus. Once inside the nucleus, beta-catenin turns on various oncogenes, thereby promoting cancer cell proliferation and tumor growth. We believe that by inhibiting phosphorylated p68, RX-5902 hinders the transport of beta-catenin into the nucleus and reduces the activation of cancer genes. In addition, multiple preclinical models have shown that RX-5902 activates the immune system against cancer and enhances the ability of immune cells to infiltrate the tumor and kill tumor cells. In preclinical models of colorectal and triple negative breast cancer ("TNBC"), the effects of RX-5902 were observed to be synergistic with other immunotherapy agents such as checkpoint inhibitors. We have evaluated RX-5902 in a Phase 1 dose escalation study in patients with a diverse range of metastatic, treatment-refractory tumors, including breast, ovarian, colorectal, and neuro-endocrine tumors. In February 2017, we initiated a Phase 2a clinical trial of RX-5902 in patients with metastatic TNBC. In August 2018, we entered into a collaboration with Merck Sharp & Dohme B.V. ("Merck") to evaluate the combination of RX-5902 and Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab) in a Phase 2 trial in patients with metastatic TNBC. In December 2018, we ceased enrollment in the ongoing Phase 2a monotherapy trial of RX-5902 in TNBC to focus RX-5902 development activities on planning the proposed combination trial with KEYTRUDA. We are currently evaluating the development strategy for RX-5902 and may or may not proceed with this trial.

- RX-0301 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. RX-0301 is the subject of a research and development collaboration with Zhejiang Haichang Biotechnology Co., Ltd. ("Haichang") for the development of RX-0301 to conduct certain preclinical and clinical activities through completion of a Phase 2a proof-of-concept clinical trial in hepatocellular carcinoma ("HCC"). RX-0301 is being developed as a nano-liposomal formulation of RX-0201 (Archexin®) using Haichang's proprietary QTsome™ technology. Rexahn was previously developing RX-0201 for the treatment of renal cell carcinoma ("RCC"). In February 2018, in response to the changing treatment landscape for metastatic RCC over the prior two years with the approval of new therapies by the FDA, we announced plans to discontinue the internally funded programs of RX-0201 and ceased enrolling patients in a Phase 2a proof-of-concept clinical trial of RX-0201 in patients with metastatic RCC. RX-0301 is currently in preclinical development.

Industry and Disease Markets

Market Overview

Our primary research and development focus is 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 claimed the lives of 600,000 Americans in 2015, the latest year for which incidence data is available, and is the second leading cause of death among Americans. The World Health Organization estimated that there were 18 million new cases of cancer diagnosed worldwide in 2018 and that cancer was responsible for 9.6 million deaths worldwide in 2018. A 2018 American Cancer Society report projected that an estimated 1.7 million new cancer cases would be diagnosed in the United States in 2018. The IQVIA Institute for Human Data Science reported in 2018 that total global spending on oncology medicines, including therapeutic treatments and supportive care, reached $133 billion in 2017.

Current Cancer Treatments

Traditional cancer treatments involve surgery, radiation therapy, and chemotherapy, either alone or in a combined approach. Surgery is widely used to treat cancer and may be curative for early disease but not 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. While for certain cancers and in certain patients, these drugs have limited efficacy, they also have debilitating and sometimes life-threatening side effects. Administration of cytotoxic cancer drugs may also result in the development of multi-drug resistance, a condition that results when certain tumor cells that have survived treatment with cytotoxic drugs are no longer susceptible to treatment by those and other drugs. Recent advances in cancer treatment include the use of targeted therapies and immunotherapies to stimulate the body's own immune system to kill cancer cells. Targeted therapies are directed against specific proteins (targets) that promote the growth of tumor cells and are overexpressed in cancer cells relative to normal tissue. Targeted therapies may be effective in killing tumors that overexpress the target protein, which are usually found in a subset of patients with any particular tumor type. Immunotherapy can significantly improve survival in certain cancers. However, for many common cancers, including pancreatic, breast cancer and colorectal cancer, immunotherapy has shown limited efficacy and there is a risk of over-stimulation of the immune system that can lead to life-threatening autoimmune side-effects, such as colitis, pneumonia, and hepatitis.

Unmet Needs in Cancer

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

- *Effective treatments for metastatic cancer:* There is a need for better treatments to prolong life and improve survival in patients diagnosed with late-stage cancers. In many cases, early stage cancer can be effectively treated with surgery and/or radiation and adjuvant drug treatment. However, once the tumor has metastasized, current treatments are usually not curative.

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

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

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

Market Opportunity

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

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

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

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

Our Strategy

Our mission is to identify, develop and, directly or through collaborations, bring to market novel products to improve patient outcomes in cancers that are difficult to treat. We currently have a portfolio of product candidates with the potential to address diseases for which the unmet medical need is high. Our goal is to be a leader in the development of novel therapeutics for cancer. Our strategy to achieve this goal is to utilize our experience and capabilities to:

- Advance our existing product candidates through late-stage clinical trials, generating meaningful clinical results;
- Work with U.S. and foreign regulatory authorities for expeditious, efficient development pathways toward registration;
- Use our industry relationships and experience to source, evaluate and in-license well-characterized product candidates to continue pipeline development; and
- Identify potential commercial or distribution partners for our products in relevant territories.

Our Pipeline Product Candidates

RX-3117: Oral Small Molecule Nucleoside Analogue

RX-3117 is a novel, investigational, oral small molecule nucleoside analogue. In preclinical models when activated (phosphorylated) by uridine-cytidine kinase 2, a protein that is overexpressed in various human cancer cells, RX-3117 was incorporated into DNA or RNA of cells and inhibited both DNA and RNA synthesis, which induced apoptotic cell death of tumor cells. We believe RX-3117 has therapeutic potential in a broad range of cancers including pancreatic, bladder, colon, lung and cervical cancer. RX-3117 has received orphan drug designation from the FDA and the EC for the treatment of patients with pancreatic cancer.

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

Final results from the Phase 1b clinical trial of RX-3117 presented in June 2016 showed evidence of single agent activity. Patients in the study had generally received four or more cancer therapies prior to enrollment. In this study, 12 patients experienced stable disease persisting for up to 276 days and three patients showed evidence of tumor burden reduction. A maximum tolerated dose of 700 mg was identified in the study. At the doses tested, RX-3117, administered orally, appeared to be safe and well-tolerated with a predictable pharmacokinetic profile following oral administration.

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

In September 2016, we initiated stage 2 of this Phase 2a clinical trial based on the satisfaction of the predefined criteria for preliminary signs of efficacy for stage 1 of the trial that showed RX-3117 appeared to be safe and well-tolerated with preliminary signs of efficacy in pancreatic cancer patients for whom three or more prior therapies had been ineffective. In January 2018, we presented the final data from this trial at the American Society of Clinical Oncology Gastrointestinal Cancers ("ASCO GI") Symposium. In this trial, evidence of tumor shrinkage was observed in some patients with metastatic pancreatic cancer that was resistant to gemcitabine and who had failed on multiple prior treatments. In this study, 31% of patients experienced progression free survival for two months or more and five patients, or 12%, had disease stabilization for greater than four months.

In November 2017, we initiated a Phase 2a trial of RX-3117 in combination with ABRAXANE in patients newly diagnosed with metastatic pancreatic cancer. The multicenter, single-arm, open-label study is designed to evaluate RX-3117 in combination with ABRAXANE in first-line metastatic pancreatic cancer patients. In February 2019, we reached the target enrollment of 40 evaluable patients in this trial. In January 2019, we presented preliminary safety and efficacy data at the 2019 ASCO GI Symposium. As of January 9, 2019, 36 patients were enrolled into the study, and 24 patients had at least one scan on treatment and were included in the evaluation of overall response. One patient (1/24, 4.2%) had a complete response after six cycles of treatment and eight patients (8/24, 33.3%) had a partial response. A further 13 patients had stable disease (13/24, 54.2%). The overall response rate was 38%, and the disease stabilization rate at eight weeks was 92%. The combination of RX-3117 and ABRAXANE appears to be safe and well-tolerated. The most commonly reported related adverse events were nausea, diarrhea, fatigue, alopecia, decreased appetite, rash, vomiting and anemia.

In September 2016, we commenced enrollment in a Phase 2a trial of RX-3117 in patients with advanced bladder cancer who had progressed on multiple prior treatments. This Phase 2a clinical trial is a multicenter, open-label, single-agent study of RX-3117 being conducted at 10 clinical centers in the United States. RX-3117 is being administered orally five times weekly on a three weeks on, one week off dosing schedule for up to eight weeks, or until patients' disease progresses. The primary endpoint for the trial is an assessment of the progression free survival rate or an objective clinical response rate and reduction in tumor size. Secondary endpoints include time to disease progression, overall response rate and duration of response, as well as pharmacokinetic assessments and safety. In February 2019, we presented data from this trial at the ASCO Genitourinary Cancers Symposium. Preliminary signs of efficacy, including a complete response, were observed. Of the 31 patients who had at least one scan on treatment and were therefore included in the preliminary efficacy analysis, five patients had stable disease for at least four months, two of whom stayed in the trial for six months or longer. Mild to moderate fatigue, nausea and diarrhea are the most common side effects observed in the trial to date. We are evaluating potential development paths for RX-3117 in advanced bladder cancer, however, no additional trials are currently planned for this indication.

RX-5902: Potential First-in-Class Inhibitor of Phosphorylated p68

RX-5902 is a potential first-in-class small molecule modulator of the Wnt/beta-catenin pathway. Activation of the Wnt/beta-catenin pathway is recognized to a key driver of cancer cell proliferation and tumor growth. Activation of the pathway leads to accumulation of beta-catenin in the nucleus of cancer cells that turns on cancer-related genes. RX-5902 inhibits a protein, phosphorylated p68, that helps to transport beta-catenin from the cytoplasm into the cell nucleus. Once inside the nucleus, beta-catenin turns on various oncogenes, thereby promoting cancer cell proliferation and tumor growth. By inhibiting phosphorylated p68, RX-5902 hinders the transport of beta-catenin into the nucleus, which results in decreased levels of beta catenin in the nucleus and in turn decreases the expression of cancer-related genes. In preclinical tissue culture models and *in-vivo* xenograft models, RX-5902 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 mouse models of human TNBC and pancreatic cancer, treatment with RX-5902 produced a dose-dependent inhibition of tumor growth and a survival benefit. In addition, multiple preclinical models have shown that RX-5902 activates the immune system against cancer and enhances the ability of immune cells to infiltrate the tumor and kill tumor cells In preclinical models of colorectal and TNBC, the effects of RX-5902 were observed to be synergistic with other immunotherapy agents such as checkpoint inhibitors.

RX-5902 was evaluated in a Phase 1 dose-escalation clinical trial in cancer patients with solid tumors designed to evaluate the safety, tolerability, dose-limiting toxicities and the recommended Phase 2 dose. Secondary endpoints include pharmacokinetic analyses and an evaluation of the preliminary anti-tumor effects of RX-5902. We completed enrollment in this study in 2016. Final results from the Phase 1 clinical trial of RX-5902 presented in September 2017 showed evidence of single-agent, clinical activity of RX-5902. In this study, RX-5902 preliminarily appeared to be safe and well-tolerated at the doses and dosing schedules tested with no dose limiting toxicities or treatment-related serious adverse events. The most frequently reported drug related adverse events were mild to moderate fatigue, nausea, and diarrhea. Thirty-nine subjects were enrolled (24 female, 15 male), of which 26 were evaluable. Fourteen subjects experienced stable disease in breast, neuroendocrine, paraganglioma, head/neck, ovarian or colorectal cancer. Three subjects received treatment for more than one year. Approximately 64% of the subjects, or 25 of 39, had received four or more therapies prior to their enrollment in the Phase 1 clinical trial.

We initiated a Phase 2a clinical trial of RX-5902 in patients with metastatic TNBC in February 2017. This trial was intended to evaluate preliminary signs of safety and efficacy of RX-5902 in patients who have failed prior treatments. As of October 12, 2018, 17 patients had been enrolled in the trial, with 13 of these patients evaluable and six showing a clinical response. In August 2018, we entered into a collaboration with Merck to evaluate the combination of RX-5902 and Merck's anti-PD-1 therapy, KEYTRUDA, in a Phase 2 trial in patients with metastatic TNBC. Data generated to date do not support further development of RX-5902 as a monotherapy for TNBC and in December 2018, we ceased enrollment in the ongoing Phase 2a trial to focus RX-5902 development activities on planning the proposed combination trial with KEYTRUDA. We are currently evaluating the development strategy for RX-5902 and may or may not proceed with this trial.

RX-0301: *Potential Best-in-Class Anti-Cancer Akt-1 Inhibitor*

RX-0301 is a potential best-in-class, potent anti-sense inhibitor of protein kinase Akt-1 synthesis and activity, which we believe plays a critical role in cancer cell proliferation, survival, angiogenesis, metastasis and drug resistance.

RX-0301 is being developed as a nano-liposomal formulation of RX-0201, an antisense oligonucleotide compound that is complementary to mRNA coding for Akt-1. RX-0201 binds to the mRNA, inhibiting transcription and production of the Akt-1 protein. RX-0201 preliminarily appeared to be safe and well-tolerated with minimal side effects in a Phase 1 trial in patients with advanced cancers, where Grade 3 fatigue was the only dose-limiting toxicity and no significant hematological abnormalities were observed. RX-0301 is being developed under a collaboration with Haichang using Haichang's proprietary QTsome™ technology. Under the agreement, Haichang intends to conduct a Phase 2a proof-of-concept clinical trial in HCC in China.

We completed a Phase 2a clinical trial for RX-0201 that was designed to assess the safety and efficacy of RX-0201 in combination with gemcitabine in patients with metastatic pancreatic cancer. RX-0201 appeared to be safe and well-tolerated with a preliminary indication of activity.

In January 2014, we initiated a Phase 2a proof-of-concept clinical trial of RX-0201 to study its safety and efficacy in combination with Novartis' Afinitor® (everolimus) in patients with RCC. In February 2018, following a portfolio review of assets and in response to the changing treatment landscape for RCC patients over the prior two years with the approval of new therapies by the FDA, we announced plans to discontinue the internally funded programs of RX-0201 and ceased enrolling patients in this trial.

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 preclinical 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

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We compete against fully integrated pharmaceutical companies and smaller companies, including smaller companies that are or may be 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 preclinical 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, 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.

There are currently marketed products and product candidates under development by our competitors that have similar mechanisms or action or target some of the same indications as our clinical stage product candidates. If approved, RX-3117 could compete with other compounds with an anti-metabolite mechanism of action in cancers, such as NUC-1031 (Acelarin®), which is under development by NuCana, and other approved nucleoside analogues such as capecitabine and gemcitabine. We are not currently aware of known inhibitors of phosphorylated p68 that would compete with RX-5902 if RX-5902 were approved, but other drugs with a different mechanism of action are approved or in development for the same indications, including AstraZeneca's LYNPARZA ® (olaparib), Immunomedics' sacituzumab govitecan and various PD-1 inhibitors, including Genentech's TECENTRIQ® (atezolizumab), that are in development for TNBC. If approved, RX-0301 could compete with other Akt-1 inhibitors under development by other companies including Merck & Company, Inc., GlaxoSmithKline, AstraZeneca, Gilead Sciences, MEI Pharma, PIQUR Therapeutics and others.

Government Regulation

Regulation by governmental authorities in the United States and in other countries is a significant consideration in our product development, manufacturing and, upon approval of our product candidates, marketing strategies. We expect that all our product 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 preclinical, clinical, and post-approval testing to demonstrate safety and effectiveness, as well as other significant regulatory requirements and restrictions in each jurisdiction in which we would seek to market our products. U.S. federal laws and regulations govern the testing, development, manufacture, quality control, safety, effectiveness, approval, storage, labeling, record keeping, reporting, distribution, import, export and marketing of all biopharmaceutical products intended for therapeutic purposes. We believe that we and the third parties that work with us are in compliance in all material respects with currently applicable rules and regulations, however, any failure to comply could have a material negative impact on our ability to successfully develop and commercialize our products, and therefore on our financial performance. In addition, the rules and regulations that apply to our business are subject to change. For example, in December 2016, the 21st Century Cures Act (the "Cures Act") was signed into law. The Cures Act included numerous provisions that may be relevant to our product candidates, including provisions designed to speed development of innovative therapies and provide funding for certain cancer-related research and technology development. Further legislative and regulatory changes appear possible in the 116th United States Congress and under the Trump Administration, and it is difficult to foresee whether, how, or when such changes may affect our business.

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

Development and Approval

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

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

IND Application. A person or entity sponsoring clinical trials in the United States to evaluate a candidate's safety and effectiveness must submit to the FDA, prior to commencing such studies, an investigational new drug ("IND") application, which contains preclinical 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 current good clinical practices ("cGCP") requirements, which establish standards for conducting, recording data from, and reporting the results of, clinical trials, with the goal of assuring that the data and results are credible and accurate and that study participants' rights, safety and well-being are protected. Each clinical trial must be conducted under a protocol that details the study objectives, parameters for monitoring safety and the efficacy criteria, if any, to be evaluated. The protocol is submitted to the FDA as part of the IND and reviewed by the agency before the study begins. Additionally, each clinical trial must be reviewed, approved and conducted under the auspices of an Institutional Review Board ("IRB"). The sponsor of a clinical trial, the investigators and IRBs each must comply with requirements and restrictions that govern, among other things, obtaining informed consent from each study subject, complying with the protocol and investigational plan, adequately monitoring the clinical trial, and timely reporting adverse events. Foreign studies conducted under an IND must meet the same requirements applicable to studies conducted in the United States. However, if a foreign study is not conducted under an IND, the data may still be submitted to the FDA in support of a product application, if the study was conducted in accordance with cGCP and the FDA is able to validate the data.

The sponsors of a clinical trial or the sponsor's designated responsible party may be required to register certain information about the trial and disclose certain results on government or independent registry websites, such as http://clinicaltrials.gov.

Clinical testing is typically performed in three phases, which may overlap or be subdivided in some cases.

In Phase 1, the drug is administered to a small number of human subjects to assess its safety and to develop detailed profiles of its pharmacological and pharmacokinetic actions (*i.e.*, absorption, distribution, metabolism and excretion). Although Phase 1 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 2, the drug is administered to a relatively small sample of the intended patient population to develop initial data regarding efficacy in the targeted disease, determine the optimal dose range, and generate additional information regarding the drug's safety. Additional animal toxicology studies may precede this phase. In some cases, Phase 2 testing can be split into Phase 2a and 2b studies in order to test smaller subject pools and to evaluate particular aspects of the drug product.

In Phase 3, the drug is administered to a larger group of patients, which may include patients with concomitant diseases and medications. Typically, Phase 3 trials are conducted at multiple study sites and may be conducted concurrently for the sake of time and efficiency. The purpose of Phase 3 clinical trials is to obtain additional information about safety and effectiveness necessary to evaluate the drug's overall risk-benefit profile and to provide a basis for product labeling. Phase 3 data often form the core basis on which the FDA evaluates a product candidate's safety and effectiveness when considering the product application.

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, preclinical 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 generally provide for action on an NDA within 12 months of its submission. That deadline can be extended under certain circumstances, including by the FDA's requests for additional information. The targeted action date can also be shortened to eight months after submission for products that are granted priority review designation because they are intended to treat serious or life-threatening conditions and demonstrate the potential to address unmet medical needs. The FDA has other programs to expedite development and review of product candidates that address serious or life-threatening conditions. For example, the Fast Track program is intended to facilitate the development and review of 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 review 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. Another FDA program intended to expedite development is Accelerated Approval, which allows approval on the basis of a surrogate endpoint that is reasonably likely to predict clinical benefit. 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, means that a drug will be eligible for all of the benefits of Fast Track designation, as well as 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 candidate qualifies for Fast Track designation or Breakthrough Therapy designation, the FDA may later decide that the product no longer meets the conditions for designation, and/or may determine that the product does not meet the standards for approval. As applicable, we anticipate seeking to utilize these programs to expedite the development and review of our product candidates, but we cannot ensure, that our product candidates will qualify for such programs.

If the FDA concludes that an NDA does not meet the regulatory standards for approval, it 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 resubmission 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 and increase our costs, such as a Risk Evaluation and Mitigation Strategy ("REMS"), and/or post-approval commitments to conduct additional clinical or non-clinical studies or to conduct surveillance programs to monitor the drug's effects.

Moreover, once a product is approved, information about its safety or effectiveness from broader clinical use may limit or prevent successful commercialization because of regulatory action or market forces or for other reasons. 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 product candidates, RX-0301 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 several ASO compounds in other therapeutic areas, such as 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, RX-0301 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 product 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 regulatory exclusivity under the under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"). The Hatch-Waxman Act provides periods of exclusivity for a branded drug product that would serve as a reference listed drug ("RLD") for a generic drug applicant filing an abbreviated new drug application ("ANDA") or for an applicant filing a 505(b)(2) NDA application. If such a product is a "new chemical entity" ("NCE") generally meaning that the active moiety has never before been approved in any drug—there is a period of five years from the product's approval during which the FDA may not accept for filing any ANDA or 505(b)(2) application for a drug with the same active moiety. An ANDA or 505(b)(2) application may be submitted after four years, however, if the sponsor of the application makes a Paragraph IV certification (as described below). Such a product that is not an NCE may qualify for a three-year period of exclusivity if its NDA contains new clinical data, derived from studies conducted by or for the sponsor, that were necessary for approval. In this instance, the three-year exclusivity period does not preclude filing or review of an ANDA or 505(b)(2) application; rather, the FDA is precluded from granting final approval to the ANDA or 505(b)(2) application until three years after approval of the RLD. This 3-year exclusivity applies only to the conditions of approval that required submission of the clinical data.

The Hatch-Waxman Act also provides for the restoration of a portion of the patent term lost during product development and FDA review of an NDA if approval of the application is the first permitted commercial marketing of a drug containing the active ingredient. The patent term restoration period is generally one-half the time between the effective date of the IND or the date of patent grant (whichever is later) and the date of submission of the NDA, plus the time between the date of submission of the NDA and the date of FDA approval of the product. The maximum period of restoration is five years, and the patent cannot be extended to more than 14 years from the date of FDA approval of the product. Only one patent claiming each approved product is eligible for restoration and the patent holder must apply for restoration within 60 days of approval.

Another form of regulatory exclusivity in the United States available is the Orphan Drug Act, which is available for drugs intended to treat rare diseases or conditions, which generally are diseases or conditions that affect fewer than 200,000 persons in the United States. If a sponsor demonstrates that a drug is intended to treat a rare disease or condition and meets other qualifying criteria, the FDA grants orphan drug designation to the product for that use. A product that has received orphan drug designation is eligible for research and development tax credits and is exempt from user fees under certain circumstances. Additionally, a drug that is the first to be approved for its orphan-designated indication generally receives seven years of orphan drug exclusivity. During that period, the FDA generally may not approve any other application for a product containing the same active moiety and proposed for the same indication. There are exceptions, however, most notably when the later product is shown to be clinically superior to the product with exclusivity. An approved orphan drug also may qualify for an exemption from the branded prescription drug fee. Products that qualify for orphan designation may also qualify for other FDA programs that are intended to expedite the development and approval process and, as a practical matter, clinical trials for orphan products may be smaller, simply because of the smaller patient population. Nonetheless, the same approval standards apply to orphan-designated products as for other drugs.

RX-3117 received orphan drug designation for pancreatic cancer from the FDA in September 2014.

A medicinal product may be granted an orphan designation in the EU if: (i) it would be used to treat or prevent a life-threatening or chronically debilitating condition and either affects no more than five in 10,000 people in the EU or for economic reasons would be unlikely to be developed without incentives; and (ii) no satisfactory method of diagnosis, prevention or treatment of the condition concerned exists, or, if such a method exists, the medicinal product would be of significant benefit to those affected by the condition. The application for orphan designation must be submitted to the European Medicines Agency ("EMA") and approved prior to market authorization. Once authorized, orphan medicinal products are entitled to ten years of market exclusivity. During this ten-year period, with limited exceptions, neither the competent authorities of the EU Member States, the EMA, nor the EC are permitted to accept applications or grant marketing authorization for other similar medicinal products with the same therapeutic indication. However, marketing authorization may be granted to a similar medicinal product with the same orphan indication during that period with the consent of the holder of the marketing authorization or if the manufacturer of the product is unable to supply sufficient quantities. Marketing authorization may also be granted to a similar medicinal product with the same orphan indication if the latter product is safer, more effective or otherwise clinically superior to the original product. The period of market exclusivity may be reduced to six years if it can be demonstrated on the basis of available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity.

RX-3117 received orphan designation from the EC in January 2018.

Competition. The Hatch-Waxman Act establishes two abbreviated approval pathways for drug products that are in some way follow-on versions of already approved branded NDA products: (i) generic versions of the approved RLD, which may be approved under an ANDA by showing that the generic product is the "same as" the approved product in key respects; and (ii) a product that is similar but not identical to the RLD, which may be approved under a 505(b)(2) NDA, in which the sponsor relies to some degree on the FDA's finding that the RLD is safe and effective, but submits its own product-specific data to support the differences between the product and the RLD.

The sponsor of an ANDA or 505(b)(2) application seeking to rely on an approved product as the RLD must make one of several certifications regarding each patent for the RLD that is listed in the FDA publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the *Orange Book*. A "Paragraph III" certification is the sponsor's statement that it will wait for the patent to expire before obtaining approval for its product. A "Paragraph IV" certification is an assertion that the patent does not block approval of the later product, either because the patent is invalid or unenforceable or because the patent, even if valid, is not infringed by the new product. Once the FDA accepts for filing an ANDA or 505(b)(2) application containing a Paragraph IV certification, the applicant must within 20 days provide notice to the RLD NDA holder and patent owner that the application has been submitted, and provide the factual and legal basis for the applicant's assertion that the patent is invalid or not infringed. If the NDA holder or patent owner files suit against the ANDA or 505(b)(2) applicant for patent infringement within 45 days of receiving the Paragraph IV notice, the FDA is prohibited from approving the ANDA or 505(b)(2) application for a period of 30 months or the resolution of the underlying suit, whichever is earlier.

Post-Approval Regulation

Once approved, drug 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 limiting, suspending or even withdrawing approval. In addition to FDA regulation, 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 seek sanctions, including fines, civil penalties, injunctions, suspension of manufacturing operations, imposition of operating restrictions, withdrawal of FDA approval, seizure or recall of products, and criminal prosecution. Although we periodically monitor FDA compliance of the third parties on which we rely for manufacturing our drug products, we cannot be certain that our present or future third-party manufacturers will consistently comply with cGMP or other applicable FDA regulatory requirements.

Sales and Marketing. Once a product is approved, its advertising, promotion and marketing will be subject to close regulation, including with regard to promotion to healthcare practitioners, direct-to-consumer advertising, communications regarding unapproved uses, industry-sponsored scientific and educational activities and promotional activities involving the internet. In addition to FDA restrictions on marketing of pharmaceutical products, state and federal fraud and abuse laws have been applied to restrict certain marketing practices in the pharmaceutical industry. Failure to comply with applicable requirements in this area may subject a company to adverse publicity, investigations and enforcement action by the FDA, the Department of Justice, the Office of the Inspector General of the Department of Health and Human Services, and/or state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug or biological products.

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. 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 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 and local 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 healthcare providers; and state and foreign laws that require drug manufacturers to report information related to clinical trials, or information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures;

- The federal Physician Payment Sunshine Act, being implemented as the Open Payments Program, which 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 CMS information related to direct or indirect payments and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held in the company by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives.

- 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 that may affect our business, including recently enacted laws in all jurisdictions where we operate. Numerous federal and state laws, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use and disclosure of personal information. Failure to comply with such laws and regulations could result in government enforcement actions and create liability for us (including the imposition of significant penalties), private litigation and/or adverse publicity that could negatively affect our business. In addition, if we successfully commercialize our product 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 of 2009 (collectively, "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 product 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 may 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.

Obtaining coverage and adequate reimbursement is a time-consuming and costly process. 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.

The Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "Affordable Care Act"), has substantially changed 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. Some of the provisions of the Affordable Care Act have yet to be fully implemented, and certain provisions have been subject to judicial and Congressional challenges. In addition, there have been efforts by the Trump Administration to repeal or replace certain aspects of the Affordable Care Act and to alter the implementation of the Affordable Care Act and related laws. For example, the Tax Cuts and Jobs Act, enacted on December 22, 2017, eliminated the tax-based shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code of 1986, commonly referred to as the individual mandate, effective January 1, 2019. Additional legislative changes, regulatory changes and judicial challenges related to the Affordable Care Act remain possible. Any such changes could decrease the number of individuals with health coverage. It is possible that the Affordable Care Act, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future could have a material adverse effect on our industry generally and on our ability to successfully commercialize our product candidates, if approved. In December 2018, a United States District Court Judge for the Northern District of Texas ruled that the entire Affordable Care Act is unconstitutional because the tax penalty associated with the individual mandate was repealed by Congress as part of the Tax Cuts and Jobs Act. This ruling is under appeal and stayed pending appeal. While the court, the Trump Administration and CMS have stated that the ruling will have no effect while this appeal is pending, it is unclear how this decision, subsequent appeals and other efforts to invalidate the Affordable Care Act, regulations promulgated under the Affordable Care Act or portions thereof will impact the Affordable Care Act and its implementation.

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 2027. Continuation of sequestration or enactment of other reductions in Medicare reimbursement for drugs could affect our ability to achieve a profit on any candidate products that are approved for marketing.

We expect that the Affordable Care Act, as well as other healthcare reform measures that have been adopted and may be adopted in the future, may result in more rigorous coverage criteria and new payment methodologies, and in additional downward pressure on coverage and payment and 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 product candidates progress, while we may build the infrastructure that would be needed to successfully market and sell any successful drug candidate on our own, we currently anticipate seeking strategic alliances and partnerships with third parties. The establishment of a sales and marketing operation can be expensive, complicated and time consuming and could delay any product candidate launch.

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 product 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, and store and distribute supplies of our product candidates for our clinical trials. If any of our product 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 product 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 product candidates that expire from 2023 to 2036. We hold U.S., European and Japanese patents for RX-3117, RX-5902 and RX-0301. In addition to these patents, we have issued or pending patents in other jurisdictions.

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

RX-3117:

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

RX-5902:

The RX-5902 patent portfolio consists of three patent families. The first family consists of patents that have been issued in the United States and Europe and are pending other jurisdictions. The patents in the first family include composition of matter, use and process claims of varying scope, including picture claims to RX-5902 or a pharmaceutically acceptable salt thereof. The patents in this first family expire in 2025 and may be extended up to five years in the United States. We also expect RX-5902 will be protected with market exclusivity in Europe for a minimum of ten years post-approval and in Japan for eight years. The second family consists of patents that are issued in the United States and Japan and pending in Europe and other jurisdictions. The patents in the second family include formulation and process claims that cover RX-5902. The patents in this second family would expire in 2034. The third family consists of a patent that is issued in the United States and pending elsewhere. The patent in the third family includes use claims that cover RX-5902. This patent will expire in 2036.

RX-0301:

The RX-0301 patent portfolio consists of a patent family that includes patents that have been issued in the United States, Europe, Japan and other jurisdictions. The patents in this family include composition of matter and use claims of varying scope, including picture claims to RX-0301 or a pharmaceutically acceptable salt thereof. The expiration date of these patents ranges from 2023 to 2025 and may be extended by up to five years in certain countries including the United States. In addition, it is expected that RX-0301 will be protected from generic launches by market and orphan designations for up to seven years in the United States, and ten years in Europe and Japan.

Collaboration and License Arrangements

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

Zhejiang Haichang Biotechnology Co., Ltd.

In February 2018, we entered into a research and development collaboration agreement with Haichang, a privately owned specialized biotechnology company incorporated in Hangzhou, China and focused on the development and manufacture of complex intravenous pharmaceutical products primarily for cancer treatment. Under the agreement, Haichang will develop RX-0301 using its proprietary QTsome™ technology and will conduct certain preclinical and clinical activities through completion of a Phase 2a proof-of-concept clinical trial in HCC in China. Haichang will fund all development activities through completion of the Phase 2a clinical trial up to an aggregate amount of $10,000,000 and the parties will share downstream licensing fees and royalties paid by third parties in an agreed ratio in connection with the further development and commercialization of RX-0301 for the treatment of HCC. If Haichang exercises its right of first negotiation after completion of the Phase 2a clinical trial to obtain an exclusive license to further develop and commercialize RX-0301 in China, Haichang will pay customary license fees, milestone payments and royalties to us. Any clinical trials conducted by Haichang will be designed to meet both FDA and China Food and Drug Administration requirements.

Merck Sharp & Dohme B.V.

In August 2018, we entered into a clinical trial collaboration and supply agreement with Merck to conduct a Phase 2 clinical trial to evaluate the safety and efficacy of the combination of RX-5902 with Merck's anti-PD-1 therapy, KEYTRUDA, in patients with metastatic TNBC. Under the terms of the agreement, we will sponsor the clinical trial and Merck will supply us with KEYTRUDA for use in the trial. The agreement provides that the parties will jointly own clinical data generated from this trial. We are currently evaluating the development strategy for RX-5902 and may or may not proceed with this trial.

Rexgene Biotech Co., Ltd. ("Rexgene") and NEXT BT Co. Ltd ("Next BT")

In February 2003, we entered into a research collaboration agreement with Rexgene, which agreed to assist us with the research, development and clinical trials necessary for registration of RX-0201 in Asia. Under the agreement, we granted Rexgene an exclusive license, with right to sublicense, to make, have made, use, sell and import RX-0201 in Asia. In accordance with the agreement, Rexgene paid us a one-time fee of $1,500,000 in 2003.

On February 5, 2018, we entered into a royalty and release agreement with Next-BT, the successor in interest to Rexgene. In exchange for Next BT terminating its rights to RX-0201 in Asia, we agreed to pay Next BT a royalty in the low single digits of any net sales of RX-0201 we make in Asia and 50% of our licensing revenue related to licensing of RX-0201 in Asia, up to an aggregate of $5,000,000. The agreement will terminate upon the earlier of Next BT's receipt of $5,000,000 under the agreement, February 5, 2025 if Next BT has received at least $3,000,000 under the agreement by that date, and the date after February 5, 2025 that Next BT has received cumulative payments of $3,000,000 under the agreement. On June 18, 2018, we amended the royalty and release agreement with Next BT, to reinstate the exclusive license to RX-0201 in Asia. We retained the rights to RX-0301 in Asia and elsewhere.

Korea Research Institute of Chemical Technology ("KRICT")

In June 2009, we entered into a license agreement with KRICT to acquire rights to all of KRICT's intellectual property related to quinoxaline-piperazine derivatives, which includes RX-5902. We paid an initial license fee of $100,000 in July 2009, and will pay a one-time milestone payment of $1,000,000 to KRICT upon marketing approval from FDA for the first commercial product stemming from licensed intellectual property (the "Milestone Payment"). Upon payment of the Milestone Payment all of the rights previously licensed to us will be transferred to us and the agreement will terminate. The agreement is terminable by either party for the other party's material breach, subject to a 60-day cure period. To date, we have paid only the $100,000 initial license fee pursuant to this agreement.

The University of Maryland Baltimore ("UMB")

In July 2013, we entered into an exclusive license agreement with UMB for a novel drug delivery platform, Nano-Polymer-Drug Conjugate Systems. In December 2018, we terminated this agreement to focus resources on the development of RX-3117 and RX-5902.

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. In December 2018, we terminated this agreement to focus resources on the development of RX-3117 and RX-5902.

Total Research and Development Costs

We have incurred research and development costs of $13,109,058 and $10,715,296, for the years ended December 31, 2018 and 2017, respectively. Research and development costs primarily consist of clinical trials and preclinical development costs, as well as payroll costs for research and development personnel.

Employees

As of February 28, 2019, we employed 10 individuals, all of whom are full-time employees. We have never had a work stoppage, and none of our employees are represented by a labor organization or covered by collective bargaining arrangements. We consider our relationship with our employees to be good.

Corporate Information

We are a Delaware corporation and trace our history to the March 2001 founding of Rexahn, Corp. Our principal executive offices are located at 15245 Shady Grove Road, Suite 455, Rockville, Maryland 20850. Our website address is www.rexahn.com. Information found on, or that can be accessed through, our website is not part of this Annual Report on Form 10-K (this "Annual Report").

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 product 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, and it may be more difficult to pursue our strategy to develop our pipeline. We will first reduce research and development activities associated with any preclinical 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 product candidate development, clinical trial and research and development efforts, including clinical trials for other new product candidates, as well as other research and development projects.

We will need additional financing to continue to develop our product 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 preclinical and clinical trials or obtain approval of our product 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.

Since our inception, we have incurred significant net losses. Our accumulated deficit as of December 31, 2018 and 2017 was $154,687,242 and $140,318,712, respectively. For the years ended December 31, 2018 and 2017, we had net losses of $14,368,530 and $25,294,503, respectively. Even if we succeed in developing and commercializing one or more of our product 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, including related to:

- continued preclinical development and clinical trials for our current and new product candidates;

- finding and maintaining suitable partnerships to help us research, develop and commercialize product candidates;
- efforts to seek regulatory approvals for our product 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, it may be more difficult to pursue our strategy to develop our pipeline, 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.

Our ability to continue as a going concern will require us to raise additional capital to fund our current operations, which may be unavailable on acceptable terms, or at all.

We have incurred negative cash flow from operations since we started our business and have an accumulated deficit. As disclosed in our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2018, we concluded at the time of filing that report that substantial doubt existed about our ability to continue as a going concern within one year from the issuance date of the financial statements contained in that report. We currently believe, based on our projected operating expenses, that our cash, cash equivalents and marketable securities, including the proceeds received from our underwritten public offering in January 2019, will be sufficient to fund current operations for at least the next 12 months following the issuance of the financial statements contained in this Annual report. Our ability to continue as a going concern in the near term is largely dependent on our actual expenses, business decisions and our ability to obtain additional capital, and over time will be impacted by our ability to attain operating efficiencies, control expenditures, and, ultimately, to generate revenue. However, no assurance can be given that additional financing will be available, or, if available, will be on terms acceptable to us. Our financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern

We have a limited operating history, we have no products approved for sale and we have not demonstrated an ability to commercialize product candidates.

We are a clinical-stage company with a limited number of product 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 product candidates. The successful commercialization of our product candidates will require us to first perform a variety of functions, including:

- successfully conducting preclinical and clinical trials;
- obtaining regulatory approval;
- 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 product candidate research and development, including preclinical studies and clinical trials of our principal product candidates. These operations provide a limited basis for assessing our ability to commercialize product candidates.

We will be unable to issue additional shares for future capital raising transactions or strategic transactions unless we obtain stockholder approval to amend our certificate of incorporation to increase the number of authorized shares of our common stock available for issuance.

We have 75,000,000 authorized shares of common stock. As of February 11, 2019, we had 48,277,420 shares of common stock outstanding, 26,435,515 shares of common stock issuable upon the exercise of outstanding stock options, settlement of restricted stock units or exercise of outstanding warrants, and 283,729 shares of common stock reserved for future issuance under our stock option plans. As a result, as of February 11, 2019, we had approximately 3,336 shares of authorized shares of common stock available for issuance. We will be limited by the number of additional shares available for future capital raising transactions or strategic transactions unless we obtain stockholder approval of an amendment to our certificate of incorporation to implement a reverse stock split without a corresponding reduction in the number of authorized shares of common stock or to increase the number of authorized shares of common stock. We have solicited the approval of our stockholders to amend our certificate of incorporation for a reverse stock split, but we cannot be certain that our stockholders will approve the amendment. A delay in securing, or a failure to secure, stockholder approval to amend our certificate of incorporation could cause a delay in our future capital raising, collaboration, partnership or other strategic transactions, and may have a material adverse effect on our business and financial condition.

If we fail to comply with the continued listing standards of NYSE American, our common stock could be delisted. If it is delisted, our common stock and the liquidity of our common stock would be impacted.

Our common stock is listed on NYSE American, and the continued listing of our common stock on NYSE American is subject to our compliance with a number of listing standards. For example, Section 1003(f)(v) of the NYSE American Company Guide provides that a company's common stock may be delisted from NYSE American if it sells for a substantial period of time at a low price per share and the company fails to effect a reverse stock split or otherwise demonstrate sustained price improvement within a reasonable time after being notified that NYSE American deems such action to be appropriate under all the circumstances. There is no assurance that the market price of our common stock will remain at the level required to remain in compliance with NYSE American listing standards or that we will otherwise remain in compliance with NYSE American listing standards.

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

Risks Related to Our Business

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

Our product 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.

Human clinical trials are 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. We estimate that clinical trials of our current product candidates will take multiple years to complete. 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:

- the cost of preclinical studies and clinical trials may be greater than we anticipate;
- 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 CROs 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, including 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 CROs to meet their contractual obligations or deadlines;
- the need to modify a study protocol;
- negative or inconclusive results during clinical trials, including the emergence of dosing issues, unforeseen safety issues or lack of effectiveness;
- changes in the standard of care of the indication being studied;
- reliance on third-party suppliers for the clinical trial supply of product 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 for various reasons, including if it appears that the clinical trial is exposing participants to unacceptable health risks or if the FDA finds deficiencies in our IND applications or the conduct of the trial. If we experience delays in the completion of, or the termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates or result in early termination of development of our product candidates.

Preclinical studies and preliminary and interim data from clinical trials of our product candidates are not necessarily predictive of the results or success of ongoing or later clinical trials of our product candidates. If we cannot replicate the results from our preclinical studies and initial clinical trials of our product candidates in later clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize our product candidates for any particular use, if at all.

Preclinical studies and any positive preliminary and interim data from our clinical trials of our product candidates may not necessarily be predictive of the results of ongoing or later clinical trials. A number of companies in the pharmaceutical and biotechnology industries, including us and many other companies with greater resources and experience than we, have suffered significant setbacks in clinical trials, even after seeing promising results in prior clinical trials. Even if we are able to complete our planned clinical trials of our product candidates according to our current development timeline, initial positive results from clinical trials of our product candidates may not be replicated in subsequent clinical trial results. The design of our later stage clinical trials could differ in significant ways (e.g., inclusion and exclusion criteria, endpoints, statistical analysis plan) from our earlier stage clinical trials, which could cause the outcomes of the later stage trials to differ from those of our earlier stage clinical trials. If we fail to produce positive results in our planned clinical trials of any of our product candidates, the development timeline and regulatory approval and commercialization prospects for our product candidates, and, correspondingly, our business and financial prospects, would be materially adversely affected.

If the results of our clinical trials fail to support the approval of any of our product 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 product candidates. Success in preclinical 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 preclinical testing. The clinical trial process may fail to demonstrate that one or more of our product candidates are safe and effective for indicated uses. As a result, we may have to conduct additional clinical trials or may decide to abandon a product 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 product candidates and generate product revenues.

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

We will need FDA approval to commercialize our product candidates in the United States and approvals from the comparable regulatory authorities to commercialize our product 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 product 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 product 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 product candidates, RX-0301, is in the drug class known as Akt-1 inhibitors that to date have not been approved by the FDA, and we have not submitted an NDA for any 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 trial results 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 preclinical 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 preclinical 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.

Any of our product candidates may cause undesirable side effects or have other properties that could delay or prevent its regulatory approval, limit its commercial viability, or result in significant negative consequences following any marketing approval.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authority. Side effects could affect patient recruitment, the ability of enrolled subjects to complete the trial, and/or result in potential product liability claims. Results of our trials could reveal an unacceptably high severity and prevalence of side effects. In such an event, our trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development or deny approval of our product candidates for any or all targeted indications. If we do not receive approval to market any product candidates, we will be unable to generate revenues from those product candidates and this may prevent us from achieving profitability.

Additionally, if any of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result, including:

- we may suspend marketing of such product;
- regulatory authorities may withdraw their approvals of such product;
- regulatory authorities may require additional warnings on the label that could diminish the usage or otherwise limit the commercial success of such products;
- we may be required to develop a REMS for such product or, if a REMS is already in place, to incorporate additional requirements under the REMS, or to develop a similar strategy as required by a comparable foreign regulatory authority;
- we may be required to conduct post-market studies;
- we could be sued and held liable for harm caused to subjects or patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and may harm our business, financial condition and prospects significantly.

We are developing RX-3117, and may develop other product candidates, in combination with other therapies, which exposes us to additional regulatory risks.

We are developing RX-3117 in combination with ABRAXANE and may develop other product candidates in combination with one or more currently approved cancer therapies. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risk that the FDA or comparable foreign regulatory authorities could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. This could result in our own products being removed from the market or being less successful commercially. Combination therapies are commonly used for the treatment of cancer, and we would be subject to similar risks if we develop any of our product candidates for use in combination with other drugs or for indications other than cancer.

We may also evaluate product candidates in combination with one or more other cancer therapies that have not yet been approved for marketing by the FDA or comparable foreign regulatory authorities. We will not be able to market and sell any product candidate we develop in combination with any such unapproved cancer therapies that do not ultimately obtain marketing approval.

If the FDA or comparable foreign regulatory authorities do not approve, or revoke their approval of, or if safety, efficacy, manufacturing or supply issues arise with, the products and product candidates we choose to evaluate in combination with our product candidates, we may be unable to obtain approval of or market our product candidates.

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 product candidates 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 one use of RX-3117 and in the future may obtain additional orphan drug designation for RX-3117 or any of our 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 we fail to obtain regulatory approval in jurisdictions outside the United States, we will not be able to market our products in those jurisdictions.

We intend to seek regulatory approval for our product candidates in a countries outside of the United States, such as China, and expect that these countries will be important markets for our product candidates, if approved. Marketing our products in these countries will require separate regulatory approvals in each market and compliance with numerous and varying regulatory requirements. The regulations that apply to the conduct of clinical trials and approval procedures vary from country to country and may require additional testing. Moreover, the time required to obtain approval in other jurisdictions may differ from that required to obtain FDA approval. In addition, in many countries outside the United States, a drug must be approved for reimbursement before it can be approved for sale in that country. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. Failure to obtain regulatory approval in one country may have a negative effect on the regulatory approval process in others. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any foreign market. If we are unable to obtain approval of any of our product candidates by regulatory authorities in jurisdictions outside the United States, the commercial prospects of that product candidate may be diminished and our business prospects could be adversely impacted.

The market opportunities for any current or future product candidate we develop, if approved, may be limited to those patients who are ineligible for established therapies or for whom prior therapies have failed, and may be small.

Any revenue we are able to generate in the future from product sales will be dependent, in part, upon the size of the market in the United States and any other jurisdiction for which we gain regulatory approval and have commercial rights. If the markets or patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, even if approved.

Cancer therapies are sometimes characterized as first-line, second-line, or third-line, and the FDA often approves new therapies initially only for third-line use. When cancer is detected early enough, first-line therapy, usually chemotherapy, hormone therapy, surgery, radiation therapy or a combination of these, is sometimes adequate to cure the cancer or prolong life without a cure. Second- and third-line therapies are administered to patients when prior therapy is not effective. We may initially seek approval for other product candidates as therapies for patients who have received one or more prior treatments. If we do so, for those products that prove to be sufficiently beneficial, if any, we would expect to seek approval potentially as a first-line therapy, but there is no guarantee that any product candidate we develop, even if approved, would be approved for first-line therapy, and, prior to any such approvals, we may have to conduct additional clinical trials.

The number of patients who have the types of cancer we are targeting may turn out to be lower than expected. Additionally, the potentially addressable patient population for our current or future product candidates may be limited, if and when approved. Even if we obtain significant market share for any product candidate, if and when approved, if the potential target populations are small, we may never achieve profitability without obtaining marketing approval for additional indications, including to be used as first- or second-line therapy.

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 product 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 product 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.

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.

The Affordable Care Act substantially changed 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.

Some of the provisions of the Affordable Care Act have yet to be fully implemented, and certain provisions have been subject to judicial and Congressional challenges. In addition, there have been efforts by the Trump Administration to repeal or replace certain aspects of the Affordable Care Act and to alter the implementation of the ACA and related laws. For example, the Tax Cuts and Jobs Act, enacted on December 22, 2017, eliminated the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code of 1986, commonly referred to as the individual mandate, beginning in 2019. In addition, in December 2018, a United States District Court Judge for the Northern District of Texas ruled that the entire Affordable Care Act is unconstitutional because the tax penalty associated with the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act. This ruling is under appeal and stayed pending appeal. While the court, the Trump Administration and CMS have stated that the ruling will have no effect while this appeal is pending, it is unclear how this decision, subsequent appeals and other efforts to invalidate the Affordable Care Act, regulations promulgated under the Affordable Care Act or portions thereof will impact the Affordable Care Act and its implementation. Additional legislative changes, regulatory changes and judicial challenges related to the Affordable Care Act remain possible. Any such changes could decrease the number of individuals with health coverage. It is possible that the Affordable Care Act, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future could have a material adverse effect on our industry generally and on our ability to successfully commercialize our product candidates, if approved.

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 2027. 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.

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.

We depend on our information technology systems, and any failure of these systems could harm our business. Security breaches, loss of data, and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business, results of operations and financial condition.

Despite the implementation of security measures, our internal computer systems, and those of our collaborators, our CROs and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs and business operations. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts for our product candidates and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the further development of our product candidates could be delayed or our commercial operations could be impacted. Moreover, if a computer security breach affects our systems or results in the unauthorized release of personally identifiable information, our reputation could be materially damaged. In addition, such a breach may require notification to governmental agencies, the media or individuals pursuant to various federal and state privacy and security laws, if applicable.

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

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

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

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

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

- the federal civil False Claims Act imposes penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement material to an obligation to pay money to the government or knowingly concealing or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government;

- 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 and its implementing regulations also impose 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 Physician Payment Sunshine Act, being implemented as the Open Payments Program, which 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 CMS information related to direct or indirect payments and other transfers of value to physicians and teaching hospitals (and certain other practitioners beginning in 2022), as well as ownership and investment interests held in the company by physicians 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 clinical trials, or 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."

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations. We can face serious consequences for violations.

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations ("Trade Laws") prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors and other partners from authorizing, promising, offering, providing, soliciting or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector.

Our business is heavily regulated and therefore involves significant interaction with public officials. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated organizations, including outside of the United States. We have engaged or plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents or partners, even if we do not explicitly authorize or have prior knowledge of such activities. Our operations are subject to the U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits, among other things, U.S. companies and their employees and agents from authorizing, promising, offering or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government-owned or affiliated entities, candidates for foreign political office, and foreign political parties or officials thereof. Recently, the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents, suppliers, manufacturers, contractors or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws.

Violations of Trade Laws could result in fines, criminal sanctions against us, our officers or our employees, the closing down of facilities, including those of our suppliers and manufacturers, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs and prohibitions on the conduct of our business. Such violations could also result in prohibitions on our ability to offer our products in one or more countries as well as difficulties in manufacturing or continuing to develop our products, and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results and financial condition.

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

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We compete against fully integrated pharmaceutical companies and smaller companies, including smaller companies that are or may be 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 preclinical 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, 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.

There are currently marketed products and product candidates under development by our competitors that have similar mechanisms of action or target some of the same indications as our clinical stage product candidates. If approved, RX-3117 could compete with other compounds with an anti-metabolite mechanism of action in cancers, such as NUC-1031 (Acelarin), which is under development by Cunanan, and other approved nucleoside analogues such as capecitabine and gemcitabine. We are not currently aware of known inhibitors of phosphorylated p68 that would compete with RX-5902 if RX-5902 were approved, but other drugs with a different mechanism of action are approved or in development for the same indications, including AstraZeneca's LYNPARZA (olaparib), Immunomedics' sacituzumab govitecan and various PD-1 inhibitors, including Genentech's TECENTRIQ (atezolizumab), that are in development for TNBC. If approved, RX-0301 could compete with other Akt-1 inhibitors under development by other companies including Merck & Company, Inc., GlaxoSmithKline, AstraZeneca, Gilead Sciences, MEI Pharma, PIQUR Therapeutics and others.

Our competitors may succeed in obtaining regulatory approval of their products more rapidly than we are able to, obtaining patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates, or developing products that are more effective and/or safer than ours, any of which could render our product candidates less competitive prior to recovery by us of expenses incurred with respect to their development and could lead us to alter our business plans or development strategies. For example, in response to the changing treatment landscape for renal cell carcinoma ("RCC") patients over the prior two years with the approval of new therapies by the FDA, in February 2018, we announced plans to discontinue the internally funded programs of RX-0201 and ceased enrolling patients in a Phase 2a proof-of-concept clinical trial of RX-0201 in patients with metastatic RCC.

We may expend our limited resources to pursue a particular product candidate and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on specific product candidates, indications and development programs. As a result, we may forgo or delay pursuit of opportunities with other product candidates that could have had greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through future collaborations, licenses and other similar arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. If we are unable to manage our limited resources effectively, we may not efficiently use these resources, which may delay the development of our product candidates and negatively impact our business, results of operations and financial condition.

We may not be successful in obtaining the rights to product candidates to continue building our development pipeline, or these in-licenses may not be successful.

In addition to our own internally developed product candidates, we are seeking opportunities to acquire or in-license compounds in oncology and other therapeutic areas that are strategic additions to our current product pipeline, which entails additional risk to us. Identifying, selecting and acquiring promising product candidates requires substantial technical, financial and human resources expertise. We may be unable to acquire or in-license any product candidates from third parties, including because we are focusing on a specific area of care and we may be unable to identify product candidates that we believe are an appropriate strategic fit for our company. In addition, efforts to do so may not result in the actual acquisition or license of a particular product candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit.

The in-licensing and acquisition of product candidates is a competitive area, and a number of more established companies are also pursuing strategies to in-license or acquire product candidates that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. Furthermore, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to in-license or acquire the relevant product candidate on terms that would allow us to make an appropriate return on our investment.

If we are unable to identify programs that ultimately result in approved products, we may spend material amounts of our capital and other resources evaluating, acquiring and developing products that ultimately do not provide a return on our investment. Such additional product candidates could significantly increase our capital requirements and place further strain on our limited resources, including on the time of our existing personnel, which may delay or otherwise adversely affect the development of our existing product candidates.

We are dependent on our executives and other key professionals and the loss of any of these individuals could harm our business.

We are dependent on the efforts of our executives, including: our President and Chief Executive Officer, Douglas J. Swirsky; our Chief Business Officer, Lisa Nolan; and other key personnel. The loss of any of these individuals, or our inability to recruit and train additional key personnel in a timely manner, could materially and adversely affect our business and our prospects. All our employees, including our chief executive officer, are employed "at-will," and any of them may elect to pursue other opportunities at any time. For example, we announced in March 2019 that Ely Benaim, M.D. resigned as Chief Medical Officer effective March 31, 2019. We have no present intention of obtaining key man life insurance on any of our executive officers or key professionals.

We may need to attract, train and retain additional experienced executives and other key professionals in the future.

In the future, we may need to attract, train and retain additional executives and other key professionals. There is a high demand for experienced executive, scientific, manufacturing and quality personnel in our industry, and competition for such individuals is intense. For example, our Chief Medical Officer recently announced that he was leaving our company to work for another company. We do not know whether we will be able to attract, train and retain such experienced personnel to support our business activities and research and development activities, which could have a material adverse effect on our business, financial condition and results of operations.

New or future changes to tax laws could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law new legislation that significantly revises the Internal Revenue Code of 1986, as amended. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted taxable income (except for certain small businesses), effective for net operating losses incurred in taxable years beginning after December 31, 2017, limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain, and our business and financial condition could be adversely affected. In addition, it is uncertain how various states will respond to the newly enacted federal tax law. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse.

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 partners. Although we currently carry clinical trial insurance and product liability insurance we, or any collaborators, may not be able to maintain such insurance at a reasonable cost. Even if our agreements with any future collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claims arise.

Risks Related to Reliance on Third Parties

Much of our drug development program depends upon third parties, and if these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for, or commercialize, our product candidates, and our business could be substantially harmed.

We have engaged third-party CROs and other investigators and collaborators, such as universities, medical institutions and other life science companies, to conduct our preclinical studies, toxicology studies and clinical trials, and to pursue development for our product candidates. For example, in February 2018, we entered into a research collaboration and license agreement with Zhejiang Haichang Biotechnology Co., Ltd. ("Haichang") pursuant to which Haichang will develop RX-0301 and will conduct certain preclinical and clinical activities through completion of a Phase 2a proof-of-concept clinical trial in hepatic cell carcinoma in China. Engaging third parties, or collaborating with third parties, is typical practice in our industry. However, relying on such organizations means that the conduct of clinical trials and other studies, and 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 efforts to oversee the work of third-party contractors, these collaborators are not our employees, and except for remedies available to us under our agreements with such third parties, 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. In addition, we are responsible for ensuring that each of our clinical and nonclinical studies is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, such as cGCP and good laboratory practice, and our reliance on collaborators and CROs does not relieve us of our regulatory responsibilities. If we or any of our collaborators or CROs fail to comply with applicable cGCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with cGCP requirements. Failure to comply with these regulations may require us to repeat preclinical and clinical trials, which would delay the regulatory approval process and our ability to generate and grow revenues.

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 or unsuccessful. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed. For example, the success of the Haichang agreement depends on, among other things, the skills, experience and efforts of Haichang, Haichang's commitment to the arrangement, and the financial condition of Haichang, all of which are beyond our control. In the event that Haichang fails to successfully develop or commercialize RX-0301, including due to early termination of the Haichang agreement, our ability to obtain license fees, milestone payments and royalties would be adversely affected, which could have an adverse effect on our financial condition and results of operation. Our 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.

If we lose our relationships with CROs, our drug development efforts could be delayed.

We rely on third-party vendors and CROs for preclinical studies and clinical trials related to our drug development efforts. Switching or adding additional CROs involves additional cost, requires management time and focus and could result in substantial delays in our development programs. Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors, or if we are liquidated. Identifying, qualifying and managing the performance of third-party service providers can be difficult, time consuming and cause delays in our development programs. In addition, there is a natural transition period when a new CRO commences work and the new CRO may not provide the same type or level of services as the original provider. If any of our relationships with our third-party CROs terminates, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms.

We rely exclusively on third parties to formulate and manufacture our product 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 product 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 product candidates for our clinical trials. If any of our product 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 candidate, and we have no long-term supply arrangements.

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

- We may be unable to contract with third-party manufacturers on acceptable terms, or at all, because the number of potential manufacturers is limited. Potential manufacturers of any product candidate that is approved will be subject to FDA compliance inspections and any new manufacturer would have to be qualified to produce our products;

- 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 direct 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.

If our contract manufacturers or other third parties fail to deliver our product candidates for clinical investigation and, if approved, for commercial sale on a timely basis, with sufficient quality, and at commercially reasonable prices, we may be required to delay or suspend development and commercialization of our product candidates. For example, our clinical trials must be conducted with product that complies with cGMP. Failure to comply may require us to repeat or conduct additional preclinical and/or clinical trials, which would increase our development costs and delay the regulatory approval process and our ability to generate and grow revenues.

In addition, any significant disruption in our supplier relationships could harm our business. We source key materials from third parties, either directly through agreements with suppliers or indirectly through our manufacturers who have agreements with suppliers. There are a small number of suppliers for certain capital equipment and key materials that are used to manufacture our product candidates. Such suppliers may not sell these key materials to our manufacturers at the times we need them or on commercially reasonable terms. We do not have any control over the process or timing of the acquisition of these key materials by our manufacturers. Moreover, we currently do not have agreements for the commercial production of a number of these key materials which are used in the manufacture of our product candidates. Any significant delay in the supply of a product candidate or its key materials for an ongoing clinical study could considerably delay completion of our clinical studies, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these key materials for our product candidates after regulatory approval, the commercial launch of our product candidates could be delayed or there could be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates, if approved.

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

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

Risks Related to Our Intellectual Property

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

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

- the degree and range of protection any patents will afford us against competitors, including whether third parties find ways to invalidate or otherwise circumvent our licensed patents;
- if and when patents will issue in the United States or any other country;
- whether or not others will obtain patents claiming aspects similar to those covered by our licensed patents and patent applications;
- whether we will need to initiate litigation or administrative proceedings to protect our intellectual property rights, which may be costly whether we win or lose;
- whether any of our patents will be challenged by our competitors alleging invalidity or unenforceability and, if opposed or litigated, the outcome of any administrative or court action as to patent validity, enforceability or scope;
- whether a competitor will develop a similar compound that is outside the scope of protection afforded by a patent or whether the patent scope is inherent in the claims modified due to interpretation of claim scope by a court;
- whether there were activities previously undertaken by a licensor that could limit the scope, validity or enforceability of licensed patents and intellectual property; or
- whether a competitor will assert infringement of its patents or intellectual property, whether or not meritorious, and what the outcome of any related litigation or challenge may be.

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

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

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

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

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act (the "America Invents Act"), the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The America Invents Act also includes a number of significant changes that affect the way patent applications are prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the U.S. Patent and Trademark Office ("USPTO") during patent prosecution and additional procedures to attack the validity or ownership of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review and derivation proceedings. The America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. Recent rulings from the U.S. Court of Appeals for the Federal Circuit and the U.S. Supreme Court have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

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

Filing, prosecuting and enforcing patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States are and could remain less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may be less likely to be able to prevent third parties from infringing our patents in all countries outside the United States, or from selling or importing products that infringe our patents in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

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 product 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 product 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 stockholder and interest on bank account balances and short-term investments. Our accumulated deficit as of December 31, 2018 and 2017 was $154,687,242 and $140,318,712 respectively. For the years ended December 31, 2018 and 2017, we had net losses of $14,368,530 and $25,294,503, 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 product 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 product 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.

Our corporate headquarters are currently located in Rockville, Maryland and consist of approximately 7,193 square feet of leased office space under a lease that expires in June 2019. We believe that these facilities are adequate for our current needs and that suitable additional or substitute space will be available in the future if needed.

Item 3. Legal Proceedings.

From time to time, we may become engaged in litigation or other legal proceedings as part of our ordinary course of business. We are not currently party to any litigation or legal proceedings that, in the opinion of management, are likely to have a material adverse effect on our business.

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 NYSE American, under the ticker symbol “RNN”. As of March 7, 2019, there were approximately 54 stockholders of record of our common stock.

Purchase of Equity Securities by the Issuer and Affiliated Purchasers

There were no repurchases of equity securities in 2018.

Recent Sales of Unregistered Equity Securities

None.

Item 6. Selected Financial Data.

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

	For the Year Ended December 31,				
Statement of Operations Data:	2018	2017	2016	2015	2014
Revenues	$ -	$ -	$ -	$ -	$ -
Expenses:					
General and administrative	7,428,615	6,639,421	6,324,236	6,115,210	6,253,328
Research and development	13,109,058	10,715,296	10,089,149	12,148,226	7,015,901
Total expenses	20,537,673	17,354,717	16,413,385	18,263,436	13,269,229
Loss from operations	(20,537,673)	(17,354,717)	(16,413,385)	(18,263,436)	(13,269,229)
Other Income (Expense), net	6,169,143	(7,939,786)	7,106,040	3,878,880	(5,252,372)
Net Loss	$ (14,368,530)	$ (25,294,503)	$ (9,307,345)	$ (14,384,556)	$(18,521,601)
Net Loss per share, basic and diluted	$ (0.44)	$ (0.92)	$ (0.43)	$ (0.79)	$ (1.05)
Weighted average shares outstanding, basic and diluted	32,915,377	27,390,527	21,744,740	18,238,822	17,610,697

	As of December 31,				
Balance Sheet Data:	2018	2017	2016	2015	2014
Cash, Cash Equivalents, and Marketable Securities	$ 14,725,821	$ 26,831,095	$ 20,315,580	$ 23,439,526	$ 32,698,296
Working Capital[(1)]	$ 12,747,118	$ 24,901,710	$ 19,041,597	$ 22,000,046	$ 30,970,020
Total Assets	$ 16,042,926	$ 28,287,881	$ 21,043,532	$ 24,805,029	$ 33,533,060
Warrant Liabilities	$ 2,307,586	$ 7,853,635	$ 1,573,366	$ 2,739,163	$ 3,768,351
Accumulated Deficit	$(154,687,242)	$(140,318,712)	$(115,024,209)	$(105,716,864)	$(91,332,308)
Total Stockholders' Equity	$ 10,562,890	$ 16,768,596	$ 17,058,462	$ 18,775,548	$ 26,580,491
Common shares outstanding	37,527,420	31,725,114	23,736,878	19,741,378	17,825,331

(1) Working Capital defined as current assets less current liabilities

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 developing innovative therapies to improve patient outcomes in cancers that are difficult to treat. Our mission is to improve the lives of cancer patients by developing next-generation cancer therapies that are designed to maximize efficacy and minimize the toxicity and side effects traditionally associated with cancer treatment. Our pipeline features two product candidates in Phase 2 clinical development and additional compounds in preclinical development. Our strategy is to advance our existing product candidates and to continue building a pipeline of innovative oncology product candidates that we intend to develop and 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 product candidates. Our major sources of working capital have been proceeds from the sale of shares of our common stock and warrants, exercises of stock warrants, interest income from cash, cash equivalents and marketable securities, and proceeds from reimbursed research and development costs.

On May 5, 2017 we effected a one-for-ten reverse stock split of the outstanding shares of our common stock, together with a corresponding proportional reduction in the number of authorized shares of our capital stock. See Note 10, "Common Stock—Reverse Stock Split," in the Notes to the Financial Statements of this Annual Report.

Critical Accounting Policies

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

Research and Development

Research and development costs are expensed as incurred. Research and development expenses consist primarily of third party service costs under research and development agreements, salaries and related personnel costs, as well as stock-based compensation related to these costs, costs to acquire pharmaceutical products and product rights for development and amounts paid to CROs, 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.

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

- CROs and investigative sites in connection with clinical studies;
- vendors in connection with product manufacturing, development, and distribution of clinical supplies; and
- vendors in connection with preclinical development activities.

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

Fair Value of Financial Instruments

The carrying amounts reported in the accompanying financial statements for cash and cash equivalents 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.

Income Taxes

We account for income taxes in accordance with Accounting Standards Codification (“ASC”) 740, “Income Taxes.” For additional information on our income tax accounting, see Note 2, “Summary of Significant Accounting Policies,” in the Notes to the Financial Statements in this Annual Report.

Warrants

We record warrants as either equity instruments or liabilities at fair value in accordance with ASC 480, "Distinguishing Liabilities from Equity" ("ASC 480") or ASC 815, "Derivatives and Hedging" ("ASC 815"), as discussed further in Note 2, "Summary of Significant Accounting Policies," in the Notes to Financial Statements in this Annual Report. We reevaluate the balance sheet classification of our warrants and the fair value of our liability-classified warrants each reporting period, and changes in the fair value of our warrant liabilities 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 recognized in the financial statements, as discussed further in Note 2, "Summary of Significant Accounting Policies" and Note 11, "Stock-Based Compensation," in the Notes to Financial Statements in this Annual Report. We estimate the fair value of stock options using the Black-Scholes valuation model. As required, we review our valuation assumptions at each grant date and, as a result, we may change our valuation assumptions used to value employee stock-based awards granted in future periods. Employee and director stock-based compensation costs are recognized over the vesting period of the award.

For more information on our critical accounting policies, see Note 2, "Summary of Significant Accounting Policies," in the Notes to Financial Statements in this Annual Report.

Concentration of Credit Risk

ASC 825, "Financial Instruments," requires disclosure of any significant off-balance sheet risk and credit risk concentration. See Note 2, "Summary of Significant Accounting Policies," in the Notes to Financial Statements in this Annual Report.

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 in this Annual Report for a discussion of recent accounting pronouncements.

Results of Operations

Comparison of the Years Ended December 31, 2018 and December 31, 2017

Total Revenues

We had no revenues for the years ended December 31, 2018 or 2017.

General and Administrative Expenses

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

General and administrative expenses increased approximately $790,000, or 11.9%, to $7,429,000 for the year ended December 31, 2018 from $6,639,000 for the year ended December 31, 2017. The year over year increase is primarily attributable to an increase in personnel expenses and severance payments.

Research and Development Expenses

Research and development expenses increased approximately $2,394,000, or 22.3%, to $13,109,000 for the year ended December 31, 2018, from $10,715,000 for the year ended December 31, 2017. The increase in research and development costs is primarily attributable to increased clinical trial costs related to the progression of our Phase 2a proof-of-concept clinical trials for RX-3117, which we are currently evaluating in patients with relapsed or refractory metastatic pancreatic cancer and locally advanced or metastatic bladder cancer, and RX-5902, which we are evaluating in metastatic triple negative breast cancer, ("TNBC"). During the year ended December 31, 2018, we incurred approximately $5,978,000 in clinical trial costs, compared to approximately $4,325,000 for the year ended December 31, 2017. The increase is also partially attributable to increases in drug manufacturing costs for manufacturing campaigns in 2018.

The table below summarizes the approximate amounts incurred on each of our research and development projects for the years ended December 31, 2018 and 2017:

	For the Year Ended December 31,	
	2018	2017
Clinical Candidates:		
RX-3117	**$ 6,126,200**	$ 4,559,200
RX-5902	**3,104,400**	2,019,700
RX-0201	**651,200**	535,700
Preclinical, Personnel and Overhead	**3,227,258**	3,600,696
Total Research and Development Expenses	**$ 13,109,058**	$ 10,715,296

Interest Income

Interest income increased approximately $47,000, or 22.9% to $254,000 for the year ended December 31, 2018 from $207,000 for the year ended December 31, 2017. The increase is primarily attributable to higher interest rates on cash and cash equivalents, and marketable securities for the year ended December 31, 2018 compared to the year ended December 31, 2017.

Other Income

During the year ended December 31, 2018, we recorded approximately $369,000 of other income related to the termination of our collaborative agreement with NEXT BT Co. Ltd, the successor in interest to Rexgene Biotech Co., Ltd. See Note 7, "Deferred Research and Development Arrangement," in the Notes to Financial Statements in this Annual Report for a discussion of the termination of this agreement.

Unrealized Gain (Loss) on Fair Value of Warrants

Our warrants that are classified as liabilities are recorded at fair value using a lattice model. Changes in the fair value of liability-classified warrants are recorded as unrealized gains or losses in our statement of operations. During the years ended December 31, 2018 and 2017, we recorded unrealized gains (losses) on the fair value of warrants of approximately $5,546,000 and ($7,594,000) respectively. Estimating fair values of warrants requires the development of significant and subjective estimates that may, and are likely to, change over the duration of the warrants due to related changes to external market factors. The unrealized gain for the year ended December 31, 2018 primarily resulted from a significant decrease in the stock price of the underlying common stock on December 31, 2018, as compared to December 31, 2017, whereas the unrealized loss for the year ended December 31, 2017 primarily resulted from a significant increase in the stock price underlying the common stock on December 31, 2017 compared to December 31, 2016.

Financing Expense

We incurred approximately $553,000 of financing expense during the year ended December 31, 2017, related to the portion of closing costs allocable to liability-classified warrants we issued in our registered direct offerings in October 2017 and June 2017. As the warrants issued in our October 2018 public offering are classified as equity, we did not incur financing expense during the year ended December 31, 2018, as those offering costs were recorded as a reduction in equity.

Net Loss

Net loss for the year ended December 31, 2018 decreased approximately $10,926,000 or 43.2%, to $14,369,000 ($0.44 per share) from $25,295,000 ($0.92 per share) for the year ended December 31, 2017, primarily as a result of the change from an unrealized loss on the fair value of warrants in 2017 to an unrealized gain on the fair value of warrants in 2018, offset by an increase in operating expenses in 2018.

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 CROs, 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 product candidates. 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 product candidates, RX-3117 and RX-5902 is uncertain, 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 product candidates, if any. If these projects are not completed as planned, our results of operations and financial condition would be negatively affected.

RX-3117

RX-3117 is a novel, investigational, oral small molecule nucleoside compound. We believe RX-3117 has therapeutic potential in a broad range of cancers including pancreatic, bladder, colon, lung and cervical cancer. Additional information about RX-3117, including about the current Phase 2a clinical trials, can be found in Item 1 of this Annual Report. We expect that expenses related to RX-3117 will remain flat in 2019 compared to 2018 as we continue our Phase 2a clinical trial of RX-3117 in combination with ABRAXANE in patients newly diagnosed with metastatic pancreatic cancer as well as for continued manufacturing costs for new campaigns.

RX-5902

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 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 RX-5902, including about the Phase 2a clinical trial in cancer patients with TNBC can be found in Item 1 of this Annual Report. We expect that expenses related to RX-5902 will decline in 2019 compared to 2018 as we evaluate the development strategy for RX-5902 and may or may not proceed with this trial.

RX-0201

RX-0201 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. We expect that expenses related to RX-0201 will decrease in 2019 compared to 2018 as we wind down our Phase 2a clinical trial of RX-0201 in patients with metastatic renal cell carcinoma.

Research and Development Process

We engage third-party CROs and other investigators and collaborators, such as universities, medical institutions and other life science companies, to conduct our preclinical studies, toxicology studies and clinical trials. Engaging third parties 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 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,	
	2018	2017
Net Cash Used in Operating Activities	$ (18,838,638)	$ (15,420,055)
Net Cash Provided By (Used In) Investing Activities	11,910,996	(9,372,778)
Net Cash Provided by Financing Activities	6,772,789	22,113,514
Net Decrease in Cash and Cash Equivalents	$ (154,853)	$ (2,679,319)

Cash used in operating activities was approximately $18,839,000 for the year ended December 31, 2018. The operating cash flows during the year ended December 31, 2018 reflect a net loss of $14,369,000, an unrealized gain on the fair value of warrants of $5,546,000, and a net increase of cash components of working capital and non-cash charges totaling $1,076,000. Cash used in operating activities was approximately $15,420,000 for the year ended December 31, 2017. The operating cash flows during the year ended December 31, 2017 reflect a net loss of $25,295,000 offset by an unrealized loss on the fair value of warrants of $7,594,000 and a net increase of cash components of working capital and non-cash charges totaling $2,281,000.

Cash provided by investing activities was approximately $11,911,000 for the year ended December 31, 2018, which consisted of $11,950,000 from the redemption of marketable securities, offset by $39,000 from the purchase of equipment. Cash used in investing activities was approximately $9,373,000 for the year ended December 31, 2017, which consisted of $21,018,000 and $75,000 for purchases of marketable securities and equipment, respectively, offset by $11,720,000 from the redemption of marketable securities.

Cash provided by financing activities was approximately $6,773,000 for the year ended December 31, 2018, which consisted of net proceeds of $6,873,000 from our registered direct public offering offset by $100,000 in deferred offering costs for our January 2019 underwritten public offering. Cash provided by financing activities was approximately $22,114,000 for the year ended December 31, 2017, which consisted of net proceeds of $16,682,000 from our registered direct public offerings in June 2017 and October 2017, and $5,354,000 and $78,000 from the exercise of stock warrants and options, respectively.

Financings

On June 12, 2017, we closed a registered direct public offering of 3,030,304 shares of common stock and warrants to purchase up to 1,515,152 shares of common stock. The common stock and warrants were sold in units at a price of $3.30 for gross proceeds of $10,000,003.

On October 17, 2017, we closed a registered direct public offering of 3,265,309 shares of common stock and warrants to purchase up to 1,632,654 shares of common stock. The common stock and warrants were sold in units at a price of $2.45 per unit for gross proceeds of $8,000,007.

On October 19, 2018, we closed a registered direct public offering of 5,769,231 shares of common stock and warrants to purchase up to 5,769,231 shares of common stock. The common stock and warrants were sold in units at a price of $1.30 per unit, for gross proceeds of $7,500,000.

On January 25, 2019, we closed an underwritten public offering of 10,750,000 shares of common stock and warrants to purchase up to 10,750,000 shares of common stock. The common stock and warrants were sold in units at a price of $0.80 per unit, for gross proceeds of $8,600,000.

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 product 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. As disclosed in our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2018, we concluded at the time of filing of that report that substantial doubt existed about our ability to continue as a going concern within one year from the issuance date of the financial statements contained in that report. We currently believe that our cash, cash equivalents, and marketable securities, including the proceeds received from our underwritten public offering in January 2019, will be sufficient to cover our cash flow requirements for our current activities for at least the next 12 months following the issuance of the financial statements contained in this Annual Report. We believe we have the capability of managing our 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.

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 preclinical 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.

Not required

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 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 principal executive officer and principal 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 principal executive officer and principal 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 principal executive officer and principal 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, 2018, 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 U.S. 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 assessed the effectiveness of our internal control over financial reporting as of December 31, 2018. 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 concluded that, as of December 31, 2018, our internal control over financial reporting was effective.

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 2019 Proxy Statement to be filed with the SEC within 120 days of December 31, 2018 and is incorporated into this Annual Report by reference.

Item 11. Executive Compensation.

The information required by this Item is set forth in our 2019 Proxy Statement to be filed with the SEC within 120 days of December 31, 2018 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 2019 Proxy Statement to be filed with the SEC within 120 days of December 31, 2018 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 2019 Proxy Statement to be filed with the SEC within 120 days of December 31, 2018 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 2019 Proxy Statement to be filed with the SEC within 120 days of December 31, 2018 and is incorporated into this Annual Report by reference.

Item 15. Exhibits, Financial Statement Schedules.

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

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

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

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

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

(c) Other schedules are not applicable.

Item 16. Form 10-K Summary.

None.

INDEX TO EXHIBITS

3.1	Amended and Restated Certificate of Incorporation, filed as Appendix G to the Company's Definitive Proxy Statement on Schedule 14A filed on April 29, 2005, is incorporated herein by reference.
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation, filed as Exhibit 3.1 to the Company's Current Report on Form 8-K, filed on May 5, 2017, is incorporated herein by reference.
3.3	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 for the year ended December 31, 2013, 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) filed on October 28, 2005, is incorporated herein by reference.
4.2	Form of Common Stock Purchase Warrant, 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.
4.3	Form of Common Stock Purchase Warrant, filed as Exhibit 4.1 to the Company's Current Report on Form 8-K filed on February 26, 2016, is incorporated herein by reference.
4.4	Form of Common Stock Purchase Warrant, filed as Exhibit 4.1 to the Company's Current Report on Form 8-K filed on September 14, 2016, is incorporated herein by reference.
4.5	Form of Common Stock Purchase Warrant, filed as Exhibit 4.1 to the Company's Current Report on Form 8-K filed on June 7, 2017, is incorporated herein by reference.
4.6	Form of Common Stock Purchase Warrant, filed as Exhibit 4.1 to the Company's Current Report on Form 8-K filed on October 13, 2017, is incorporated herein by reference.
4.7	Form of Common Stock Purchase Warrant, filed as Exhibit 4.1 to the Company's Current Report on Form 8-K filed on October 19, 2018, is incorporated herein by reference.
4.8	Form of Common Stock Purchase Warrant, filed as Exhibit 4.1 to the Company's Current Report on Form 8-K filed on January 25, 2019, 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) filed on 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) filed on 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) filed on October 28, 2005, is incorporated herein by reference.
*10.4	Rexahn Pharmaceuticals, Inc. 2013 Stock Option Plan, as amended and restated, filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 10, 2016, is incorporated herein by reference.
*10.5	First Amendment to the Rexahn Pharmaceuticals, Inc. 2013 Stock Option Plan, as amended and restated as of June 9, 2016, filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on April 13, 2017, is incorporated herein by reference.

*10.6	Form of Stock Option Grant Agreement under the Rexahn Pharmaceuticals, Inc. 2013 Stock Option Plan filed as Exhibit 10.5 to the Company's Annual Report on Form 10-K for the year ended December 31, 2015 is incorporated herein by reference.
*10.7	Form of Restricted Stock Unit Agreement under the Rexahn Pharmaceuticals, Inc. 2013 Stock Option Plan.
*10.8	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.
*10.9	Separation, Transition and General Release Agreement, dated as of December 11, 2017, by and between Rexahn Pharmaceuticals, Inc. and Tae Heum (Ted) Jeong, filed as Exhibit 10.8 to the Company's Annual Report on Form 10-K for the year ended December 31, 2017, is incorporated herein by reference.
*10.10	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.
*10.11	Separation, Transition and General Release Agreement, dated as of November 14, 2018, by and between Rexahn Pharmaceuticals, Inc. and Peter Suzdak, filed as Exhibit 10.2 to the Company's Current Report on Form 8-K filed on November 16, 2018, is herein incorporated by reference.
*10.12	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 Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2015, is incorporated herein by reference.
*10.13	Employment Agreement, dated as of July 6, 2016, by and between Rexahn Pharmaceuticals, Inc. and Lisa Nolan, Ph.D., filed as Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2016, is incorporated herein by reference.
*10.14	Employment Agreement, dated as of January 2, 2018, by and between Rexahn Pharmaceuticals, Inc. and Douglas Swirsky, filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 4, 2018 is incorporated herein by reference.
*10.15	Amendment to Employment Agreement, dated as of November 14, 2018, by and between Rexahn Pharmaceuticals, Inc. and Douglas Swirsky, filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 16, 2018 is incorporated herein by reference.
10.16	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.
10.17	First Amendment to Lease Agreement, dated as of June 7, 2013, by and between Rexahn Pharmaceuticals, Inc. and SG Plaza Holdings, LLC, filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2013, is incorporated herein by reference.

10.18	Second Amendment to Lease Agreement, dated as of July 26, 2014, by and between Rexahn Pharmaceuticals, Inc. and SG Plaza Holdings, LLC, filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2014, is incorporated herein by reference.
10.19	Third Amendment to Lease Agreement, dated as of May 6, 2015, by and between Rexahn Pharmaceuticals, Inc. and SG Plaza Holdings, LLC, filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2015, is incorporated herein by reference.
10.20	Fourth Amendment to Lease Agreement, dated as of April 4, 2016, by and between Rexahn Pharmaceuticals, Inc. and SG Plaza Holdings, LLC, filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2016, is incorporated herein by reference.
10.21	Fifth Amendment to Lease Agreement, dated as of April 13, 2017, by and between Rexahn Pharmaceuticals, Inc. and SG Plaza Holdings, LLC, filed as Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2017, is incorporated herein by reference.
10.22	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.
10.23	Form of Securities Purchase Agreement, dated as of February 26, 2016, by and between Rexahn Pharmaceuticals, Inc. and the purchasers identified on the signature pages thereto, filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on February 26, 2016, is incorporated herein by reference.
10.24	Form of Securities Purchase Agreement, dated as of September 14, 2016, by and between Rexahn Pharmaceuticals, Inc. and the purchasers identified on the signature pages thereto, filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on September 14, 2016, is incorporated herein by reference.
10.25	Form of Securities Purchase Agreement, dated as of June 6, 2017, 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 June 7, 2017, is incorporated herein by reference.
10.26	Form of Securities Purchase Agreement, dated as of October 13, 2017, 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 13, 2017, is incorporated herein by reference.
10.27	Form of Securities Purchase Agreement, dated as of October 17, 2018, 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 19, 2018, is incorporated herein by reference.
**10.28	Clinical Trial Collaboration and Supply Agreement, dated August 13, 2018, by and between Merck Sharp & Dohme B.V., and Rexahn Pharmaceuticals, Inc., filed as Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2018, is herein incorporated by reference.

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)
32.1	Certification of Chief Executive 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
**Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

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/ Douglas J. Swirsky
Douglas J. Swirsky
Chief Executive Officer and President

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

Name	Title	Date
/s/ Douglas J. Swirsky Douglas J. Swirsky	President, Chief Executive Officer and Director (Principal Executive, Financial and Accounting Officer)	March 7, 2019
/s/ Peter Brandt* Peter Brandt	Chairman	March 7, 2019
/s/ Charles Beever* Charles Beever	Director	March 7, 2019
/s/ Kwang Soo Cheong* Kwang Soo Cheong	Director	March 7, 2019
/s/ Ben Gil Price* Ben Gil Price	Director	March 7, 2019
/s/ Richard J. Rodgers* Richard J. Rodgers	Director	March 7, 2019
/s/ Lara Sullivan* Lara Sullivan	Director	March 7, 2019

* By: /s/ Douglas J. Swirsky, Attorney-in Fact
Douglas J. Swirsky, Attorney-in-Fact**

** By authority of the power of attorney filed as Exhibit 24.1 hereto

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the board of directors of Rexahn Pharmaceuticals, Inc.:

Opinion on the Financial Statements

We have audited the accompanying balance sheet of Rexahn Pharmaceuticals, Inc. (the "Company") as of December 31, 2018 and 2017, the related statements of operations, comprehensive loss, stockholders' equity and cash flows, for the years then ended and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Baker Tilly Virchow Krause, LLP

We are uncertain as to the year we (or our predecessor firms) began serving consecutively as the auditor of the Company's financial statements; however, we are aware that we (or our predecessor firms) have been the Company's auditor consecutively since at least 2003.

Wyomissing, Pennsylvania

March 7, 2019

REXAHN PHARMACEUTICALS, INC.
Balance Sheet

	December 31, 2018	December 31, 2017
ASSETS		
Current Assets:		
Cash and cash equivalents	**$ 8,744,301**	$ 8,899,154
Marketable securities	**5,981,520**	17,931,941
Prepaid expenses and other current assets	**1,173,847**	1,304,541
Total Current Assets	**15,899,668**	28,135,636
Security Deposits	**30,785**	30,785
Equipment, Net	**112,473**	121,460
Total Assets	**$ 16,042,926**	$ 28,287,881
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	**$ 3,152,550**	$ 3,233,926
Deferred Research and Development Arrangement	**-**	375,000
Other Liabilities	**19,900**	56,724
Warrant Liabilities	**2,307,586**	7,853,635
Total Liabilities	**5,480,036**	11,519,285
Commitments and Contingencies (note 15)		
Stockholders' Equity:		
Preferred stock, par value $0.0001, 10,000,000 authorized shares, none issued and outstanding	**-**	-
Common stock, par value $0.0001, 75,000,000 and 50,000,000 authorized shares, 37,527,420 and 31,725,114 issued and outstanding	**3,753**	3,173
Additional paid-in capital	**165,264,215**	157,141,021
Accumulated other comprehensive loss	**(17,836)**	(56,886)
Accumulated deficit	**(154,687,242)**	(140,318,712)
Total Stockholders' Equity	**10,562,890**	16,768,596
Total Liabilities and Stockholders' Equity	**$ 16,042,926**	$ 28,287,881

(See accompanying notes to the financial statements)

REXAHN PHARMACEUTICALS, INC.
Statement of Operations

	For the Year Ended December 31, 2018	2017
Revenues:	**$ -**	$ -
Expenses:		
General and administrative	**7,428,615**	6,639,421
Research and development	**13,109,058**	10,715,296
Total Expenses	**20,537,673**	17,354,717
Loss from Operations	**(20,537,673)**	(17,354,717)
Other Income (Expense)		
Interest income	**254,344**	207,003
Other income	**368,750**	**-**
Unrealized gain (loss) on fair value of warrants	**5,546,049**	(7,594,162)
Financing expense	**-**	(552,627)
Total Other Income (Expense)	**6,169,143**	(7,939,786)
Net Loss Before Provision for Income Taxes	**(14,368,530)**	(25,294,503)
Provision for income taxes	**-**	-
Net Loss	**$ (14,368,530)**	$ (25,294,503)
Net loss per share, basic and diluted	**$ (0.44)**	$ (0.92)
Weighted average number of shares outstanding, basic and diluted	**32,915,377**	27,390,527

(See accompanying notes to the financial statements)

REXAHN PHARMACEUTICALS, INC.
Statement of Comprehensive Loss

	For the Year Ended December 31,	
	2018	2017
Net Loss	**$ (14,368,530)**	$ (25,294,503)
Unrealized gain (loss) on available-for-sale securities	**39,050**	(50,764)
Comprehensive Loss	**$ (14,329,480)**	$ (25,345,267)

(See accompanying notes to the financial statements)

REXAHN PHARMACEUTICALS, INC.
Statement of Stockholders' Equity
For the Year Ended December 31, 2018 and 2017

	Common Stock					
	Number of Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
Balances at January 1, 2017	23,736,878	$ 2,374	$132,086,419	$(115,024,209)	$ (6,122)	$ 17,058,462
Issuance of common stock and units, net of issuance costs	6,295,613	630	10,495,217	-	-	10,495,847
Common stock issued in exchange for services	15,000	2	31,198	-	-	31,200
Stock-based compensation	-	-	1,044,167	-	-	1,044,167
Stock options exercised	25,000	2	77,498	-	-	77,500
Stock warrants exercised	1,652,623	165	13,406,522	-	-	13,406,687
Net loss	-	-	-	(25,294,503)	-	(25,294,503)
Other comprehensive loss	-	-	-	-	(50,764)	(50,764)
Balances at December 31, 2017	31,725,114	$ 3,173	$157,141,021	$(140,318,712)	$ (56,886)	$ 16,768,596
Issuance of common stock and units, net of issuance costs	5,769,231	577	6,872,212	-	-	6,872,789
Common stock issued in exchange for services	15,000	1	22,649	-	-	22,650
Stock-based compensation	-	-	1,228,335	-	-	1,228,335
Common stock issued from vested restricted stock units	18,075	2	(2)	-	-	-
Net loss	-	-	-	(14,368,530)	-	(14,368,530)
Other comprehensive gain	-	-	-	-	39,050	39,050
Balances at December 31, 2018	**37,527,420**	**$ 3,753**	**$165,264,215**	**$(154,687,242)**	**$ (17,836)**	**$ 10,562,890**

(See accompanying notes to the financial statements)

REXAHN PHARMACEUTICALS, INC.
Statement of Cash Flows

	For the Year Ended December 31, 2018	2017
Cash Flows from Operating Activities:		
Net loss	**$(14,368,530)**	$(25,294,503)
Adjustments to reconcile net loss to net cash used in operating activities:		
Compensatory stock	**22,650**	31,200
Depreciation and amortization	**48,211**	42,358
Amortization of premiums and discounts on marketable securities, net	**39,251**	52,012
Stock-based compensation	**1,228,335**	1,044,167
Amortization and termination of deferred research and development arrangement	**(375,000)**	(75,000)
Unrealized (gain) loss on fair value of warrants	**(5,546,049)**	7,594,162
Financing expense	**-**	552,627
Amortization of deferred lease incentive	**(12,443)**	(12,444)
Deferred rent	**(24,381)**	(10,036)
Changes in assets and liabilities:		
Prepaid expenses and other assets	**230,694**	(696,024)
Accounts payable and accrued expenses	**(81,376)**	1,351,426
Net Cash Used in Operating Activities	**(18,838,638)**	(15,420,055)
Cash Flows from Investing Activities:		
Purchase of equipment	**(39,224)**	(75,168)
Purchase of marketable securities	**-**	(21,017,610)
Redemption of marketable securities	**11,950,220**	11,720,000
Net Cash Provided by (Used In) Investing Activities	**11,910,996**	(9,372,778)
Cash Flows from Financing Activities:		
Issuance of common stock and units, net of issuance costs	**6,872,789**	16,681,921
Payment of deferred offering costs	**(100,000)**	-
Proceeds from exercise of stock warrants	**-**	5,354,093
Proceeds from exercise of stock options	**-**	77,500
Net Cash Provided by Financing Activities	**6,772,789**	22,113,514
Net Decrease in Cash and Cash Equivalents	**(154,853)**	(2,679,319)
Cash and Cash Equivalents – beginning of period	**8,899,154**	11,578,473
Cash and Cash Equivalents - end of period	**$ 8,744,301**	$ 8,899,154
Supplemental Cash Flow Information		
Non-cash financing and investing activities:		
Warrants issued	**$ 4,841,830**	$ 6,738,701
Warrant liability extinguishment from exercise of warrants	**$ -**	$ 8,052,594

(See accompanying notes to the financial statements)

REXAHN PHARMACEUTICALS, INC.
Notes to Financial Statements

1. Operations and Organization

Rexahn Pharmaceuticals, Inc. (the "Company"), a Delaware corporation, is a biopharmaceutical company whose principal operations are the development of innovative treatments for cancer. The Company had an accumulated deficit of $154,687,242 at December 31, 2018 and anticipates incurring losses through fiscal year 2019 and beyond. The Company has not yet generated commercial revenues and has funded its operations to date through the sale of shares of its common stock and warrants, exercises of stock warrants, 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, including the proceeds from its underwritten public offering in January 2019 as described in Note 18, will be sufficient to cover its cash flow requirements for its current activities for at least for the next 12 months from the date these financial statements were issued. Management believes it has the capability of managing the Company's operations within existing cash available by focusing on select research and development activities, selecting projects in conjunction with potential financings and milestones, and efficiently managing its general and administrative affairs.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America 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

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.

Marketable Securities

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

Equipment

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

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

Fair Value of Financial Instruments

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

Warrants

The Company classifies its stock warrants as either liability or equity instruments in accordance with ASC 480, "Distinguishing Liabilities from Equity" (ASC 480), depending on the specific terms of the warrant agreement. Warrants that the Company may be required to redeem through payment of cash or other assets outside its control are classified as liabilities pursuant to ASC 480 and are initially and subsequently measured at their estimated fair values. Stock warrants are also classified as warrant liabilities in accordance with ASC 815, "Derivatives and Hedging" (ASC 815) if the warrant contains terms that could require "net cash settlement" and therefore, do not meet the conditions necessary for equity classification according to ASC 815. Warrant instruments that could require "net cash settlement" in the absence of express language precluding such settlement are initially classified as warrant liabilities at their estimated fair values, regardless of the likelihood that such instruments will ever be settled in cash. The Company will continue to record liability-classified warrants at fair value until the warrants are exercised, expire or are amended in a way that would no longer require these warrants to be classified as a liability. For additional discussion on warrants, see Note 12.

Research and Development

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

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

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 net 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.

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 U.S. 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. For additional discussion on stock-based compensation, see Note 11.

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, 2018, the Company's uninsured cash balance was $8,494,301. Management does not consider this to be a significant credit risk as the banks are large, established financial institutions.

Reclassification

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

Recent Accounting Pronouncements Affecting the Company

Revenue from Contracts with Customers

In May 2014, the FASB issued Accounting Standards Update ("ASU") 2014-09, "Revenue from Contracts with Customers," a comprehensive new revenue recognition standard that will supersede nearly all existing revenue recognition guidance under U.S. generally accepted accounting standards. 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 deferred 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. The Company adopted this guidance for the quarterly reporting period ended March 31, 2018, using the modified retrospective method. As the Company does not have revenue contracts, the adoption of this guidance did not have a material impact on the operating results of the Company, there were no significant changes to disclosures and there was no cumulative adjustment to the opening balance of retained earnings as of January 1, 2018.

Leases

In February 2016, the FASB issued ASU No. 2016-02, Leases ("ASU 2016-02"). ASU 2016-02 requires the recognition of lease assets and lease liabilities by lessees for those leases classified as operating leases under previous GAAP. The classification criteria for distinguishing between finance leases and operating leases are substantially similar to the classification criteria for distinguishing between capital leases and operating leases in the previous leases guidance. ASU 2016-02 is effective for annual reporting periods beginning after December 15, 2018 and early adoption is permitted. The Company elected not to early adopt the standard, and therefore, will adopt the standard on January 1, 2019. We will elect the package of practical expedients permitted under the transition guidance within the new standard, which among other things, allows us to carryforward the historical lease classification. We are not electing the hindsight practical expedient. We will make an accounting policy election to keep leases with an initial term of 12 months or less off of the balance sheet. We will recognize those lease payments in the consolidated statements of operations on a straight-line basis over the lease term.

We estimate adoption of the standard will result in recognition of additional net lease assets and lease liabilities, after the effect of the lease modifications discussed in Note 18, the amount of both of which will not be material, , and there will be no impact on the accumulated deficit. We do not believe the new standard will have a notable impact on our liquidity.

REXAHN PHARMACEUTICALS, INC.
Notes to 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, 2018 and 2017:

	December 31, 2018			
	Cost Basis	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate Bonds	$ 5,999,356	$ -	$ (17,836)	$ 5,981,520

	December 31, 2017			
	Cost Basis	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial Paper	$ 3,241,005	$ -	$ (2,505)	$ 3,238,500
Corporate Bonds	14,747,822	-	(54,381)	14,693,441
Total Marketable Securities	$ 17,988,827	$ -	$ (56,886)	$ 17,931,941

The Company typically invests in highly rated securities, with the primary objective of minimizing the potential risk of principal loss. As of December 31, 2018, the Company had six corporate bonds with an aggregate fair value of $5,981,520 and unrealized losses of $17,836, all of which have been unrealized losses 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, 2018, all of the Company's marketable securities are due to mature in less than one year.

REXAHN PHARMACEUTICALS, INC.
Notes to Financial Statements

4. Prepaid Expenses and Other Current Assets

	December 31, 2018	December 31, 2017
Deposits on contracts	**$ 618,417**	$ 793,940
Prepaid expenses and other current assets	**555,430**	510,601
	$ 1,173,847	$ 1,304,541

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

5. Equipment, Net

	December 31, 2018	December 31, 2017
Furniture and fixtures	**$ 82,686**	$ 82,686
Office and computer equipment	**159,489**	171,724
Lab equipment	**447,653**	445,134
Leasehold improvements	**131,762**	133,762
Total equipment	**821,590**	833,306
Less: Accumulated depreciation and amortization	**(709,117)**	(711,846)
Net carrying amount	**$ 112,473**	$ 121,460

6. Accounts Payable and Accrued Expenses

	December 31, 2018	December 31, 2017
Trade payables	**$ 547,519**	$ 895,638
Accrued expenses	**140,637**	95,416
Accrued research and development contract costs	**1,782,131**	1,435,109
Payroll liabilities	**682,263**	807,763
	$ 3,152,550	$ 3,233,926

REXAHN PHARMACEUTICALS, INC.
Notes to Financial Statements

7. Deferred Research and Development Arrangement

Rexgene Biotech Co., Ltd.

In 2003, the Company entered into a collaborative research agreement with Rexgene Biotech Co., Ltd. ("Rexgene"), which agreed to assist the Company with the research, development and clinical trials necessary for registration of the Company's product candidate RX-0201 in Asia. In accordance with the agreement, Rexgene paid the Company a one-time fee of $1,500,000 in 2003. The agreement provided that it would expire upon the later of (i) 20 years after the date of the agreement or (ii) the expiration of the patents relating to RX-0201. The amortization reduces research and development expenses for the periods presented. The payment from Rexgene was used in the cooperative funding of the costs of development of RX-0201.

On February 5, 2018, the Company and NEXT BT Co. Ltd. ("Next BT"), the successor in interest to Rexgene, terminated the agreement. In exchange for Next BT terminating its rights to RX-0201 in Asia, the Company agreed to pay Next BT a royalty in the low single digits of any net sales of RX-0201 the Company makes in Asia and 50% of the Company's licensing revenue related to the licensing of RX-0201 in Asia, up to an aggregate of $5,000,000. Upon termination of the agreement, the unamortized deferred research and development arrangement liability of $368,750 was eliminated and recognized as other income.

The Company historically used 20 years as its basis for recognition and accordingly research and development expenses were reduced by $6,250 for the period beginning January 1, 2018 up to the agreement's termination. For the year ended December 31, 2017, $75,000 was reduced from research and development expenses.

8. Other Liabilities

Deferred Lease Incentive

In accordance with the Company's office lease agreement, as amended and further discussed in Note 15, the Company has been granted leasehold improvement allowances from the lessor to be used for the construction cost of improvements to the leased property. The Company accounted for the benefit of the leasehold improvement allowance as a reduction of rental expense over the term of the office lease.

The following table sets forth the cumulative deferred lease incentive:

	December 31, 2018	December 31, 2017
Deferred lease incentive	**$ 154,660**	$ 154,660
Less accumulated amortization	**(148,438)**	(135,995)
Balance	**$ 6,222**	$ 18,665

Deferred Rent

The lease agreement, as amended, provided for an initial annual base rent with annual increases over the lease term. The Company recognizes rental expense on a straight-line basis over the term of the lease, which resulted in a deferred rent liability of $13,678 and $38,059 as of December 31, 2018 and 2017, 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, 2018 and 2017, there were stock options, restricted stock units and warrants to acquire, in the aggregate, 15,871,708 and 8,961,140 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 for those periods because the inclusion of common share equivalents would be anti-dilutive.

REXAHN PHARMACEUTICALS, INC.
Notes to Financial Statements

10. Common Stock

The following transactions occurred during the years ended December 31, 2018 and 2017:

Reverse Stock Split

On May 5, 2017, the Company effected a one-for-ten reverse stock split of the outstanding shares of the Company's common stock, together with a corresponding proportional reduction in the number of authorized shares of the Company's capital stock. All share and per share amounts of common stock, stock options, stock warrants and restricted stock units have been restated for periods to give retroactive effect to the reverse stock split.

Authorized Shares

On August 30, 2018, the Company's stockholders approved an increase in the Company's authorized shares of stock from 50,000,000 to 75,000,000.

Public Offerings

June 2017

On June 12, 2017 the Company closed a registered direct public offering of 3,030,304 shares of common stock and warrants to purchase up to 1,515,152 shares of common stock. The common stock and warrants were sold in units, consisting of a share of common stock and a warrant to purchase 0.5 shares of common stock, at a price of $3.30 per unit, with an exercise price for the warrants of $4.00 per share. The total gross proceeds of the offering were $10,000,003. The warrants issued became exercisable December 12, 2017, and will remain exercisable until December 12, 2022 and were recorded as liabilities at fair value.

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

Gross Proceeds:	$ 10,000,003
Allocated to warrant liabilities	3,673,168
Allocated to common stock and additional paid-in capital	6,326,835
Total allocated gross proceeds:	$ 10,000,003

The Company also issued warrants to purchase up to an aggregate 181,818 shares of common stock to the placement agent in the offering. The closing costs for the offering of $1,193,052 included $434,320 for the placement agent warrants and $758,732 for placement agent and other fees. Based on the estimated fair value of the stock and warrants in the units, the Company allocated $333,050 to financing expense for the warrants and $860,002 as stock issuance costs.

October 2017

On October 17, 2017 the Company closed a registered direct public offering of 3,265,309 shares of common stock and warrants to purchase up to 1,632,654 shares of common stock. The common stock and warrants were sold in units, consisting of a share of common stock and a warrant to purchase 0.5 shares of common stock, at a price of $2.45 per unit, with an exercise price for the warrants of $2.85 per share. The total gross proceeds of the offering were $8,000,007. The warrants issued became exercisable April 17, 2018 and will remain exercisable until April 17, 2023 and were recorded as liabilities at fair value.

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

Gross Proceeds:	$ 8,000,007
Allocated to warrant liabilities	2,360,459
Allocated to common stock and additional paid-in capital	5,639,548
Total allocated gross proceeds:	$ 8,000,007

The Company also issued warrants to purchase up to an aggregate 195,919 shares of common stock to the placement agent in the offering. The closing costs for the offering of $830,111 included $270,754 for the placement agent warrants and $559,357 for placement agent and other fees. Based on the estimated fair value of the stock and warrants in the units, the Company allocated $219,577 to financing expense for the warrants and $610,534 as stock issuance costs.

October 2018

On October 19, 2018, the Company closed a registered direct offering of 5,769,231 shares of common stock and warrants to purchase up to 5,769,231 shares of common stock, resulting in gross proceeds to the Company of approximately $7,500,000. The common stock and warrants were sold in units, consisting of a share of common stock and a warrant to purchase a share of common stock, at a price of $1.30 per unit, with an exercise price for the warrants of $1.67 per share. The warrants will become exercisable April 19, 2019 and will remain exercisable through April 19, 2024. The Company also issued warrants to purchase up to 346,154 shares of the Company's common stock, at an exercise price of $1.625 per share, to designees of the placement agent in the offering. The warrants issued to the investors and to the placement agent are classified as equity instruments. The closing costs of this offering of $896,117 included $286,906 for the placement agent warrants and $627,211 in placement agent and other fees that are recorded as a reduction of the gross proceeds of the offering.

Compensatory Shares

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

	For the Year Ended December 31,	
	2018	2017
Compensatory shares issued	**15,000**	15,000
Aggregate market value	**$ 22,650**	$ 31,200

Stock Warrant and Stock Option Exercises

During the year ended December 31, 2017, warrant holders exercised warrants to purchase shares of the Company's common stock for cash of $5,354,093 and the Company issued 1,652,623 shares.

During the year ended December 31, 2017, a stock option holder exercised options to purchase shares of the Company's common stock for cash of $77,500 and the Company issued 25,000 shares.

Restricted Stock Units

During the year ended December 31, 2018, the Company issued 18,075 shares resulting from the vesting of restricted stock units ("RSUs").

REXAHN PHARMACEUTICALS, INC.
Notes to Financial Statements

11. Stock-Based Compensation

As of December 31, 2018, the Company had 3,071,721 options to purchase common stock and 16,725 RSUs outstanding.

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 equity awards to key employees, directors and consultants of the Company. On June 9, 2016, the Company's stockholders voted to approve an amendment and restatement of the 2013 Plan, including to provide for awards of restricted stock and restricted stock units. The Company initially reserved 1,700,000 shares of common stock for issuance pursuant to the 2013 Plan, and on April 11, 2017, the Company's stockholders approved an increase of 1,700,000 shares of common stock reserved for issuance pursuant to the 2013 Plan. As of December 31, 2018, there were 2,790,721 options and 16,725 RSUs outstanding under the 2013 Plan, and 573,729 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, 2018, there were 269,000 outstanding options under the 2003 Plan.

In March 2016, the Company granted to a third party an option to purchase up to 12,000 shares of the Company's common stock. Of the Company's outstanding options as of December 31, 2018, these were the only options that were not issued pursuant to the 2013 Plan or the 2003 Plan.

Accounting for Awards

Stock-based compensation expense is the estimated fair value of options and RSUs granted amortized on a straight-line basis over the requisite vesting service period for the entire portion of the award. Total stock-based compensation recognized by the Company for the years ended December 31, 2018 and 2017 is as follows:

	For the Year Ended December 31,	
	2018	2017
Statement of operations line item:		
General and administrative	**$ 883,855**	$ 765,726
Research and development	**344,480**	278,441
Total	**$ 1,228,335**	$ 1,044,167

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 net deferred tax assets.

REXAHN PHARMACEUTICALS, INC.
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Summary of Stock Option Transactions

There were 1,483,185 stock options granted at exercise prices ranging from $1.09 to $2.29, with an aggregate fair value of $1,540,866, during the year ended December 31, 2018. There were 483,260, stock options granted at exercise prices ranging from $1.84 to $6.18, with an aggregate fair value of $738,937 during the year ended December 31, 2017.

For the majority of the grants to employees, the vesting period is 25% on the first anniversary of the grant date and, thereafter, one thirty-sixth of the remaining option vests in equal installments on the first business day of each month until fully vested. Options generally expire ten years from the date of grant. For the majority of 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.

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 and SAB 107 when reviewing and updating assumptions.

Significant assumptions are determined as follows:

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

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

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

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

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

	For the Year Ended December 31,	
	2018	2017
Black-Scholes assumptions		
Expected dividend yield	**0%**	0%
Expected volatility	**69-73%**	69-79%
Risk-free interest rate	**2.3-2.9%**	1.7-2.0%
Expected term (in years)	**5.5-6 years**	5.5-6 years

The following table summarizes share-based transactions:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding, January 1, 2018	1,814,231	$ 5.33	7.1 years	$ 53,883
Granted	1,483,185	$ 1.60		
Exercised	-	$ -		
Expired	(56,000)	$ 14.04		
Cancelled	(169,695)	$ 3.14		
Outstanding, December 31, 2018	3,071,721	$ 3.49	7.8 years	$ -
Exercisable, December 31, 2018	1,493,365	$ 5.39	6.2 years	$ -

There were no stock options exercised during the year ended December 31, 2018. The total intrinsic value of options exercised was $97,872 for the year ended December 31, 2017. The weighted average fair value of options granted was $1.04 and $1.53 for the years ended December 31, 2018 and 2017, respectively.

A summary of the Company's unvested options as of December 31, 2018 and changes during the year ended December 31, 2018 is presented below:

	2018	
	Number of Options	**Weighted Average Fair Value at Grant Date**
Unvested at January 1, 2018	727,543	$ 2.39
Granted	1,483,185	$ 1.04
Vested	(513,177)	$ 2.67
Cancelled	(119,195)	$ 1.49
Unvested at December 31, 2018	1,578,356	$ 1.10

As of December 31, 2018, there was $1,393,837 of total unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted average vesting period of 2.9 years.

REXAHN PHARMACEUTICALS, INC.
Notes to Financial Statements

Summary of Restricted Stock Unit Transactions

The fair value of an RSU award is the closing price of the Company's common stock on the date of grant. A summary of RSU activity for the year ended December 31, 2018 is as follows:

	Number of RSUs	Weighted Average Grant Date Fair Value
Outstanding, January 1, 2018	47,300	$ 1.84
Granted	-	$ -
Vested and Released	(18,075)	$ 1.84
Cancelled	(12,500)	$ 1.84
Outstanding, December 31, 2018	16,725	$ 1.84

As of December 31, 2018, there was $21,774 of total unrecognized compensation cost related to unvested RSUs, which is expected to be recognized over a weighted average vesting period of 2.2 years.

REXAHN PHARMACEUTICALS, INC.
Notes to Financial Statements

12. Warrants

The following table summarizes the Company's outstanding warrants to purchase common stock as of December 31, 2018 and 2017:

	Number of Warrants:			
Warrant Issuance	**December 31, 2018**	December 31, 2017	Exercise Price	Expiration Date
Liability-classified Warrants				
July 2013 Investor Warrants	**-**	200,000	$ 5.90	July 2018
October 2013 Investor Warrants	**-**	231,732	$ 5.75	Oct. 2018
January 2014 Investor Warrants	**476,193**	476,193	$ 12.80	Jan. 2019
November 2015 Investor Warrants	**1,250,001**	1,250,001	$ 5.30	May 2021
November 2015 Placement Agent Warrants	**3,334**	3,334	$ 5.30	Nov. 2020
March 2016 Investor Warrants	**607,806**	607,806	$ 4.20	Sept. 2021
September 2016 Investor Warrants	**805,000**	805,000	$ 3.00	Mar. 2022
June 2017 Investor Warrants	**1,515,152**	1,515,152	$ 4.00	Dec. 2022
June 2017 Placement Agent Warrants	**181,818**	181,818	$ 4.13	Jun. 2022
October 2017 Investor Warrants	**1,632,654**	1,632,654	$ 2.85	Apr. 2023
October 2017 Placement Agent Warrants	**195,919**	195,919	$ 3.06	Oct. 2022
Total liability classified warrants	**6,667,877**	7,099,609		
Equity-classified Warrants				
October 2018 Investor Warrants	**5,769,231**	-	$ 1.67	Apr. 2024
October 2018 Placement Agent Warrants	**346,154**	-	$ 1.63	Oct. 2023
Total equity-classified warrants	**6,115,385**	-		
Total outstanding warrants	**12,783,262**	7,099,609		

The following table summarizes the Company's warrant activity for the year ended December 31, 2018:

	Number of Warrants			
	Liability-classified	Equity-classified	Total	Weighted average exercise price
Balance, January 1	7,099,609	-	7,099,609	$ 4.55
Issued during the period	-	6,115,385	6,115,385	$ 1.67
Exercised during the period	-	-	-	$ -
Expired during the period	(431,732)	-	(431,732)	$ 5.82
Balance, December 31	6,667,877	6,115,385	12,783,262	$ 4.55

At December 31, 2018, the weighted average remaining contractual life of the outstanding warrants was 4.2 years.

Accounting for Liability-classified Warrants

The warrants issued to investors in the November 2015, March 2016 and September 2016 offerings contain a provision for net cash settlement in the event of a fundamental transaction (contractually defined to include a merger, sale of substantially all assets, tender offer or share exchange). Pursuant to the November 2015, March 2016, and September 2016 warrants, if a fundamental transaction occurs, then the warrant holder has the option to receive cash, equal to the fair value of the remaining unexercised portion of the warrant. In addition, the warrants from these three offerings and the June 2017 and October 2017 warrants 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 these warrants require liability classification.

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

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

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

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

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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, 2018**	December 31, 2017
July 2013 Investor Warrants	**$ -**	$ 8,762
October 2013 Investor Warrants	**-**	26,288
January 2014 Investor Warrants	**-**	29,257
November 2015 Investor Warrants	**234,918**	1,260,050
November 2015 Placement Agent Warrants	**435**	2,936
March 2016 Investor Warrants	**160,099**	697,554
September 2016 Investor Warrants	**333,834**	1,054,083
June 2017 Investor Warrants	**623,324**	1,981,864
June 2017 Placement Agent Warrants	**65,149**	221,591
October 2017 Investor Warrants	**801,551**	2,305,552
October 2017 Placement Agent Warrants	**88,276**	265,698
Total:	**$ 2,307,586**	$ 7,853,635

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

	December 31, 2018	December 31, 2017
Trading market prices	**$ 0.93**	$ 2.02
Estimated future volatility	**105%**	104%
Dividend	**-**	-
Estimated future risk-free rate	**2.35-2.53%**	2.14-2.45%
Equivalent volatility	**99-104%**	85-104%
Equivalent risk-free rate	**2.51-2.55%**	1.30-1.89%

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

	For the Year Ended December 31,	
	2018	2017
Expired and Fully Exercised Warrants	**$ -**	$ (855,000)
July 2013 Investor Warrants	**8,762**	(6,702)
October 2013 Investor Warrants	**26,288**	(22,580)
January 2014 Investor Warrants	**29,257**	(28,543)
November 2015 Investor Warrants	**1,025,132**	(999,550)
November 2015 Placement Agent Warrants	**2,501**	(365,748)
March 2016 Investor Warrants	**537,455**	(2,708,163)
September 2016 Investor Warrants	**720,249**	(4,571,872)
June 2017 Investor Warrants	**1,358,540**	1,691,304
June 2017 Placement Agent Warrants	**156,442**	212,729
October 2017 Investor Warrants	**1,504,001**	54,907
October 2017 Placement Agent Warrants	**177,422**	5,056
Total:	**$ 5,546,049**	$ (7,594,162)

13. Income Taxes

No provision for federal and state income taxes was required for the years ended December 31, 2018 and 2017 due to the Company's operating losses and increased deferred tax asset valuation allowance. At December 31, 2018 and 2017, the Company had unused net operating loss carry-forwards of approximately $147,086,000 and $127,877,000 respectively, portions of which expire at various dates beginning in 2021. 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, 2018 and 2017, the deferred tax assets related to the aforementioned carry-forwards have been fully offset by valuation allowances, because significant utilization of such amounts is not presently expected in the foreseeable future.

Deferred tax assets and valuation allowances consist of:

	December 31, 2018	December 31, 2017
Net Operating Loss Carryforwards	**$ 41,184,000**	$ 35,805,000
Stock Compensation Expense	**1,608,000**	1,458,000
Book tax differences on assets and liabilities	**195,000**	365,000
Valuation Allowance	**(42,987,000)**	(37,628,000)
Net Deferred Tax Assets	$ -	$ -

The Company files income tax returns in the U.S. federal and Maryland state jurisdictions. Tax years for fiscal 2015 through 2018 are open and potentially subject to examination by the federal and Maryland state taxing authorities.

14. Collaboration Agreements

Merck Sharp & Dohme B.V.

On August 16, 2018, the Company entered into a clinical trial collaboration and supply agreement (the "Collaboration Agreement") with Merck Sharp & Dohme B.V. ("Merck") to conduct a Phase 2 clinical trial to evaluate the safety and efficacy of the combination of RX-5902 with Merck's anti-PD-1 therapy, KEYTRUDA (pembrolizumab), in patients with metastatic triple negative breast cancer (TNBC). Under the terms of the Collaboration Agreement, the Company will sponsor the clinical trial and Merck will supply the Company with KEYTRUDA for use in the trial at no cost to the Company. The Collaboration Agreement provides that the Company and Merck will jointly own clinical data generated from the clinical trial. The Company is currently evaluating the development strategy for RX-5902 and may or may not proceed with this trial.

Zhejiang Haichang Biotechnology Co., Ltd.

On February 8, 2018, the Company entered into a research and development collaboration agreement with Zhejiang Haichang Biotechnology Co., Ltd. ("Haichang") under which Haichang will develop RX-0301, a nano-liposomal formulation of RX-0201, using its proprietary QTsome™ technology and will conduct certain preclinical and clinical activities through completion of a Phase 2a proof-of-concept clinical trial in hepatocellular carcinoma in China.

15. Commitments and Contingencies

a) The Company has contracted with various vendors for research and development services, with terms that 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, 2018, the total estimated cost to complete these agreements was approximately $6,340,000. 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 property. As of December 31, 2018, the milestone has not occurred.

c) *Office Space Lease*

On June 5, 2009, the Company entered into a commercial lease agreement for 5,466 square feet of office space in Rockville, Maryland. The lease was amended on June 7, 2013 to extend the term until June 30, 2019.

On July 26, 2014, the lease was amended to add 1,727 square feet of office space, for a term beginning on September 1, 2014 and ending on August 31, 2015. The lease of additional space was subsequently renewed through June 30, 2019. 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, 2018 and 2017 was $213,321 and $206,667, respectively.

Laboratory Lease

On April 20, 2015, the Company signed a five-year lease agreement for 2,552 square feet of laboratory space commencing on July 1, 2015 and ending on June 30, 2020. Under the lease agreement, the Company pays its allocable portion of real estate taxes and common area operating charges. Rent paid under this lease during the years ended December 31, 2018 and 2017 was $65,953 and $64,032, respectively.

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

For the year ending December 31:	2019	176,080
	2020	34,468
	Total	**$ 210,548**

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 $120,558 and $123,145, for the years ended December 31, 2018 and 2017 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. The agreement required the Company to make payments to the University of Maryland if any products from the licensed delivery platform would have achieved development milestones. In December 2018, the Company terminated the license agreement. At the time of termination, no development milestones had 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. The agreement required the Company to make payments to the Ohio State Innovation Foundation if any products from the licensed delivery platform would have achieved development milestones. In December 2018, the Company terminated the license agreement. At the time of termination, no development milestones had occurred.

g) On February 5, 2018, the Company and Next BT terminated the research collaboration agreement between the Company and Rexgene. In exchange for Next BT terminating its rights to RX-0201 in Asia, the Company agreed to pay Next BT a royalty in the low single digits of any net sales of RX-0201 the Company makes in Asia and 50% of the Company's licensing revenue related to licensing of RX-0201 in Asia, up to an aggregate of $5,000,000.

REXAHN PHARMACEUTICALS, INC.
Notes to Financial Statements

16. Fair Value Measurements

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

The three levels are described below:

Level 1 Inputs	—	Unadjusted quoted prices in active markets for identical assets or liabilities that are accessible by the Company;
Level 2 Inputs	—	Quoted prices in markets that are not active or financial instruments for which all significant inputs are observable, either directly or indirectly;
Level 3 Inputs	—	Unobservable inputs for the asset or liability including significant assumptions of the Company and other market participants.

The following tables present assets and liabilities that are measured at fair value on a recurring basis and are categorized using the fair value hierarchy. There have been no changes in the methodologies used at December 31, 2018 and 2017.

Fair Value Measurements at December 31, 2018

	Total	Level 1	Level 2	Level 3
Assets:				
Corporate Bonds	**$ 5,981,520**	**$ -**	**$ 5,981,520**	**$ -**
Liabilities:				
Warrant Liabilities	**$ 2,307,586**	**$ -**	**$ -**	**$ 2,307,586**

Fair Value Measurements at December 31, 2017

	Total	Level 1	Level 2	Level 3
Assets:				
Commercial Paper	3,238,500	-	3,238,500	-
Corporate Bonds	14,693,441	-	14,693,441	-
Total Assets:	$ 17,931,941	$ -	$ 17,931,941	$ -
Liabilities:				
Warrant Liabilities	$ 7,853,635	$ -	$ -	$ 7,853,635

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 used 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), 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, 2018 and 2017 in the fair value of the liabilities classified as Level 3 in the fair value hierarchy:

	Warrant Liabilities
Balance at January 1, 2018	$ 7,853,635
Additions	-
Unrealized gains, net	(5,546,049)
Transfers out of level 3	-
Balance at December 31, 2018	$ 2,307,586

	Warrant Liabilities
Balance at January 1, 2017	$ 1,573,366
Additions	6,738,701
Unrealized losses, net	7,594,162
Transfers out of level 3	(8,052,594)
Balance at December 31, 2017	$ 7,853,635

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.

REXAHN PHARMACEUTICALS, INC.
Notes to Financial Statements

17. Select Quarterly Data (Unaudited)

	2018 For the Quarter Ended			
	March 31	June 30	September 30	December 31
Revenues	$ -	$ -	$ -	$ -
Expenses	5,885,855	5,001,441	4,683,907	4,966,470
Loss from Operations	(5,885,855)	(5,001,441)	(4,683,907)	(4,966,470)
Other Income (Expense), net	3,810,982	1,163,173	(654,912)	1,849,900
Net Loss	$ (2,074,873)	$ (3,838,268)	$ (5,338,819)	$ (3,116,570)
Net Loss per share, basic and diluted	$ (0.07)	$ (0.12)	$ (0.17)	$ (0.09)

	2017 For the Quarter Ended			
	March 31	June 30	September 30	December 31
Revenues	$ -	$ -	$ -	$ -
Expenses	3,953,241	4,283,925	4,219,322	4,898,229
Loss from Operations	(3,953,241)	(4,283,925)	(4,219,322)	(4,898,229)
Other Income (Expense), net	(17,657,783)	5,230,981	3,181,250	1,305,766
Net Income (Loss)	$(21,611,024)	$ 947,056	$ (1,038,072)	$ (3,592,463)
Net Income (Loss) per share, basic	$ (0.91)	$ 0.04	$ (0.04)	$ (0.12)
Net Income (Loss) per share, diluted	$ (0.91)	$ 0.03	$ (0.04)	$ (0.12)

18. Subsequent Events

On January 25, 2019, the Company closed an underwritten public offering of 10,750,000 shares of common stock and warrants to purchase up to 10,750,000 shares of common stock, resulting in gross proceeds to the Company of approximately $8,600,000. The common stock and warrants were sold in units, consisting of a share of common stock and a warrant to purchase a share of common stock, at a price of $0.80 per unit, with an exercise price for the warrants of $0.80 per share. The warrants were immediately exercisable and will remain exercisable until January 25, 2024.

Since December 31, 2018, the Company granted 374,968 stock options to officers and other employees.

The Company terminated its laboratory lease agreement on February 4, 2019 and surrendered the premises on February 28, 2019.

Exhibit 10.7

REXAHN PHARMACEUTICALS, INC.
2013 STOCK OPTION PLAN, AS AMENDED AND RESTATED
RESTRICTED STOCK UNIT GRANT AGREEMENT

Rexahn Pharmaceuticals, Inc., a Delaware corporation (the "**Company**"), hereby grants restricted stock units relating to shares of its common stock, par value $0.0001 per share (the "**Stock**") to the Grantee named below, subject to the achievement of vesting conditions set forth below and in the attached Restricted Stock Unit Agreement (the "**Agreement**"). Additional terms and conditions of the grant are set forth on this cover sheet to the Agreement and in the Agreement and the Rexahn Pharmaceuticals, Inc. 2013 Stock Option Plan, as amended from time to time (the "**Plan**").

Grantee:	_____
Grant Date:	_____
Number of Restricted Stock Units:	_____
Vesting:	So long as Grantee shall be employed by the Company and Grantee shall not have violated the provisions of this Agreement, and further subject to the provisions of the Plan and this Agreement, Grantee shall become vested in the Shares as follows:
	_____

By your signature below, you agree to all of the terms and conditions described in the Agreement and in the Plan, copies of which will be provided on request. You acknowledge that you have carefully reviewed the Plan, and agree that the Plan will control in the event any provision of this cover sheet or Agreement should appear to be inconsistent.

Grantee: _____ Date: _____

(Signature)

Company: _____ Date: _____

(Signature)

Title: _____

Attachment

This is not a stock certificate or a negotiable instrument.

REXAHN PHARMACEUTICALS, INC.
2013 STOCK OPTION PLAN
RESTRICTED STOCK UNIT GRANT AGREEMENT

1. Grant of Restricted Stock Units.

1.1. Subject to the terms and conditions hereafter set forth, the Company hereby grants to Grantee the number of restricted stock units set forth on the Cover Sheet (the "**RSUs**") with respect to shares of Stock of the Company (the "**Shares**").

1.2. This Agreement shall be construed in accordance and consistent with, and subject to, the provisions of the Plan (the provisions of which are incorporated herein by reference) and, except as otherwise expressly set forth herein, the capitalized terms used in this Agreement shall have the same definitions as set forth in the Plan. In the event any provision of this Agreement shall conflict with any of the terms in the Plan as constituted on the Grant Date, the terms of the Plan as constituted on the Grant Date shall control.

2. Vesting of RSUs.

2.1. So long as Grantee shall be employed by the Company and Grantee shall not have violated the provisions of this Agreement, and further subject to the provisions of the Plan and this Agreement, Grantee shall become vested in the Shares as set forth on the Cover Sheet. For purposes of this Agreement, the RSUs which are vested are referred to as the "Vested RSUs".

3. Effect of a Change in Control.

3.1. In the event of any Change in Control (as defined in the Plan) prior to vesting of the RSUs, the RSUs shall automatically accelerate so that the RSUs shall, immediately prior to the effective date of the Change in Control, become fully vested. However, the vesting of outstanding RSUs shall NOT so accelerate if and to the extent such RSUs are, in connection with the Change in Control, either to be assumed by the successor corporation (or parent thereof) or to be replaced with comparable restricted stock units for shares of the capital stock of the successor corporation (or the parent thereof). The determination of restricted stock unit comparability shall be made by the administrator of the Plan, and its determination shall be final, binding and conclusive.

4. Delivery. Delivery of the shares of Stock represented by the RSUs will be made as soon as practicable after the date on which the RSUs vest and, in any event, by no later than March 15th of the calendar year after the RSUs vest.

5. Evidence of Issuance. The issuance of the shares of Stock with respect to the RSUs will be evidenced in such a manner as the Company, in its discretion, deems appropriate, including, without limitation, book-entry, registration (including transaction advices) or issuance of one or more share certificates.

6. Termination of Employment.

6.1. Termination By Reason of Death or Disability. If Grantee's employment is terminated by reason of death or Disability, the RSUs that have not yet vested as of the termination date will accelerate and be deemed to be vested as of the termination date.

"**Disability**" shall mean a physical or mental impairment that prevents Grantee from performing the essential duties of Grantee's position, with or without reasonable accommodation, for (i) a period of ninety (90) consecutive calendar days, or (ii) an aggregate of ninety (90) work days in any six (6) month period. The determination of whether Grantee incurred a Disability shall be made by the Board of Directors of the Company (the "**Board**"), in its sole discretion, after consultation with Grantee's physician.

6.2. Termination for Cause. If Grantee's employment is terminated for Cause, all of the vested and unvested RSUs held by Grantee as of the termination date will be cancelled.

"**Cause**" shall mean (i) the commission by Grantee of an act of malfeasance, dishonesty, fraud, or breach of trust against the Company or any of its employees, clients, or suppliers, (ii) the material breach by the Grantee of any of Grantee's obligations under this Agreement, or any other agreement between Grantee and the Company, (iii) Grantee's failure to comply in all material respects with the Company's written policies; (iv) Grantee's failure, neglect, or refusal to perform Grantee's duties under this Agreement, or to follow the lawful written directions of the Board, (v) Grantee's indictment, conviction of, or plea of guilty or no contest to, any felony or any crime involving moral turpitude, (vi) any act or omission by Grantee involving dishonesty or fraud or that is, or is reasonably likely to be, injurious to the financial condition or business reputation of the Company, or that otherwise is injurious to the Company's employees, clients, or suppliers, or (vii) the inability of Grantee, as a result of repeated alcohol or drug use, to perform the duties and/or responsibilities of Grantee's position.

6.3. Termination without Cause. If Grantee's employment is terminated without Cause (and not as a result of a Disability), then on the effective date of the termination of the Grantee's employment, the following additional RSUs shall vest:

> 1/48th of the total number of RSUs subject to the grant multiplied by the number of months (rounded to the nearest whole month) since the last vesting date until the effective date of termination of the Grantee's employment.

All remaining unvested RSUs will terminate as of the effective date of the termination of the Grantee's employment.

6.4. Termination Following a Change in Control. If Grantee's employment is terminated without Cause (and not as a result of death or a Disability), and such termination date falls within the one-year period immediately following a "Change in Control" (as defined in the Plan), the RSUs that have not yet vested as of the termination date will accelerate and be deemed to be vested as of the termination date.

6.5. Other Terminations. If Grantee's employment is terminated for any other reason than those specified above, whether voluntary or involuntary, Grantee will forfeit all of the unvested RSUs on the date of Grantee's termination of service.

7. No Pre-Emptive Rights or Registration Rights.

Grantee shall not be entitled to any pre-emptive rights with respect to the Company's issuance of any Stock or other securities, nor shall Grantee be entitled to registration rights with respect to any Shares in the event that the Company files a registration statement under the Securities Act of 1933 with respect to the Stock or any other securities.

8. Nontransferability.

The RSUs granted hereunder shall not be sold, transferred, assigned, pledged, or otherwise encumbered or disposed of by Grantee other than by will or the laws of descent and distribution. The terms of the RSUs shall be final, binding and conclusive upon the beneficiaries, executors, administrators, heirs and successors of Grantee.

9. No Right to Continued Employment.

Nothing in this Agreement or the Plan shall be interpreted or construed to confer upon Grantee any right with respect to continuance of employment by the Company, nor shall this Agreement or the Plan interfere in any way with the right of the Company to terminate Grantee's employment at any time. By Grantee's execution of this Agreement, Grantee acknowledges that Grantee's employment with the Company is "at will". No change of Grantee's duties as an employee of the Company shall result in, or be deemed to be, a modification of any terms of this Agreement.

10. Adjustments.

In the event of a reclassification, recapitalization, stock split, stock dividend, combination of shares, or other similar event with respect to the Stock, the Committee shall make appropriate adjustments to the number and class of Shares or other stock or securities subject to the RSUs and the purchase price for such Shares or other stock or securities in accordance with the provisions of Section 11 of the Plan, and such adjustments, if any, shall be effective, final, binding and conclusive for all purposes of the Plan and this Agreement.

11. Withholding of Taxes.

In the event that the Company determines that any federal, state, or local tax or withholding payment is required relating to the grant of RSUs or the issuance of shares of Stock with respect to the RSUs (the "**Withholding Taxes**"), the Company will have the right to (i) require Grantee to tender a cash payment or (ii) deduct from payments of any kind otherwise due to Grantee (including salary or bonus) to pay the Withholding Taxes.

12. Treatment of Information.

12.1. Grantee acknowledges that, in and as a result of Grantee's employment by the Company, Grantee shall or may be making use of, acquiring and/or adding to confidential information of a special and unique nature and value relating to such matters as the Company's trade secrets, systems, programs, procedures, manuals, confidential reports and communications and lists of customers and clients. Grantee further acknowledges that any information and materials received by the Company from third parties in confidence (or subject to nondisclosure or similar covenants) shall be deemed to be and shall be confidential information within the meaning of this Section 12. As a material inducement to the Company to grant to Grantee the RSUs, Grantee covenants and agrees that Grantee shall not, except with the prior written consent of the Company, or except if Grantee is acting as an employee of the Company solely for the benefit of the Company in connection with the Company's business and in accordance with the Company's business practices and employee policies, at any time during or following the term of Grantee's employment by the Company, directly or indirectly, disclose, divulge, reveal, report, publish, transfer or use, for any purpose whatsoever, any of such information which has been obtained by or disclosed to Grantee as a result of Grantee's employment with the Company, including any of the information referred to in Section 13 hereof.

12.2. Disclosure of any of the information referred to in Section 12.1 hereof shall not be prohibited if such disclosure is directly related to a valid and existing order of a court or other governmental body or agency within the United States; provided, however, that (i) Grantee shall first have given prompt notice to the Company of any possible or prospective order (or proceeding pursuant to which any such order may result) and (ii) the Company shall have been afforded a reasonable opportunity to prevent or limit any such disclosure.

13. Definition of Protected Information.

13.1. For purposes of this Agreement, the term "Protected Information" shall mean all of the information referred to in Section 12 hereof and all of the following materials and information (whether or not reduced to writing and whether or not patentable or protectible by copyright) which Grantee receives, receives access to, conceives or develops or has received, received access to, conceived or developed, in whole or in part, directly or indirectly, in connection with Grantee's employment with the Company or in the course of Grantee's employment with the Company (in any capacity, whether executive, managerial, planning, technical, sales, research, development, manufacturing, engineering or otherwise) or through the use of any of the Company's facilities or resources:

(a) Application, operating system, data base, communication and other computer software, whether now or hereafter existing, developed for use on any operating system, all modifications, enhancements and versions and all options available with respect thereto, and all future products developed or derived therefrom;

(b) Source and object codes, flowcharts, algorithms, coding sheets, routines, sub-routines, compilers, assemblers, design concepts and related documentation and manuals;

(c) Production processes, marketing techniques and arrangements, mailing lists, purchasing information, pricing policies, quoting procedures, financial information, customer and prospect names and requirements, employee, customer, supplier and distributor data and other materials or information relating to the Company's business and activities and the manner in which the Company does business;

(d) Discoveries, concepts and ideas including, without limitation, the nature and results of research and development activities, processes, formulas, inventions, computer-related equipment or technology, techniques, "know-how", designs, drawings and specifications;

(e) Any other materials or information related to the business or activities of the Company which are not generally known to others engaged in similar businesses or activities; and

(f) All ideas which are derived from or relate to Grantee's access to or knowledge of any of the above enumerated materials and information.

13.2. Failure to mark any of the Protected Information as confidential, proprietary or Protected Information shall not affect its status as part of the Protected Information under the terms of this Agreement.

14. For purposes of this Agreement, the term "Protected Information" shall not include information which is or becomes publicly available without breach of (i) this Agreement, (ii) any other agreement or instrument to which the Company is a party or a beneficiary or (iii) any duty owed to the Company by Grantee or any third party; provided, however, that Grantee hereby acknowledges and agrees that, except as otherwise provided in Section 12.2 hereof, if Grantee shall seek to disclose, divulge, reveal, report, publish, transfer or use, for any purpose whatsoever, any Protected Information, Grantee shall bear the burden of proving that any such information shall have become publicly available without any such breach.

15. Ownership of Information.

15.1. Grantee covenants and agrees that all right, title and interest in any Protected Information shall be and shall remain the exclusive property of the Company; provided, however, that the foregoing shall not apply to any invention for which no equipment, supplies, facility or Protected Information of the Company was used, which was developed entirely on Grantee's own time, and which does not (i) relate to the business of the Company, (ii) relate to the Company's actual or demonstrably anticipated research or development or (iii) result from any work performed by Grantee for the Company. Grantee agrees immediately to disclose to the Company all Protected Information developed in whole or in part by Grantee during the term of Grantee's employment with the Company and to assign to the Company any right, title or interest Grantee may have in such Protected Information. Grantee agrees to execute any instruments and to do all other things reasonably requested by the Company (both during and after Grantee's employment with the Company) in order to vest more fully in the Company all ownership rights in those items hereby transferred by Grantee to the Company.

15.2. If any one or more of the items described in Section 14.1 above are protectible by copyright and are deemed in any way to fall within the definition of "work made for hire," as such term is defined in 17 U.S.C. §101, such work shall be considered a "work made for hire," the copyright of which shall be owned solely, completely and exclusively by the Company. If any one or more of the aforementioned items are protectible by copyright and are not considered to be included in the categories of works covered by the "work made for hire" definition contained in 17 U.S.C. §101, such items shall be deemed to be assigned and transferred completely and exclusively to the Company by virtue of the execution of this Agreement.

16. Materials.

All notes, data, tapes, reference items, sketches, drawings, memoranda, records and other materials in any way relating to any of the information referred to in Sections 12 and 13 hereof (including, without limitation, any Protected Information) or to the Company's business shall belong exclusively to the Company and Grantee agrees to turn over to the Company all copies of such materials in Grantee's possession or under Grantee's control at the request of the Company or, in the absence of such a request, upon the termination of employment of Grantee.

17. Covenants Not to Compete or Hire Employees.

It is recognized and understood by the parties hereto that Grantee, through Grantee's association with the Company as an employee, shall acquire a considerable amount of knowledge and goodwill with respect to the business of the Company, which knowledge and goodwill are extremely valuable to the Company and which would be extremely detrimental to the Company if used by Grantee to compete with the Company. It is, therefore, understood and agreed by the parties hereto that, because of the nature of the business of the Company, it is necessary to afford fair protection to the Company from such competition by Grantee. Consequently, as a material inducement to the Company to grant Grantee the RSUs, Grantee covenants and agrees that for the period commencing with the date hereof and ending one (1) year after Grantee's termination of employment from the Company for any reason whatsoever, Grantee shall not (a) engage, directly, indirectly or in concert with any other person or entity, in any activity, any service or promote any product which in any way competes with any service or product provided, sold, licensed or promoted by the Company or (b) directly or indirectly, solicit or divert or attempt to solicit or divert from the Company any customer, client, account or business of the Company. Grantee further covenants and agrees that for the period commencing with the date hereof and ending one (1) year after Grantee's termination of employment from the Company for any reason whatsoever, Grantee shall not, directly or indirectly, hire or engage or attempt to hire or engage any employee of the Company, whether for or on behalf of Grantee or for any entity in which Grantee shall have a direct or indirect interest (or any subsidiary or affiliate of any such entity), whether as a proprietor, partner, co-venturer, financier, investor or stockholder, director, officer, employer, employee, servant, agent, representative or otherwise.

18. No Prior Agreements.

Grantee represents that Grantee's performance of all the terms of this Agreement and any services to be rendered as an employee of the Company do not and shall not breach any fiduciary or other duty or any covenant, agreement or understanding (including, without limitation, any agreement relating to any proprietary information, knowledge or data acquired by Grantee in confidence, trust or otherwise prior to Grantee's employment by the Company) to which Grantee is a party or by the terms of which Grantee may be bound. Grantee covenants and agrees that Grantee shall not disclose to the Company, or induce the Company to use, any such proprietary information, knowledge or data belonging to any previous employer or others. Grantee further covenants and agrees not to enter into any agreement or understanding, either written or oral, in conflict with the provisions of this Agreement.

19. Injunctive Relief.

Grantee understands and agrees that the Company will suffer irreparable harm in the event that Grantee breaches any of Grantee's obligations under Sections 12, 14, 15, 16 or 17 hereof and that monetary damages will be inadequate to compensate the Company for such breach. Accordingly, Grantee agrees that, in the event of a breach or threatened breach by Grantee of any of the provisions of Sections 12, 14, 15, 16 or 17 hereof, the Company, in addition to and not in limitation of any other rights, remedies or damages available to the Company at law or in equity, shall be entitled to a temporary restraining order, preliminary injunction and permanent injunction in order to prevent or to restrain any such breach by Grantee, or by any or all of Grantee's partners, co-venturers, employers, employees, servants, agents, representatives and any and all persons directly or indirectly acting for, on behalf of or with Grantee.

20. Accounting for Profits; Indemnification.

Grantee covenants and agrees that, if Grantee shall violate any of Grantee's covenants or agreements contained in Sections 12, 14, 15 or 16 hereof, the Company shall be entitled to an accounting and repayment of all profits, compensation, royalties, commissions, remunerations or benefits which Grantee directly or indirectly shall have realized or may realize relating to, growing out of or in connection with any such violation; such remedy shall be in addition to and not in limitation of any injunctive relief or other rights or remedies to which the Company is or may be entitled at law or in equity or otherwise under this Agreement. Grantee hereby agrees to defend, indemnify and hold harmless the Company against and in respect of: (i) any and all losses and damages resulting from, relating or incident to, or arising out of any misrepresentation or breach by Grantee of any warranty, covenant or agreement made or contained in this Agreement; and (ii) any and all actions, suits, proceedings, claims, demands, judgments, costs and expenses (including reasonable attorneys' fees) incident to the foregoing.

21. Reasonableness of Restrictions.

GRANTEE HAS CAREFULLY READ AND CONSIDERED THE PROVISIONS OF SECTIONS 12 THROUGH 19 HEREOF INCLUSIVE AND, HAVING DONE SO, AGREES THAT THE RESTRICTIONS SET FORTH IN SUCH SECTIONS ARE FAIR AND REASONABLE AND ARE REASONABLY REQUIRED FOR THE PROTECTION OF THE INTERESTS OF THE CORPORATION, AND ITS OFFICERS, DIRECTORS, STOCKHOLDERS AND EMPLOYEES. GRANTEE FURTHER AGREES THAT ALL SUCH PROVISIONS ARE IN FURTHERANCE AND NOT IN LIMITATION OF ANY OTHER COVENANTS AND RESTRICTIONS APPLICABLE TO GRANTEE.

22. Stockholder Rights.

Grantee does not have any of the rights of a stockholder with respect to the RSUs unless and until the Stock relating to the RSUs Units has been delivered to Grantee.

23. Grantee Bound by the Plan.

Grantee hereby acknowledges receipt of a copy of the Plan and agrees to be bound by all the terms and provisions thereof.

24. Modification of Agreement.

This Agreement may be modified, amended, suspended or terminated, and any terms or conditions may be waived, but only by a written instrument executed by the parties hereto.

25. Data Privacy.

To administer the Plan, the Company may process personal data about Grantee. Such data includes, but is not limited to, information provided in this Agreement and any changes to such information, other appropriate personal and financial data about Grantee such as Grantee's contact information, payroll information and any other information that might be deemed appropriate by the Company to facilitate the administration of the Plan. By accepting this grant, Grantee gives explicit consent to the Company to process any such personal data.

26. Severability.

Whenever possible, each provision in this Agreement shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement shall be held by a court of competent jurisdiction to be prohibited by or invalid or unenforceable under applicable law, then (a) such provision shall be deemed amended to accomplish the objectives of the provision as originally written to the fullest extent permitted by law and (b) all other provisions of this Agreement shall remain in full force and effect.

27. Governing Law.

The validity, interpretation, construction and performance of this Agreement shall be governed by the laws of the State of Maryland without giving effect to the conflicts of laws principles thereof.

28. Successors in Interest.

This Agreement shall inure to the benefit of and be binding upon any successor to the Company. This Agreement shall inure to the benefit of Grantee's legal representatives. All obligations imposed upon Grantee and all rights granted to the Company under this Agreement shall be final, binding and conclusive upon Grantee's heirs, executors, administrators and successors. As used herein, the term "Company" shall also include any corporation which is a parent or a subsidiary of the Company or any corporation or entity which is an affiliate of the Company by virtue of common (although not identical) ownership. Grantee hereby consents to the enforcement of any and all of the provisions of this Agreement by or for the benefit of the Company and any such other corporation or entity.

29. Resolution of Disputes.

Any dispute or disagreement which may arise under, or as a result of, or in any way relate to, the interpretation, construction or application of this Agreement shall be determined by the Committee. Any determination made hereunder shall be final, binding and conclusive on Grantee and Company for all purposes.

30. Specific Performance.

Strict compliance by Grantee shall be required with each and every provision of this Agreement. The parties hereto agree that the Shares are unique, that Grantee's failure to perform the obligations provided by this Agreement will result in irreparable damage to the Company and that specific performance of Grantee's obligations may be obtained by suit in equity.

31. Interpretation.

31.1. This Agreement and the Plan set forth all of the promises, agreements, conditions, understandings, warranties and representations between the parties hereto with respect to the RSUs and the Shares, and there are no promises, agreements, conditions, understandings, warranties or representations, oral or written, express or implied, between them with respect to the RSUs or the Shares other than as set forth herein and in the Plan, as amended. Any and all prior agreements between the parties hereto with respect to the Shares or the RSUs are hereby revoked. This Agreement and the Plan are intended by the parties to be an integration of any and all prior agreements or understandings, oral or written, with respect to the RSUs and the Shares.

31.2. The captions herein are for reference purposes only and in no way define or limit the scope or content of this Agreement or in any way affect the interpretation of its provisions.

32. Notices.

Any and all notices provided for herein shall be sufficient if in writing and shall either be hand delivered, with receipt therefor, or sent by Federal Express or other nationally recognized courier, or by certified or registered mail, postage prepaid, return receipt requested, in the case of the Company, to its principal office, and, in the case of Grantee, to Grantee's address as shown on the Company's records. A notice that is sent by Federal Express or other nationally recognized courier or that is sent by certified or registered mail will be deemed given on the earlier of the date the notice is received by the addressee or three (3) business days after the date the notice is sent. Either party may change the address to which notices or other communications are to be delivered to them hereunder by giving written notice to the other party as provided in this paragraph.

By signing this Agreement, Grantee agrees to all of the terms and conditions described above and in the Plan.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (File No. 333-218285) and Form S-8 (File No. 333-189240, 333-129294 and 333-217627) of Rexahn Pharmaceuticals, Inc., of our report dated March 7, 2019, relating to the financial statements of Rexahn Pharmaceuticals, Inc. which appear in this Annual Report on Form 10- K for the year ended December 31, 2018.

/s/ BAKER TILLY VIRCHOW KRAUSE, LLP

Wyomissing, Pennsylvania
March 7, 2019

Exhibit 24.1

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Douglas J. Swirsky, as his true and lawful attorney-in-fact and agent, with full power to him (including the full power of substitution and resubstitution), to sign for him or her and in his or her name, place and stead, in the capacity or capacities set forth below, (1) the Annual Report on Form 10-K for the fiscal year ended December 31, 2018 to be filed by Rexahn Pharmaceuticals, Inc. (the "Company") with the Securities and Exchange Commission (the "Commission") pursuant to Section 13 of the Securities Exchange Act of 1934, as amended, and (2) any amendments to the foregoing Annual Report, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Signature	**Title**	**Date**
/s/ Douglas J. Swirsky Douglas J. Swirsky	Chief Executive Officer, President and Director	March 5, 2019
/s/ Peter Brandt Peter Brandt	Chairman	March 5, 2019
/s/ Charles Beever Charles Beever	Director	March 5, 2019
/s/ Kwang Soo Cheong Kwang Soo Cheong	Director	March 5, 2019
/s/ Ben Gil Price Ben Gil Price	Director	March 6, 2019
/s/ Richard J. Rodgers Richard J. Rodgers	Director	March 5, 2019
/s/ Lara Sullivan Lara Sullivan	Director	March 5, 2019

Exhibit 31.1

**CERTIFICATION PURSUANT TO RULES 13A-14(D)
AND 15D-14(D)**

I, Douglas J. Swirsky, certify that:

1. I have reviewed this Annual Report on Form 10-K of Rexahn Pharmaceuticals, Inc.;

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

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

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

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

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

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

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

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

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

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

Dated: March 7, 2019
/s/ Douglas J. Swirsky
Douglas J. Swirsky
Chief Executive Officer and President

Exhibit 32.1

CERTIFICATION OF
CHIEF FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350

SECTION 1350 CERTIFICATION*

In connection with the Annual Report of Rexahn Pharmaceuticals, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Douglas J. Swirsky, Chief Financial Officer and President of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Dated: March 7, 2019

By: /s/ Douglas J. Swirsky
Douglas J. Swirsky,
Chief Executive Officer and President

* This Certification is being furnished as required by Rule 13a-14(b) under the Securities Exchange Act of 1934 (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code, and shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that section. This Certification shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Exchange Act, except as otherwise stated in such filing.

A signed original of this written statement required by 18 U.S.C. § 1350 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.