

RXi Pharmaceuticals Corp  
Form 10-K  
March 30, 2015  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**Washington, D.C. 20549**

**FORM 10-K**

(Mark One)

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

**For the fiscal year ended December 31, 2014**

**Or**

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

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_**

**Commission File Number 001-36304**

**RXi PHARMACEUTICALS CORPORATION**  
**(Exact name of registrant as specified in its charter)**

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

**45-3215903**  
**(I.R.S. Employer**  
**Identification No.)**

**257 Simarano Drive, Suite 101 Marlborough, Massachusetts 01752**

**(Address of principal executive offices and Zip Code)**

**(508) 767-3861**

**(Registrant's telephone number, including area code)**

**Securities registered pursuant to Section 12(b) of the Act:**

**Title of each class**  
**Common stock, par value \$0.0001 per share**

**Name of exchange on which registered**  
**The NASDAQ Capital Market**

**Securities registered pursuant to Section 12(g) of the Act:**

**None.**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ☐ Yes ☒ No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. ☐ Yes ☒ No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for any such shorter time that the registrant was required to submit and post such files). ☒ Yes ☐ No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

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Large accelerated filer ☐

Accelerated filer ☐

Non-accelerated filer ☐ (Do not check if a smaller reporting company)

Smaller reporting company ☒

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

The aggregate market value of the voting common stock held by non-affiliates of the registrant, based on the closing sale price of the registrant's common stock as reported on The NASDAQ Capital Market on June 30, 2014, was approximately \$37,709,309. Shares of common stock held by each officer and director and by each person who is known to own 10% or more of the outstanding Common Stock have been excluded in that such persons may be deemed to be affiliates of the Company. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 30, 2015, RXi Pharmaceuticals Corporation had 31,221,598 shares of common stock, \$0.0001 par value, outstanding.

### **Documents incorporated by reference:**

Portions of the registrant's definitive proxy statement for its 2015 annual meeting of stockholders, to be filed with the Securities and Exchange Commission not later than 120 days after the registrant's fiscal year ended December 31, 2014, are incorporated by reference into Part III in this Form 10-K.

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**FORWARD-LOOKING STATEMENTS**

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as intends, believes, anticipates, indicates, plans, expects, suggests, may, should, potential, designed to, will and similar references. Such statements but are not limited to, statements about: our ability to successfully develop RXI-109, Samcyprone, and our other product candidates (collectively our product candidates); the future success of our clinical trials with our product candidates; the timing for the commencement and completion of clinical trials; the future success of our strategic partnerships; and our ability to implement cost-saving measures. Forward-looking statements are neither historical facts nor assurances of future performance. These statements are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause our actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others: the risk that our clinical trials with our product candidates may not be successful in evaluating the safety and tolerability of these candidates or providing evidence of increased surgical scar reduction compared to placebo; the successful and timely completion of clinical trials; uncertainties regarding the regulatory process; the availability of funds and resources to pursue our research and development projects, including clinical trials with our product candidates; general economic conditions; and those identified in this Annual Report on Form 10-K under the heading Risk Factors and in other filings the Company periodically makes with the Securities and Exchange Commission. Forward-looking statements contained in this Annual Report on Form 10-K speak as of the date hereof and the Company does not undertake to update any of these forward-looking statements to reflect a change in its views or events or circumstances that occur after the date of this Annual Report on Form 10-K.

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**PART I**

**ITEM 1. *BUSINESS***

**Overview**

RXi Pharmaceuticals Corporation ( **RXi**, **we**, **our** or the **Company** ) is a biotechnology company focused on discovering and developing innovative therapies addressing high unmet medical needs, primarily in the areas of dermatology and ophthalmology. Our development programs are based on our siRNA technology and immunotherapy agents. Our clinical development programs include, but are not limited to, our proprietary, self-delivering RNAi (sd-rxRNA<sup>®</sup>) compounds for the treatment of dermal and retinal scarring and an immunomodulating agent, Samcyprone , for the treatment of such disorders as alopecia areata, warts and cutaneous metastases of melanoma. In addition to these clinical programs, we have a pipeline of discovery and preclinical product candidates in our core therapeutic areas, as well as in other areas of interest. The Company's pipeline, coupled with our extensive patent portfolio, provides for the advancement to further discover and develop innovative therapies either on our own or in collaboration with strategic partners.

**Our Therapeutic Pipeline**

The following is a summary of our therapeutic development programs.

**RXI-109 Clinical Development Program**

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Our first clinical product candidate is RXI-109, a self-delivering RNAi compound (sd-rxRNA) developed for the reduction of dermal scar formation. RXI-109 is designed to reduce the expression of connective tissue growth factor ( **CTGF** ), a critical regulator of several biological pathways involved in fibrosis, including scar formation in the skin. RXI-109 is currently being developed to prevent or reduce dermal scarring following surgery or trauma, as well as for the management of hypertrophic scars and keloids. Hypertrophic scars are abnormal scars that are raised above the normal skin surface and can be reddened or darker than the existing skin tone. These scars result in part from an increased level of collagen and are less elastic than the surrounding skin. Keloids are also raised and reddened or darkened scars resulting from increased collagen production, but keloids often spread beyond the original site of skin injury and may continue to grow in size. Keloids can result from skin trauma as common as an ear piercing or vaccination and may grow to cover large areas.

The two Phase 1 clinical trials with RXI-109 (Study 1201 and Study 1202), which commenced in 2012, showed excellent safety and tolerability with ascending single and multiple doses, as well as dose-dependent effects on the CTGF protein and on the mRNA that controls production of this protein.

Based on the safety profile shown in our two Phase 1 clinical trials, in November 2013, the Company started its first Phase 2a study (Study 1301) in subjects who had pre-existing hypertrophic scars present on their lower abdomen for at least one year. In this study, the subjects underwent scar revision surgery, after which they were treated with RXI-109 on one end of the scar and placebo on the opposite end of the scar. In this first Phase 2a study, treatment was limited: three intradermal doses over a period of two weeks. Enrollment in this study has been completed and subjects will continue to be monitored after this two-week treatment period according to the Study 1301 protocol. The 3-month observations support a clinical effect of RXI-109 in hypertrophic scars and have provided guidance on a dosing regimen. From this early data, the Company also determined that initiating treatment two weeks post-surgery is more beneficial than initiating treatment immediately and that there may be a benefit to extending the treatment window farther into the proliferation phase of healing. With these observations, the Company will be able to optimize the dosing regimens for our current and future clinical trials.

In April 2014, the Company began its second Phase 2a study (Study 1401) to evaluate RXI-109 for treatment to prevent the recurrence of keloids in subjects undergoing a keloidectomy (removal of a keloid). In this study, subjects with two keloids of similar size and location are eligible for the study. After keloidectomy, the lesions are closed and one is treated with RXI-109, and the other is treated with placebo. Enrollment has completed and subjects will be followed for several months after the end of treatment.

The Company's third Phase 2a study (Study 1402) for RXI-109 was initiated in July 2014 to evaluate RXI-109 for the reduction of recurrence of hypertrophic scars following elective scar revision surgery. Subjects with either one long hypertrophic scar, or two scars comparable in length, anatomical location and characteristics will be enrolled and be eligible to receive scar revision surgery. For a single scar, a portion of the revised scar segment will be treated with RXI-109 and a comparably sized length on the opposite end of the revised scar segment will be left untreated. If two scars are revised, one revised scar segment will be treated with RXI-109 and one scar will be left untreated after revision surgery. Subjects in Study 1402 have entered on a rolling basis, of which enrollment is more than 50% complete, and will be evaluated to month nine. This study incorporates the findings from Study 1301 regarding dosing regimen and includes six doses, initiating two weeks after surgery, thus extending the dosing period. Results from this study will help to further define the dose and treatment duration to be used in the formal Phase 2b dose finding studies and ultimately in Phase 3 pivotal studies.

## **Samcyprone Clinical Development Program**

The Company entered into an assignment and exclusive license agreement (the **Assignment and License Agreement**) with Hapten Pharmaceuticals, LLC ( **Hapten** ) under which we acquired from Hapten certain patent rights and related assets and rights, including an investigational new drug application ( **IND** ) and clinical data for Hapten's Samcyprone gel products for therapeutic and prophylactic use. Samcyprone is a proprietary topical formulation of diphenylcyclopropanone ( **DPCP** ), an immunomodulation agent that works by initiating a T-cell response.



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Typically, patients treated with DPCP are initially sensitized with a single, high concentration of drug and subsequently treated with low, non-irritant concentrations. Use of high concentrations of DPCP during the sensitization dose can result in hyper-sensitizing the patient to subsequent challenge doses. In contrast, the use of Samcyprone allows sensitization using a much lower concentration of DPCP, avoiding hyper-sensitization to challenge doses. This should result in an improved safety and tolerability profile while maintaining the known efficacy of DPCP.

Samcyprone is being evaluated for the treatment of alopecia areata, warts and cutaneous metastases of malignant melanoma. A Phase 2a trial to evaluate the efficacy and safety of Samcyprone for the treatment of viral warts has been completed and investigator-sponsored trials for the treatment of cutaneous metastases of various cancers including melanoma and for the treatment of alopecia areata are underway. The Company is currently evaluating next steps for Samcyprone and expects to initiate a second Phase 2a clinical trial for the treatment of warts by the end of 2015.

The mechanism of action of Samcyprone is linked to DPCP's ability to alter the expression of multiple genes and miRNAs involved in the immune response. The Company's work with Samcyprone may allow us to discover specific targets for the potential treatment of immunological disorders that are relevant to the skin, as well as various systemic diseases. This approach may result in the development of sd-rxRNA compounds or other drugs that are more selective for various indications, including treatment of alopecia areata, warts and cutaneous metastases of malignant melanoma.

## **Preclinical Program**

While focusing our efforts on our RXI-109 and Samcyprone development programs, we also continue to advance our ophthalmology franchise into the clinic. The Company's preclinical program for ocular indications with RXI-109 include retinal and corneal scarring. To date, we have shown that CTGF protein levels are reduced in a dose-dependent manner in both the retina and cornea following an intravitreal injection of RXI-109 in a monkey. Toxicity testing of RXI-109 in the eye to support an IND is currently in progress and the Company is working toward filing an IND in mid-2015 for RXI-109 as a potential therapeutic for the scarring component of retinal diseases in the eye, such as age-related macular degeneration (AMD). In AMD, a leading cause of severe visual impairment in people over age 50, blood vessels grow into the retina (neovascularization) and disrupt vision. Current available therapies for AMD rely on suppression of vascular endothelial growth factor to address the neovascularization component of AMD, but not the subsequent retinal scarring that often occurs over time. Treatment with RXI-109 could be of great benefit to these patients.

## **Discovery Program**

We also intend to continue to advance additional development programs both on our own and through collaborations with academic and corporate third parties. Within our dermatology franchise, the Company has selected collagenase and tyrosinase as new discovery stage targets for our self-delivering RNAi platform. Collagenase, or MMP1, is a matrix metalloproteinase involved in the breakdown of extracellular matrix. Selective reduction of MMP1 may be beneficial in the treatment of skin aging disorders, arthritis, acne scarring, blistering skin disorders, corneal erosions and endometriosis. Tyrosinase is the key enzyme in the synthesis of melanin. Melanin is produced by melanocytes and is the pigment that gives human skin, hair and eyes their color. The inhibition of tyrosinase can play a key role in the management of diseases such as cutaneous hyperpigmentation disorders such as lentigines (freckles, age spots and liver spots), retinitis pigmentosa, neuroblastoma and glioblastoma. We have identified potent sd-rxRNA compounds that target MMP1 or tyrosinase for further evaluation.

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Current areas of focus in the discovery stage of the Company's ophthalmology franchise include a grant-funded program for discovery of sd-rxRNA compounds for novel targets for oncology indications specifically including retinoblastoma, and other exploratory efforts to identify potential sd-rxRNA lead compounds and targets from the RNAi-related assets acquired from OPKO Health Inc. ( **OPKO** ) in March 2013.

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### **Future Potential Applications of RXI-109**

Overexpression of CTGF is implicated in dermal scarring and fibrotic disease, and because of this, we believe that RXI-109 or other CTGF-targeting RNAi compounds may be able to treat the fibrotic component of numerous indications, including acute spinal injury, endometriosis, organ fibrosis and vascular restenosis. If the current clinical trials of RXI-109 produce successful results in dermal anti-scarring, we may explore opportunities in these additional indications that can be accessed by local administration, as well as other possible dermatology applications (e.g., cutaneous scleroderma). In addition, overexpression of CTGF has been implicated in diseases such as liver and pulmonary fibrosis. Although the Company does not intend to develop systemic uses of RXI-109 at this time, the Company is open to business development and out-licensing opportunities for those applications.

### **Market Opportunity**

As there are currently no Food and Drug Administration ( **FDA** )-approved drugs to prevent scar formation, a therapeutic of this type could have great benefit for trauma and surgical patients, as a treatment during the surgical revision of existing unsatisfactory scars, and in the treatment, removal and inhibition of keloids (scars that extend beyond the original skin injury). There are over 42 million procedures in the United States each year that could potentially benefit from a therapeutic treatment that could successfully reduce or prevent scarring; thus, the market potential is quite large. According to the American Society for Plastic Surgery, there were 177,000 scar revision surgeries in the United States alone in 2013. In addition to cosmetic and reconstructive surgeries, medical interventions which could incorporate an anti-scarring agent include scarring that results from trauma, surgery or burns (especially relating to raised or hypertrophic scarring or contracture scarring), and surgical revision of existing unsatisfactory scars and keloids.

In November 2013, we signed a distribution agreement with Ethicor Ltd. ( **Ethicor** ), a UK-based unlicensed medicinal products ( **Specials** ) pharmaceutical company. The agreement provides Ethicor with the distribution rights to RXI-109 in the European Union. Ethicor will pay us a double-digit percentage of any gross profits from its sales of RXI-109. Once RXI-109 becomes an approved drug in a given country, the marketing rights in that country revert back to RXi. Under the European medicines legislation (Directive 2001/83/EC, Article 5(1)), we expect that Ethicor will be able to supply, prior to regulatory approval, RXI-109 as a Special drug. A Special drug may be requested by an authorized health-care professional to meet the special needs of an individual patient under their direct responsibility. The collaboration is important for health-care professionals and patients who can get safe controlled early access to a development drug and is a significant milestone for the Company, not only in possible early revenue, but as increased exposure to RXI-109 may be key in accelerating the development of our drug. The Company has not yet generated product revenue and expects minimal revenue during the early stages of the distribution agreement with Ethicor.

### **Financial Condition**

We have generated significant losses to date, have not generated any product revenue to date and may not generate product revenue in the foreseeable future, if ever. We expect to incur significant operating losses as we advance our product candidates through the drug development and regulatory process. We will need to generate significant revenues to achieve profitability and might never do so. In the absence of product revenues, our potential sources of operational funding are expected to be the proceeds from the issuance of debt, sale of equity, funded research and development payments and payments received under partnership and collaborative agreements.

On April 22, 2014, the Company entered into a purchase agreement (the **Prior Purchase Agreement** ) with Lincoln Park Capital Fund, LLC ( **LPC** ), pursuant to which and subject to the terms and conditions contained in the Prior Purchase Agreement, the Company had the right to sell to LPC up to \$20,000,000 in shares of the Company's common

stock over a 30-month term. The Prior Purchase Agreement was terminable, among

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other circumstances, by mutual agreement of LPC and the Company at any time. The Company and LPC executed a termination agreement dated December 18, 2014, whereby the parties mutually agreed to terminate the Prior Purchase Agreement effective immediately. The Company sold a total of \$2.0 million in shares of common stock under the Prior Purchase Agreement and received net proceeds of approximately \$1.9 million after deducting commissions and other offering expenses of approximately \$0.1 million.

On December 18, 2014, the Company entered into a purchase agreement (the **Purchase Agreement**) with LPC, pursuant to which the Company has the right to sell to LPC up to \$10,800,000 in shares of the Company's common stock, subject to certain limitations and conditions set forth in the Purchase Agreement. The Company intends to use the net proceeds from this offering for working capital, to fund the development of the Company's therapeutic programs, as well as for other general corporate purposes. Subsequent to year end, the Company sold a total of 50,000 shares of common stock to LPC under the Purchase Agreement for proceeds of \$0.07 million. There have been no other purchases to date.

We believe that our existing cash and cash equivalents, along with our equity facility with LPC, should be sufficient to fund our operations into at least the third quarter of fiscal 2016. In the future, we will be dependent on obtaining funding from third parties, such as proceeds from the issuance of debt, sale of equity, funded research and development programs and payments under partnership and collaborative research and business development agreements, in order to maintain our operations and meet our obligations to licensors. There is no guarantee that debt, additional equity or other funding will be available to us on acceptable terms, or at all. If we fail to obtain additional funding when needed, we would be forced to scale back or terminate our operations or to seek to merge with or to be acquired by another company.

## **Introduction to the Field of RNAi Therapeutics**

RNAi is a naturally occurring phenomenon where short, double-stranded RNA molecules interfere with the expression of targeted genes. RNAi technology takes advantage of this phenomenon and potentially allows us to effectively interfere with particular genes within living cells by designing RNA-derived molecules targeting those genes.

RNAi offers a novel approach to the drug development process because, as described below under **The RNAi Mechanism**, RNAi compounds can potentially be designed to target any one of the thousands of human genes, many of which are **undruggable** by other modalities. The specificity of RNAi is achieved by an intrinsic, well-understood biological mechanism based on designing the sequence of an RNAi compound to match the sequence of the targeted gene. The sequence of the entire human genome is now known, and the mRNA coding sequence for many proteins is already available. Supported by numerous gene-silencing reports and our own research, we believe that this sequence information can be used to design RNAi compounds to interfere with the expression of almost any specific gene.

## **The RNAi Mechanism**

The genome is made of double-stranded DNA (the double helix) with 20,000–25,000 protein coding genes that act as instruction manuals for the production of all human proteins. Proteins are important molecules that allow cells and organisms to live and function. With rare exceptions, each cell in the human body has the entire complement of genes. However, only a subset of these genes directs the production of proteins in any particular cell type. For example, a muscle cell produces muscle-specific protein, whereas a skin cell does not.

In order for a gene to guide the production of a protein, it must first be copied into a single-stranded chemical messenger (messenger RNA or mRNA), which is then translated into protein. RNAi is a naturally occurring process by which a particular messenger RNA can be destroyed before it is translated into protein. The process of RNAi can

be artificially induced by introducing a small, double-stranded fragment of RNA corresponding to a particular messenger RNA into a cell. A protein complex within the cell called RISC (RNA-

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Induced Silencing Complex) recognizes this double-stranded RNA fragment and binds to it. RISC then splits the double strands apart, retaining one strand in the RISC complex. The RISC then helps this guide strand of RNA bind to and destroy its corresponding cellular messenger RNA target. Thus, RNAi provides a method to potentially block the creation of the proteins that cause disease.

Since gene expression controls most cellular processes, the ability to inhibit gene expression provides a potentially powerful tool to treat human diseases. Furthermore, since the human genome has already been decoded, and based on numerous gene-silencing reports, we believe that RNAi compounds can readily be designed to interfere with the expression of any specific gene. Based on our internal research and our review of certain scientific literature, we also believe that our RNAi platform may allow us to develop therapeutics with significant potential advantages over therapeutics developed using traditional methods, including:

High specificity for targeted genes;

High potency (low doses);

Ability to interfere with the expression of potentially any gene;

Accelerated generation of lead compounds; and

Low toxicity due to a natural mechanism of action.

## **RXi's RNAi Therapeutic Platform**

### **RNAi Compound Design**

Synthetic RNAi compounds are made from a strand or strands of RNA that are manufactured by a nucleic acid synthesizer. The synthesizer is programmed to assemble a strand of RNA of a particular sequence using primarily four nucleotide units (Adenine ( **A** ), Uracil ( **U** ), Cytidine ( **C** ) and Guanosine ( **G** )) that match a small segment of the targeted gene. The hallmark of an RNAi compound is that it has a double-stranded region. The compounds can be of various lengths of nucleotide units and can contain various modifications of the nucleotide units or linkages. The two strands can have overhangs or blunt ends. In some cases, a single strand can form an RNAi compound by forming a structure referred to as a hairpin.

The length and structure of the compound can affect the activity and hence the potency of the RNAi in cells. The first design of RNAi compounds to be pursued for development as human therapeutics were short, double-stranded RNAs that included at least one overhanging single-stranded region and limited modifications, known as small-interfering RNA, or siRNA, which we also refer to as classic siRNA.

We believe that classic siRNAs have drawbacks that may limit the usefulness of those agents as human therapeutics, and that we may be able to utilize the technologies we have licensed and developed internally to optimize RNAi compounds for use as human therapeutic agents. It is the combination of the length, the nucleotide sequence and the configuration of chemical modifications that are important for effective RNAi therapeutics.

Our internal research leads us to believe that next generation rxRNA<sup>®</sup> compounds offer significant advantages over classic siRNA used by other companies developing RNAi therapeutics, highlighted by the following characteristics:

Potent RNAi activity in the absence of a delivery vehicle;

More resistant to nuclease degradation;

Readily manufactured;

Potentially more specific for the target gene;



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More reliable at blocking immune side effects than classic siRNA; and

In the case of sd-rxRNA, the unique ability to be self-delivering, without the need for any additional delivery vehicle.

Based on our own research, we have developed a variety of novel siRNA configurations with potential advantages for therapeutic use. The first of these has been termed rxRNAori®. This configuration has some similarities to classic siRNA in that it is composed of two short RNA strands. We have found that by using a somewhat longer length (25-29 base pairs), removing the overhangs and using proprietary chemical modification patterns, we achieve a high hit rate of very potent (picomolar potency) compounds in a given target sequence. These rxRNAori compounds are modified to increase resistance to nucleases and to prevent off-target effects including induction of an immune response. These novel RNAi compounds are distinct from the siRNA compounds used by many other companies developing RNAi therapeutics in that they are designed specifically for therapeutic use and offer many of the properties that we believe are important to the clinical development of RNAi-based drugs.

The second novel configuration has been called sd-rxRNA to indicate its novel self-delivering properties, which make additional delivery vehicles unnecessary for efficient cellular uptake and RISC-mediated silencing. A combination of at least three characteristics is required for activity: (1) specific, proprietary chemical modifications; (2) a precise number of chemical modifications; and (3) reduction in oligonucleotide content. Kinetic analyses of fluorescently-labeled compounds demonstrate that efficient cellular internalization is observed within minutes of exposure. These molecules are taken up efficiently and cause target gene silencing in diverse cell types (cell lines and primary cells). This novel class of RNAi compounds may afford a broad opportunity for therapeutic development.

We believe that both chemical modification and formulation of RNAi compounds may be utilized to develop RNA drugs suitable for therapeutic use. The route by which an RNAi therapeutic is brought into contact with the body depends on the intended organ or tissue to be treated. Delivery routes can be simplified into two major categories: (1) local (when a drug is delivered directly to the tissue of interest); and (2) systemic (when a drug accesses the tissue of interest through the circulatory system). Local delivery may avoid some hurdles associated with systemic approaches such as rapid clearance from circulation and inefficient tissue extravasation (crossing the endothelial barrier from the blood stream). However, the local delivery approach can only be applied to a limited number of organs or tissues (*e.g.*, skin, eye, lung and potentially the central nervous system).

The key to therapeutic success with RNAi lies in delivering intact RNAi compounds to the target tissue and the interior of the target cells. To accomplish this, we have developed a comprehensive platform that includes a local delivery approach. We work with chemically synthesized RNAi compounds that are optimized for stability and efficacy and combine delivery at the site of action and formulation with delivery agents to achieve optimal delivery to specific target tissues.

### **Local Delivery**

sd-rxRNA molecules have unique properties that improve tissue and cell uptake. Delivery of sd-rxRNA by a local route of administration may avoid hurdles associated with systemic approaches such as rapid clearance from the bloodstream and inefficient extravasation (*e.g.*, crossing the endothelial barrier from the blood stream). We have studied sd-rxRNA molecules in animal models of dermal and ocular delivery. Direct administration of sd-rxRNA via intradermal injection with no additional delivery vehicle to the skin or to the eye demonstrates that target gene silencing can be measured after local administration. The dose levels required for these direct-injection methods are small and suitable for clinical development, suggesting that local delivery indications will be very accessible with the sd-rxRNA technology platform. Target tissues that are potentially accessible for local delivery using sd-rxRNA

compounds include the skin, the eye, the lung, the central nervous system, mucosal tissues, sites of inflammation and tumors (direct administration).

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### **Systemic Delivery**

Systemic delivery occurs when a drug accesses the targeted tissue through the circulatory system. In some cases, such as in targeting a treatment to the liver, the optimal route of delivery may be by a systemic route. We have developed a portfolio of systemic delivery solutions utilizing our RNAi therapeutic platforms. One novel approach involves the use of sd-rxRNA compounds. The self-delivering technology introduces properties required for *in vivo* efficacy such as cell and tissue penetration, reduced blood clearance and improved distribution properties. Systemic delivery of these sd-rxRNAs to mice has resulted in gene-specific inhibition in the liver with no additional delivery vehicle required, albeit at high concentrations. A proof-of-concept preclinical study using rxRNA in conjunction with a standard lipid-based delivery vehicle has enabled us to demonstrate gene-specific inhibition in liver at much lower doses in a mouse model after intravenous, systemic delivery. While delivery of RNAi to the liver may be critical for the treatment of many diseases, additional target tissues that are potentially accessible using rxRNA compounds by systemic delivery include kidney, fat, heart, lung, bone marrow, sites of inflammation, tumors and vascular endothelium.

### **Introduction to Immunomodulators**

Immunotherapy is the treatment of disease by inducing, enhancing or suppressing an immune response. Active agents in immunotherapy are collectively called immunomodulators. They are a diverse array of recombinant, synthetic and natural preparations that help to regulate or normalize the immune system. Samcyprone, licensed by the Company in 2014, is an immunomodulator that works by initiating a T-cell response. T-cells or T lymphocytes are a type of white blood cell that play a key role in cell-mediated immunity. Recently published articles have supported the use of DPCP, the active ingredient in Samcyprone, as an immunomodulator for the treatment of alopecia areata, warts and cutaneous metastases of malignant melanoma. Although DPCP has been used by physicians for several decades, it has never been reviewed or approved by a regulatory authority as a drug. The use of Samcyprone, a topical formulation of DPCP, will allow for lower sensitizing and challenge doses levels than in current use, and should result in an improved safety margin and a more consistent immune response.

### **Intellectual Property**

We protect our proprietary information by means of United States and foreign patents, trademarks and copyrights. In addition, we rely upon trade secret protection and contractual arrangements to protect certain of our proprietary information and products. We have pending patent applications that relate to potential drug targets, compounds we are developing to modulate those targets, methods of making or using those compounds and proprietary elements of our drug discovery platform.

Much of our technology and many of our processes depend upon the knowledge, experience and skills of key scientific and technical personnel. To protect our rights to our proprietary know-how and technology, we require all employees, as well as our consultants and advisors when feasible, to enter into confidentiality agreements that require disclosure and assignment to us of ideas, developments, discoveries and inventions made by these employees, consultants and advisors in the course of their service to us, and we vigorously defend that position with partners, as well as with employees who leave the Company.

We have also obtained rights to various patents and patent applications under licenses with third parties, which require us to pay royalties or milestone payments, or both. The degree of patent protection for biotechnology products and processes, including ours, remains uncertain, both in the United States and in other important markets, because the scope of protection depends on decisions of patent offices, courts and lawmakers in these countries. There is no certainty that our existing patents or others, if obtained, will afford us substantial protection or commercial benefit.

Similarly, there is no assurance that our pending patent applications or patent applications licensed from third parties will ultimately be granted as patents or that those patents that have been issued or are issued in the future will stand if they are challenged in court. We assess our license agreements on

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an ongoing basis, and may from time to time terminate licenses to technology that we do not intend to employ in our immunotherapy or RNAi technology platforms, or in our product discovery or development activities.

***Patents and Patent Applications***

We are actively prosecuting twenty-eight patent families covering our compounds and technologies, including RXI-109, Samcyprone and the RNAi patents and patent applications acquired from OPKO in March 2013. A summary of these patents and patent applications is set forth below in the following table.

	RNAi Platform		Immunomodulator Platform	
	Pending Applications	Issued Patents	Pending Applications	Issued Patents
United States	16	22	2	1
Canada	7	1	0	0
Europe	8	24	1	0
Japan	5	3	0	0
Other Markets	10	1	0	0

***RNAi Platform Patents and Patent Applications***

Our portfolio includes fifty-one issued patents, two of which cover our self-delivering RNAi platform. The first patent covers the use of sd-rxRNAs targeting CTGF for the treatment of fibrotic disorders. The second patent, titled Reduced Size Self-Delivering RNAi Compounds, broadly covers both the composition and methods of use of our self-delivering platform technology. These patents (U.S. Patent Number 8,664,189 and U.S. Patent Number 8,796,443) are scheduled to expire in 2029. The patent applications, including one that was filed as an Patent Cooperation Treaty application, encompass what we believe to be important new RNAi compounds and their use as therapeutics, chemical modifications of RNAi compounds that improve the compounds suitability for therapeutic uses (including delivery) and compounds directed to specific targets (*i.e.*, that address specific disease states).

The patents and any patents that may issue from these pending patent applications will, if issued, be set to expire between 2022 and 2031, not including any patent term extensions that may be afforded under the Federal Food, Drug and Cosmetic Act (and the equivalent provisions in foreign jurisdictions) for any delays incurred during the regulatory approval process relating to human drug products (or processes for making or using human drug products).

***Immunomodulator Platform Patent and Patent Applications***

The Samcyprone portfolio includes one issued patent and three patent applications. The patent and patent applications cover both the compositions and methods of use of Samcyprone for the treatment of warts, human papilloma virus (HPV) skin infections, skin cancer (including melanoma) and immunocompromised patients. The patent and any patents that may issue from the pending applications will be set to expire between 2019 and 2031, not including any patent term extensions that may be afforded under the Federal Food, Drug and Cosmetic Act (and the equivalent provisions in foreign jurisdictions) for any delays incurred during the regulatory approval process relating to human drug products (or processed for making or using human drug products).

***License Agreements***

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We have secured exclusive and non-exclusive rights to develop therapeutics by licensing key RNAi and immunotherapy technologies and patent rights from third parties. These rights relate to chemistry and configuration of compounds, delivery technologies of compounds to cells and therapeutic targets. As we continue to develop our own proprietary compounds, we continue to evaluate both our in-licensed portfolio as well as the

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field for new technologies that could be in-licensed to further enhance our intellectual property portfolio and unique position in the RNAi and immunotherapy space.

*Advirna.* We have entered into agreements with Advirna, LLC ( **Advirna** ) pursuant to which Advirna assigned to us its existing patent and technology rights related to sd-rxRNA<sup>®</sup> technology in exchange for our agreement to pay Advirna an annual maintenance fee of \$100,000 and a one-time milestone payment of \$350,000 upon the issuance of the first patent with valid claims covering the assigned technology, which was paid in the first quarter of 2014. Additionally, we will be required to pay a 1% royalty to Advirna on any licensing revenue received by us with respect to future licensing of the assigned Advirna patent and technology rights. We also granted back to Advirna a license under the assigned patent and technology rights for fields of use outside human therapeutics and diagnostics and issued to Advirna 5% of the Company's fully-diluted shares of common stock upon the completion of the spin-off transaction in 2012.

Our rights under the Advirna agreement will expire upon the later of: (i) the expiration of the last-to-expire of the patent rights (as defined therein) included in the Advirna agreement or (ii) the abandonment of the last-to-be abandoned of such patents, unless earlier terminated in accordance with the provisions of the agreement.

We may terminate the Advirna agreement at any time upon 90 days' written notice to Advirna, and Advirna may terminate the agreement upon 90 days' prior written notice in the event that we cease using commercially reasonable efforts to research, develop, license or otherwise commercialize the patent rights or royalty-bearing products (as defined therein), provided that we may refute such claim within such 90-day period by showing budgeted expenditures for the research, development, licensing or other commercialization consistent with other technologies of similar stage of development and commercial potential as the patent rights or royalty-bearing products. Further, either party at any time may provide to the other party written notice of a material breach of the agreement. If the other party fails to cure the identified breach within 90 days after the date of the notice, the aggrieved party may terminate the agreement by written notice to the party in breach.

*OPKO.* In March 2013, we acquired from OPKO substantially all of its RNAi-related assets, which included patents and patent applications, licenses, clinical and preclinical data and other related assets. In exchange for the assets that we purchased from OPKO, we issued to OPKO 1,666,666 shares of our common stock and agreed to pay, if applicable: (i) up to \$50 million in development and commercialization milestones for the successful development and commercialization of each Qualified Drug (as defined in the Asset Purchase Agreement with OPKO) (collectively, the Milestone Payments ) and (ii) royalty payments equal to: (a) a mid-single-digit percentage of Net Sales (as defined in the Asset Purchase Agreement) with respect to each Qualified Drug sold for an ophthalmologic use during the applicable Royalty Period (as defined in the Asset Purchase Agreement) and (b) a low-single-digit percentage of Net Sales with respect to each Qualified Drug sold for a non-ophthalmologic use during the applicable Royalty Period (collectively, the Royalty Payments ).

*Hapten.* On December 17, 2014, the Company entered into an Assignment and License Agreement with Hapten under which Hapten agreed, effective at a closing that was subject to the satisfaction of certain closing conditions which occurred in February 2015, to sell and assign to us certain patent rights and related assets and rights, including an investigational new drug application and clinical data, for Hapten's Samcyprone gel products for therapeutic and prophylactic use. Under the Assignment and License Agreement and upon the closing, Hapten received a one-time upfront cash payment of \$100,000 and we issued to Hapten 200,000 shares of Company common stock. Pursuant to the Assignment and License Agreement, Hapten will be entitled to receive: (i) future milestone payments tied to the achievement of certain clinical and commercial objectives (all of which payments may be made at our option in cash or through the issuance of common stock) and (ii) escalating royalties based on product sales by us and any sublicensees.

## **Research and Development**

To date, our research programs have focused on identifying product candidates for diseases for which we intend to develop a therapeutic drug. Since we commenced operations, research and development has comprised



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a significant proportion of our total operating expenses and is expected to comprise the majority of our spending for the foreseeable future. There are risks in any new field of drug discovery that preclude certainty regarding the successful development of a product. We cannot reasonably estimate or know the nature, timing and costs of the efforts necessary to complete the development of, or the period in which material net cash inflows are expected to commence from, any product candidate.

For more information on our research and development activity, see Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations Research and Development Expenses of this Annual Report on Form 10-K.

## **Competition**

We believe numerous companies are investigating or plan to investigate a variety of proposed anti-scarring therapies in clinical trials. The companies include large and small pharmaceutical, chemical and biotechnology companies, as well as universities, government agencies and other private and public research organizations. Such companies include CoDa Therapeutics, Inc., Sirnaomics, Inc., FirstString Research, Inc., Promedior, Inc., FibroGen, Inc., miRagen Therapeutics, Inc. and Excaliard Pharmaceuticals, Inc., which was acquired by Pfizer, Inc.

We believe that other companies working in the RNAi area, generally, include Alnylam Pharmaceuticals, Inc., Benitec Limited, Silence Therapeutics plc, Quark Pharmaceuticals, Inc., Tekmira Pharmaceuticals Corporation, Arrowhead Research Corporation, Dicerna Pharmaceuticals, Inc., Sylentis, S.A. and Roche Innovation Center Copenhagen A/S, as well as a number of large pharmaceutical companies. Many other companies are pursuing non-RNAi-based therapies for one or more fibrotic disease indications, including ocular scarring or other indications that we may seek to pursue. See Item 1A, Risk Factors Risks Relating to Our Business and Industry.

We believe numerous companies are developing, investigating, or plan to investigate a variety of proposed topical immunotherapies in the areas of warts, alopecia areata and cutaneous metastasis of malignant melanoma. The companies include large, global pharmaceutical companies in the research phase and with products on the market. Such companies include Leo Pharma, Inc., Astellas Pharma US, Inc., Valeant Pharmaceuticals International, Inc. and Perrigo Company, plc.

## **Government Regulation**

The United States and other developed countries extensively regulate the preclinical and clinical testing, manufacturing, labeling, storage, record-keeping, advertising, promotion, export, marketing and distribution of drugs and biologic products. The FDA regulates pharmaceutical and biologic products under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act and other federal statutes and regulations.

To obtain approval of our future product candidates from the FDA, we must, among other requirements, submit data supporting safety and efficacy for the intended indication as well as detailed information on the manufacture and composition of the product candidate. In most cases, this will require extensive laboratory tests and preclinical and clinical trials. The collection of these data, as well as the preparation of applications for review by the FDA involve significant time and expense. The FDA also may require post-marketing testing to monitor the safety and efficacy of approved products or place conditions on any approvals that could restrict the therapeutic claims and commercial applications of these products. Regulatory authorities may withdraw product approvals if we fail to comply with regulatory standards or if we encounter problems at any time following initial marketing of our products.

The first stage of the FDA approval process for a new biologic or drug involves completion of preclinical studies and the submission of the results of these studies to the FDA. These data, together with proposed clinical

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protocols, manufacturing information, analytical data and other information submitted to the FDA in an IND application, must become effective before human clinical trials may commence. Preclinical studies generally involve FDA regulated laboratory evaluation of product characteristics and animal studies to assess the efficacy and safety of the product candidate.

After the IND becomes effective, a company may commence human clinical trials. These are typically conducted in three sequential phases, but the phases may overlap. Phase 1 trials consist of testing the product candidate in a small number of patients or healthy volunteers, primarily for safety at one or more doses. Phase 2 trials, in addition to safety, evaluate the efficacy of the product candidate in a patient population somewhat larger than Phase 1 trials. Phase 3 trials typically involve additional testing for safety and clinical efficacy in an expanded population at multiple test sites. A company must submit to the FDA a clinical protocol, accompanied by the approval of the Institutional Review Board ( **IRB** ) at the institutions participating in the trials, prior to commencement of each clinical trial.

To obtain FDA marketing authorization, a company must submit to the FDA the results of the preclinical and clinical testing, together with, among other things, detailed information on the manufacture and composition of the product candidate, in the form of a new drug application (an **NDA** ), or, in the case of a biologic, a biologics license application (a **BLA** ).

The amount of time taken by the FDA for approval of an NDA or BLA will depend upon a number of factors, including whether the product candidate has received priority review, the quality of the submission and studies presented, the potential contribution that the compound will make in improving the treatment of the disease in question and the workload at the FDA.

The FDA may, in some cases, confer upon an investigational product the status of a fast track product. A fast track product is defined as a new drug or biologic intended for the treatment of a serious or life threatening condition that demonstrates the potential to address unmet medical needs for this condition. The FDA can base approval of an NDA or BLA for a fast track product on an effect on a surrogate endpoint, or on another endpoint that is reasonably likely to predict clinical benefit. If a preliminary review of clinical data suggests that a fast track product may be effective, the FDA may initiate review of entire sections of a marketing application for a fast track product before the sponsor completes the application.

We anticipate that our products will be manufactured by our strategic partners, licensees or other third parties. Before approving an NDA or BLA, the FDA will inspect the facilities at which the product is manufactured and will not approve the product unless the manufacturing facilities are in compliance with the FDA's current good manufacturing practices ( **cGMP** ), which are regulations that govern the manufacture, holding and distribution of a product. Manufacturers of biologics also must comply with the FDA's general biological product standards. Our manufacturers also will be subject to regulation under the Occupational Safety and Health Act, the Nuclear Energy and Radiation Control Act, the Toxic Substance Control Act and the Resource Conservation and Recovery Act and other applicable environmental statutes. Following approval, the FDA periodically inspects drug and biologic manufacturing facilities to ensure continued compliance with the cGMP. Our manufacturers will have to continue to comply with those requirements. Failure to comply with these requirements subjects the manufacturer to possible legal or regulatory action, such as suspension of manufacturing or recall or seizure of product. Adverse patient experiences with the product must be reported to the FDA and could result in the imposition of marketing restrictions through labeling changes or market removal. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following approval.

The labeling, advertising, promotion, marketing and distribution of a drug or biologic product also must be in compliance with FDA and Federal Trade Commission requirements which include, among others, standards and

regulations for off-label promotion, industry sponsored scientific and educational activities, promotional activities involving the internet, and direct-to-consumer advertising. We also will be subject to a variety of

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federal, state and local regulations relating to the use, handling, storage and disposal of hazardous materials, including chemicals and radioactive and biological materials. In addition, we will be subject to various laws and regulations governing laboratory practices and the experimental use of animals. In each of these areas, as above, the FDA has broad regulatory and enforcement powers, including the ability to levy fines and civil penalties, suspend or delay issuance of product approvals, seize or recall products and deny or withdraw approvals.

We will also be subject to a variety of regulations governing clinical trials and sales of our products outside the United States. Whether or not FDA approval has been obtained, approval of a product candidate by the comparable regulatory authorities of foreign countries and regions must be obtained prior to the commencement of marketing the product in those countries. The approval process varies from one regulatory authority to another and the time may be longer or shorter than that required for FDA approval. In the European Union, Canada and Australia, regulatory requirements and approval processes are similar, in principle, to those in the United States.

## **Environmental Compliance**

Our research and development activities involve the controlled use of potentially harmful biological materials as well as hazardous materials, chemicals and various radioactive compounds. We are subject to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specific waste products. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of bio-hazardous materials. The cost of compliance with these laws and regulations could be significant and may adversely affect capital expenditures to the extent we are required to procure expensive capital equipment to meet regulatory requirements.

## **Human Resources**

As of March 23, 2015, we had fifteen full-time employees, ten of whom were engaged in research and development, and five of whom were engaged in management, administration and finance. None of our employees are represented by a labor union or covered by a collective bargaining agreement, nor have we experienced any work stoppages.

## **ITEM 1A. RISK FACTORS**

### **Risks Relating to Our Business and Industry**

*We are dependent on the success of our lead drug candidate, which may not receive regulatory approval or be successfully commercialized.*

RXI-109, our first RNAi-based product candidate, targets CTGF and may have a variety of medical applications. We began Phase 1 clinical trials for RXI-109 in June 2012 and began Phase 2 clinical trials for RXI-109 in November 2013. The FDA did not require additional information prior to the commencement of our ongoing Phase 2 clinical trials, but may require additional information from the Company regarding our current or planned trials at any time, and such information may be costly to provide or cause potentially significant delays in development. There is no assurance that we will be able to successfully develop RXI-109 or any other product candidate.

We have no commercial products and currently generate no revenue from commercial sales or collaborations and may never be able to develop marketable products. The FDA or similar foreign governmental agencies must approve our products in development before they can be marketed. The process for obtaining FDA approval is both time-consuming and costly, with no certainty of a successful outcome. Before obtaining regulatory approval for the

sale of any drug candidate, we must conduct extensive preclinical tests and successful clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Although the results of

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our Phase 1 clinical trials and preliminary results of our Phase 2 clinical trials of RXI-109 are promising, additional clinical trials will be required to establish the safety and efficacy of RXI-109. We have not yet shown safety or efficacy in humans for any of our other RNAi-based product candidates. A failure of any preclinical study or clinical trial can occur at any stage of testing. The results of preclinical and initial clinical testing of these products may not necessarily indicate the results that will be obtained from later or more extensive testing. Additionally, any observations made with respect to blinded clinical data are inherently uncertain as we cannot know which set of data come from subjects treated with an active drug versus the placebo vehicle. Investors are cautioned not to rely on observations coming from blinded data and not to rely on initial clinical trial results as necessarily indicative of results that will be obtained in subsequent clinical trials.

***A number of different factors could prevent us from obtaining regulatory approval or commercializing our product candidates on a timely basis, or at all.***

We, the FDA or other applicable regulatory authorities or an IRB may suspend clinical trials of a drug candidate at any time for various reasons, including if we or they believe the subjects participating in such trials are being exposed to unacceptable health risks. Among other reasons, adverse side effects of a drug candidate on subjects in a clinical trial could result in the FDA or other regulatory authorities suspending or terminating the trial and refusing to approve a particular drug candidate for any or all indications of use.

Clinical trials of a new drug candidate require the enrollment of a sufficient number of subjects, including subjects who are suffering from the disease or condition the drug candidate is intended to treat and who meet other eligibility criteria. Rates of subject enrollment are affected by many factors, and delays in subject enrollment can result in increased costs and longer development times.

Clinical trials also require the review and oversight of IRBs, which approve and continually review clinical investigations and protect the rights and welfare of human subjects. An inability or delay in obtaining IRB approval could prevent or delay the initiation and completion of clinical trials, and the FDA may decide not to consider any data or information derived from a clinical investigation not subject to initial and continuing IRB review and approval.

Numerous factors could affect the timing, cost or outcome of our drug development efforts, including the following:

Delays in filing or acceptance of initial drug applications for our product candidates;

Difficulty in securing centers to conduct clinical trials;

Conditions imposed on us by the FDA or comparable foreign authorities regarding the scope or design of our clinical trials;

Problems in engaging IRBs to oversee trials or problems in obtaining or maintaining IRB approval of studies;

Difficulty in enrolling subjects in conformity with required protocols or projected timelines;

Third-party contractors failing to comply with regulatory requirements or to meet their contractual obligations to us in a timely manner;

Our drug candidates having unexpected and different chemical and pharmacological properties in humans than in laboratory testing and interacting with human biological systems in unforeseen, ineffective or harmful ways;

The need to suspend or terminate clinical trials if the participants are being exposed to unacceptable health risks;

Insufficient or inadequate supply or quality of our drug candidates or other necessary materials necessary to conduct our clinical trials;



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Effects of our drug candidates not being the desired effects or including undesirable side effects or the drug candidates having other unexpected characteristics;

The cost of our clinical trials being greater than we anticipate;

Negative or inconclusive results from our clinical trials or the clinical trials of others for similar drug candidates or inability to generate statistically significant data confirming the efficacy of the product being tested;

Changes in the FDA's requirements for testing during the course of that testing;

Reallocation of our limited financial and other resources to other clinical programs; and

Adverse results obtained by other companies developing similar drugs.

It is possible that none of the product candidates that we may attempt to develop will obtain the appropriate regulatory approvals necessary to begin selling them or that any regulatory approval to market a product may be subject to limitations on the indicated uses for which we may market the product. The time required to obtain FDA and other approvals is unpredictable, but often can take years following the commencement of clinical trials, depending upon the complexity of the drug candidate. Any analysis we perform of data from clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. Any delay or failure in obtaining required approvals could have a material adverse effect on our ability to generate revenue from the particular drug candidate.

We also are subject to numerous foreign regulatory requirements governing the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process includes all of the risks associated with the FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Approval by the FDA does not assure approval by regulatory authorities outside of the United States.

***The approach we are taking to discover and develop novel therapeutics using RNAi is unproven and may never lead to marketable products.***

RNA interference is a relatively new scientific discovery. Our RNAi technologies have been subject to only limited clinical testing. To date, no company has received regulatory approval to market therapeutics utilizing RNAi, and a number of clinical trials of RNAi technologies by other companies have been unsuccessful. The scientific evidence to support the feasibility of developing drugs based on these discoveries is both preliminary and limited. To successfully develop RNAi-based products, we must resolve a number of issues, including stabilizing the RNAi material and delivering it into target cells in the human body. We may spend large amounts of money trying to resolve these issues and may never succeed in doing so. In addition, any compounds that we develop may not demonstrate in subjects the chemical and pharmacological properties ascribed to them in laboratory studies, and they may interact with human biological systems in unforeseen, ineffective or even harmful ways.

***The FDA could impose a unique regulatory regime for RNAi therapeutics.***

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The substances we intend to develop may represent a new class of drug, and the FDA has not yet established any definitive policies, practices or guidelines in relation to these drugs. While we expect any product candidates that we develop will be regulated as a new drug under the Federal Food, Drug, and Cosmetic Act, the FDA could decide to regulate them or other products we may develop as biologics under the Public Health Service Act. The lack of policies, practices or guidelines may hinder or slow review by the FDA of any regulatory filings that we may submit. Moreover, the FDA may respond to these submissions by defining requirements that we may not have anticipated.

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***Even if we receive regulatory approval to market our product candidates, our product candidates may not be accepted commercially, which may prevent us from becoming profitable.***

The RNAi product candidates that we are developing are based on new technologies and therapeutic approaches. RNAi products may be more expensive to manufacture than traditional small molecule drugs, which may make them more costly than competing small molecule drugs. Additionally, RNAi products do not readily cross the so-called blood brain barrier and, for various applications, are likely to require injection or implantation, which will make them less convenient to administer than drugs administered orally. Key participants in the pharmaceutical marketplace, such as physicians, medical professionals working in large reference laboratories, public health laboratories and hospitals, third-party payors and consumers may not accept products intended to improve therapeutic results based on RNAi technology. As a result, it may be more difficult for us to convince the medical community and third-party payors to accept and use our products or to provide favorable reimbursement. If medical professionals working with large reference laboratories, public health laboratories and hospitals choose not to adopt and use our RNAi technology, our products may not achieve broader market acceptance.

Additionally, although we expect that we will have intellectual property protection for our technology, certain governments may elect to deny patent protection for drugs targeting diseases with high unmet medical need (e.g., as in the case of HIV) and allow in their country internationally unauthorized generic competition. If this were to happen, our commercial prospects for developing any such drugs would be substantially diminished in these countries.

***We are subject to significant competition and may not be able to compete successfully.***

We believe numerous companies are investigating or plan to investigate a variety of proposed anti-scarring therapies in clinical trials. The companies include large and small pharmaceutical, chemical and biotechnology companies, as well as universities, government agencies and other private and public research organizations. Such companies include CoDa Therapeutics, Inc., Sirnaomics, Inc., FirstString Research, Inc., Promedior, Inc., FibroGen, Inc., miRagen Therapeutics, Inc. and Excaliard Pharmaceuticals, Inc., which was acquired by Pfizer, Inc.

We believe other companies working in the RNAi area, generally, include Alnylam Pharmaceuticals, Inc., Benitec Limited, Silence Therapeutics plc, Quark Pharmaceuticals, Inc., Tekmira Pharmaceuticals Corporation, Arrowhead Research Corporation, Dicerna Pharmaceuticals, Inc., Sylentis, S.A. and Roche Innovation Center Copenhagen A/S, as well as a number of large pharmaceutical companies. Many other companies are pursuing non-RNAi-based therapies for one or more fibrotic disease indications, including ocular scarring or other indications that we may seek to pursue.

We believe numerous companies are developing, investigating, or plan to investigate a variety of proposed topical immunotherapies in the areas of warts, alopecia areata and cutaneous metastasis of malignant melanoma. The companies include large, global pharmaceutical companies in the research phase and with products on the market. Such companies include Leo Pharma, Inc., Astellas Pharma US, Inc., Valeant Pharmaceuticals International, Inc. and Perrigo Company, plc.

Most of these competitors have substantially greater research and development capabilities and financial, scientific, technical, manufacturing, marketing, distribution and other resources than we have, and we may not be able to successfully compete with them. In addition, even if we are successful in developing our product candidates, in order to compete successfully we may need to be first to market or to demonstrate that our products are superior to therapies based on different technologies. A number of our competitors have already commenced clinical testing of product candidates and may be more advanced than we are in the process of developing products. If we are not first to market or are unable to demonstrate superiority, any products for which we are able to obtain approval may not be successful.



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***We are dependent on technologies we license, and if we lose the right to license such technologies or fail to license new technologies in the future, our ability to develop new products would be harmed.***

Many patents in the RNAi field have already been exclusively licensed to third parties, including our competitors. If any of our existing licenses are terminated, the development of the products contemplated by the licenses could be delayed or terminated and we may not be able to negotiate additional licenses on acceptable terms, if at all, which would have a material adverse effect on our business.

***We may be unable to protect our intellectual property rights licensed from other parties; our intellectual property rights may be inadequate to prevent third parties from using our technologies or developing competing products; and we may need to license additional intellectual property from others.***

Therapeutic applications of gene silencing technologies, delivery methods and other technologies that we license from third parties are claimed in a number of pending patent applications, but there is no assurance that these applications will result in any issued patents or that those patents would withstand possible legal challenges or protect our technologies from competition. The United States Patent and Trademark Office and patent granting authorities in other countries have upheld stringent standards for the RNAi patents that have been prosecuted so far. Consequently, pending patents that we have licensed and those that we own may continue to experience long and difficult prosecution challenges and may ultimately issue with much narrower claims than those in the pending applications. Third parties may hold or seek to obtain additional patents that could make it more difficult or impossible for us to develop products based on RNAi technology without obtaining a license to such patents, which licenses may not be available on attractive terms, or at all.

In addition, others may challenge the patents or patent applications that we currently license or may license in the future or that we own and, as a result, these patents could be narrowed, invalidated or rendered unenforceable, which would negatively affect our ability to exclude others from using RNAi technologies described in these patents. There is no assurance that these patent or other pending applications or issued patents we license or that we own will withstand possible legal challenges. Moreover, the laws of some foreign countries may not protect our proprietary rights to the same extent as do the laws of the United States. Any patents issued to us or our licensors may not provide us with any competitive advantages, and there is no assurance that the patents of others will not have an adverse effect on our ability to do business or to continue to use our technologies freely. Our efforts to enforce and maintain our intellectual property rights may not be successful and may result in substantial costs and diversion of management time. Even if our rights are valid, enforceable and broad in scope, competitors may develop products based on technology that is not covered by our licenses or patents or patent application that we own.

There is no guarantee that future licenses will be available from third parties for our product candidates on timely or satisfactory terms, or at all. To the extent that we are required and are able to obtain multiple licenses from third parties to develop or commercialize a product candidate, the aggregate licensing fees and milestones and royalty payments made to these parties may materially reduce our economic returns or even cause us to abandon development or commercialization of a product candidate.

Our success depends upon our ability to obtain and maintain intellectual property protection for our products and technologies.

The applications based on RNAi technologies claim many different methods, compositions and processes relating to the discovery, development, delivery and commercialization of RNAi therapeutics. Because this field is so new, very few of these patent applications have been fully processed by government patent offices around the world, and there is a great deal of uncertainty about which patents will issue, when, to whom and with what claims. Although we are not

aware of any blocking patents or other proprietary rights, it is likely that there will be significant litigation and other proceedings, such as interference and opposition proceedings in various patent offices, relating to patent rights in the RNAi field. It is possible that we may become a party to such proceedings.

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***We may not be able to obtain sufficient financing and may not be able to develop our product candidates.***

We believe that our existing cash and cash equivalents and funding available under our LPC purchase agreement should be sufficient to fund our currently planned operations, including the planned Phase 2 programs for RXI-109 and Samcyprone, into the third quarter of fiscal 2016. However, in the future, we may need to incur debt or issue equity in order to fund our planned expenditures as well as to make acquisitions and other investments. We cannot assure you that debt or equity financing will be available to us on acceptable terms or at all. If we cannot, or are limited in the ability to, incur debt, issue equity or enter into strategic collaborations, we may be unable to fund the discovery and development of our product candidates, address gaps in our product offerings or improve our technology.

We anticipate that we will need to raise substantial amounts of money to fund a variety of future activities integral to the development of our business, which may include but are not limited to the following:

To conduct research and development to successfully develop our RNAi and immunotherapy technologies;

To obtain regulatory approval for our products;

To file and prosecute patent applications and to defend and assess patents to protect our technologies;

To retain qualified employees, particularly in light of intense competition for qualified scientists;

To manufacture products ourselves or through third parties;

To market our products, either through building our own sales and distribution capabilities or relying on third parties; and

To acquire new technologies, licenses or products.

We cannot assure you that any needed financing will be available to us on acceptable terms or at all. If we cannot obtain additional financing in the future, our operations may be restricted and we may ultimately be unable to continue to develop and potentially commercialize our product candidates.

***Future financing may be obtained through, and future development efforts may be paid for by, the issuance of debt or equity, which may have an adverse effect on our stockholders or may otherwise adversely affect our business.***

If we raise funds through the issuance of debt or equity, any debt securities or preferred stock issued will have rights, preferences and privileges senior to those of holders of our common stock in the event of a liquidation. In such event, there is a possibility that once all senior claims are settled, there may be no assets remaining to pay out to the holders of common stock. In addition, if we raise funds through the issuance of additional equity, whether through private placements or public offerings, such an issuance would dilute your ownership in us.

The terms of debt securities may also impose restrictions on our operations, which may include limiting our ability to incur additional indebtedness, to pay dividends on or repurchase our capital stock, or to make certain acquisitions or investments. In addition, we may be subject to covenants requiring us to satisfy certain financial tests and ratios, and our ability to satisfy such covenants may be affected by events outside of our control.

***We expect to continue to incur significant research and development expenses, which may make it difficult for us to attain profitability, and may lead to uncertainty as to our ability to continue as a going concern.***

We expend substantial funds to develop our RNAi and immunotherapy technologies, and additional substantial funds will be required for further research and development, including preclinical testing and clinical trials of any product candidates, and to manufacture and market any products that are approved for commercial



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sale. Because the successful development of our products is uncertain, we are unable to precisely estimate the actual funds we will require to develop and potentially commercialize them. In addition, we may not be able to generate enough revenue, even if we are able to commercialize any of our product candidates, to become profitable.

If we are unable to achieve or sustain profitability or to secure additional financing, we may not be able to meet our obligations as they come due, raising substantial doubts as to our ability to continue as a going concern. Any such inability to continue as a going concern may result in our common stockholders losing their entire investment. There is no guarantee that we will become profitable or secure additional financing. Our financial statements contemplate that we will continue as a going concern and do not contain any adjustments that might result if we were unable to continue as a going concern. Changes in our operating plans, our existing and anticipated working capital needs, the acceleration or modification of our expansion plans, increased expenses, potential acquisitions or other events will all affect our ability to continue as a going concern.

***We will rely upon third parties for the manufacture of our clinical product candidates.***

We do not have the facilities or expertise to manufacture supplies of any of our potential product candidates for clinical trials. Accordingly, we will be dependent upon contract manufacturers for these supplies. We currently obtain supplies for RXI-109 from a single supplier, Agilent Technologies, Nucleic Acid Solutions Division. If for any reason we are unable to obtain RXI-109 from this supplier, we would have to seek to obtain it from another major oligonucleotide manufacturer. There is no assurance that we will be able to timely secure needed supply arrangements on satisfactory terms, or at all. Our failure to secure these arrangements as needed could have a material adverse effect on our ability to complete the development of our product candidates or, if we obtain regulatory approval for our product candidates, to commercialize them.

***We may not be able to establish or maintain the third-party relationships that are necessary to develop or potentially commercialize some or all of our product candidates.***

We expect to depend on collaborators, partners, licensees, clinical research organizations and other third parties to support our discovery efforts, to formulate product candidates, to manufacture our product candidates and to conduct clinical trials for some or all of our product candidates. We cannot guarantee that we will be able to successfully negotiate agreements for or maintain relationships with collaborators, partners, licensees, clinical investigators, vendors and other third parties on favorable terms, if at all. Our ability to successfully negotiate such agreements will depend on, among other things, potential partners' evaluation of the superiority of our technology over competing technologies, the quality of the preclinical and clinical data that we have generated and the perceived risks specific to developing our product candidates. If we are unable to obtain or maintain these agreements, we may not be able to clinically develop, formulate, manufacture, obtain regulatory approvals for or commercialize our product candidates. We cannot necessarily control the amount or timing of resources that our contract partners will devote to our research and development programs, product candidates or potential product candidates, and we cannot guarantee that these parties will fulfill their obligations to us under these arrangements in a timely fashion. For example, Ethicor may never achieve significant profits, or any profits, from its distribution of RXI-109 pursuant to our distribution agreement, and we may receive limited or no revenue under the profit-sharing provisions of our agreement. We may not be able to readily terminate any such agreements with contract partners even if such contract partners do not fulfill their obligations to us.

***We are subject to potential liabilities from clinical testing and future product liability claims.***

If any of our future products are alleged to be defective, they may expose us to claims for personal injury by subjects in clinical trials of our products or as a result of our distribution agreement with Ethicor. If our products are approved

by the FDA, users may claim that such products caused unintended adverse effects. We will seek to obtain clinical trial insurance for clinical trials that we conduct, as well as liability insurance for any products that

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we market. There is no assurance that we will be able to obtain insurance in the amounts we seek, or at all. We anticipate that licensees who develop our products will carry liability insurance covering the clinical testing and marketing of those products. There is no assurance, however, that any insurance maintained by us or our licensees will prove adequate in the event of a claim against us. Even if claims asserted against us are unsuccessful, they may divert management's attention from our operations and we may have to incur substantial costs to defend such claims.

***Any drugs we develop may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which could have a material adverse effect on our business.***

If approved, we intend to sell our products to physicians, plastic surgeons and dermatologists, as well as hospitals, oncologists and clinics that receive reimbursement for the healthcare services they provide to their patients from third-party payors, such as Medicare, Medicaid and other domestic and international government programs, private insurance plans and managed care programs. Most third-party payors may deny reimbursement if they determine that a medical product was not used in accordance with cost-effective treatment methods, as determined by the third-party payor, was used for an unapproved indication or if they believe the cost of the product outweighs its benefits. Third-party payors also may refuse to reimburse for experimental procedures and devices. Furthermore, because our programs are still in development, we are unable at this time to determine their cost-effectiveness and the level or method of reimbursement for them. Increasingly, the third-party payors who reimburse patients are requiring that drug companies provide them with predetermined discounts from list prices, and are challenging the prices charged for medical products. If the price we are able to charge for any products we develop is inadequate in light of our development and other costs, our profitability could be adversely affected.

We currently expect that any drugs we develop may need to be administered under the supervision of a physician. Under currently applicable law, drugs that are not usually self-administered may be eligible for coverage by the Medicare program if:

They are incidental to a physician's services;

They are reasonable and necessary for the diagnosis or treatment of the illness or injury for which they are administered according to accepted standard of medical practice;

They are not excluded as immunizations; and

They have been approved by the FDA.

Insurers may refuse to provide insurance coverage for newly approved drugs, or insurance coverage may be delayed or be more limited than the purpose for which the drugs are approved by the FDA. Moreover, eligibility for insurance coverage does not imply that any drug will be reimbursed in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement may be based on payments for other services and may reflect budgetary constraints or imperfections in Medicare data. 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. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting

their own reimbursement rates. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for new drugs that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to develop products and our overall financial condition.

Additionally, third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for medical products and services. Levels of reimbursement may decrease in the future, and future legislation, regulation or reimbursement policies of third-party payors may

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adversely affect the demand for and price levels of our products. If our customers are not reimbursed for our products, they may reduce or discontinue purchases of our products, which could have a material adverse effect on our business, financial condition and results of operations.

Comprehensive healthcare reform legislation, which became law in 2010, could adversely affect our business and financial condition. Among other provisions, the legislation provides that a biosimilar product may be approved by the FDA on the basis of analytical tests and certain clinical studies demonstrating that such product is highly similar to an existing, approved product and that switching between an existing product and the biosimilar product will not result in diminished safety or efficacy. This abbreviated regulatory approval process may result in increased competition if we are able to bring a product to market. The legislation also includes more stringent compliance programs for companies in various sectors of the life sciences industry with which we may need to comply and enhanced penalties for non-compliance with the new healthcare regulations. Complying with new regulations may divert management resources, and inadvertent failure to comply with new regulations may result in penalties being imposed on us.

Some states and localities have established drug importation programs for their citizens, and federal drug import legislation has been introduced in Congress. The Medicare Prescription Drug Plan legislation, which became law in 2003, required the Secretary of Health and Human Services to promulgate regulations for drug reimportation from Canada into the United States under some circumstances, including when the drugs are sold at a lower price than in the United States. The Secretary, however, retained the discretion not to implement a drug reimportation plan if he finds that the benefits do not outweigh the costs, and has so far declined to approve a reimportation plan. Proponents of drug reimportation may attempt to pass legislation that would directly allow reimportation under certain circumstances. Legislation or regulations allowing the reimportation of drugs, if enacted, could decrease the price we receive for any products that we may develop and adversely affect our future revenues and prospects for profitability.

***Even if we obtain regulatory approvals, our marketed drugs will be subject to ongoing regulatory review. If we fail to comply with continuing U.S. and foreign regulations, we could lose our approvals to market drugs and our business would be materially and adversely affected.***

Following regulatory approval of any drugs we may develop, we will remain subject to continuing regulatory review, including the review of adverse drug experiences and clinical results that are reported after our drug products are made available to patients. This would include results from any post-marketing tests or vigilance required as a condition of approval. The manufacturer and manufacturing facilities we use to make any of our drug products will also be subject to periodic review and inspection by the FDA. The discovery of any new or previously unknown problems with the product, manufacturer or facility may result in restrictions on the drug or manufacturer or facility, including withdrawal of the drug from the market. We would continue to be subject to the FDA requirements governing the labeling, packaging, storage, advertising, promotion, recordkeeping and submission of safety and other post-market information for all of our product candidates, even those that the FDA had approved. If we fail to comply with applicable continuing regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approval, product recalls and seizures, operating restrictions and other adverse consequences.

***If we fail to attract, hire and retain qualified personnel, we may not be able to design, develop, market or sell our products or successfully manage our business.***

Our business prospects are dependent on our management team and all of our employees. The loss of any of our key employees, including Drs. Cauwenbergh and Pavco, who serve as our Chief Executive Officer and our Chief Development Officer, respectively, or our inability to identify, attract, retain and integrate additional qualified key personnel, could make it difficult for us to manage our business successfully and achieve our business objectives.



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Competition for skilled research, product development, regulatory and technical personnel is intense, and we may not be able to recruit and retain the personnel we need. The loss of the services of any key research, product development, regulatory and technical personnel, or our inability to hire new personnel with the requisite skills, could restrict our ability to develop our product candidates.

### **Risks Relating to Our Common Stock**

***The price of our common stock has been and may continue to be volatile and our recent relisting on the Nasdaq Capital Market may further increase volatility.***

The stock markets, in general, and the markets for drug delivery and pharmaceutical company stocks, in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. These broad market fluctuations may adversely affect the trading price of our common stock. In addition, the limited trading volume of our stock may contribute to its volatility.

Further, in February 2014 our common stock commenced trading on the Nasdaq Capital Market. Our stock price may be subject to additional volatility as a result of this listing on the Nasdaq Capital Market.

In the past, following periods of volatility in the market price of a particular company's securities, litigation has often been brought against that company. If litigation of this type is brought against us, it could be extremely expensive and divert management's attention and the Company's resources.

***We have issued preferred stock in the past and possibly may issue more preferred stock in the future, and the terms of the preferred stock may reduce the value of our common stock.***

We are authorized to issue up to 10,000,000 shares of preferred stock in one or more series. There were 3,000 shares of our Series A convertible preferred stock issued and outstanding at March 30, 2015. Our Board of Directors may determine the terms of future preferred stock offerings without further action by our stockholders. The issuance of our preferred stock could affect your rights or reduce the value of our outstanding common stock. In particular, rights granted to holders of preferred stock may include voting rights, preferences as to dividends and liquidation, conversion and redemption rights and restrictions on our ability to merge with or sell our assets to a third party. Additionally, the sale of a significant number of shares of common stock received upon conversion of our Series A or Series A-1 convertible preferred stock could cause the market price of our common stock to decline.

***We may acquire other businesses or form joint ventures that may be unsuccessful and could dilute your ownership interest in the Company.***

As part of our business strategy, we may pursue future acquisitions of other complementary businesses and technology licensing arrangements. We also may pursue strategic alliances. We have no experience with respect to acquiring other companies and limited experience with respect to the formation of collaborations, strategic alliances and joint ventures. We may not be able to integrate such acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. We also could experience adverse effects on our reported results of operations from acquisition related charges, amortization of acquired technology and other intangibles and impairment charges relating to write-offs of goodwill and other intangible assets from time to time following the acquisition. Integration of an acquired company requires management resources that otherwise would be available for ongoing development of our existing business. We may not realize the anticipated benefits of any acquisition, technology license or strategic alliance. For example, pursuant to the OPKO Asset Purchase, we acquired substantially all of OPKO's RNAi-related assets, including patents, licenses, clinical and preclinical data and other assets. These assets are

at an early stage of development and will require a significant investment of time and capital if we are to be successful in developing them. There is no assurance that we will be successful in developing the assets that we acquired in the OPKO Asset Purchase, and a failure to



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successfully develop these assets could diminish our prospects. Further, if we fail to use commercially reasonable efforts to develop the OPKO assets for at least one clinical indication, OPKO would have the right, after a 180-day cure period, to reacquire the assets from us without any consideration.

To finance future acquisitions, we may choose to issue shares of our common stock or preferred stock as consideration, which would dilute your ownership interest in us. Alternatively, it may be necessary for us to raise additional funds through public or private financings. Additional funds may not be available on terms that are favorable to us and, in the case of equity financings, may result in dilution to our stockholders. Any future acquisitions by us also could result in large and immediate write-offs, the incurrence of contingent liabilities or amortization of expenses related to acquired intangible assets, any of which could harm our operating results.

***The holders of our Series A and Series A-1 convertible preferred stock may be able to delay or prevent a change in corporate control that would be beneficial to our stockholders.***

The holders of our Series A convertible preferred stock ( **Series A Preferred Stock** ) and Series A-1 convertible preferred stock ( **Series A-1 Preferred Stock** ) have the right to convert at any time their shares of our Series A Preferred Stock and Series A-1 Preferred Stock into shares of our common stock, except to the extent that any such holder would own more than 9.999% of our common stock outstanding immediately after giving effect to the conversion. Although our Series A and Series A-1 Preferred Stock generally are non-voting stock, the holders of our Series A and Series A-1 Preferred Stock will be entitled to vote on an as-converted basis together with our common stock with respect to any transaction that would constitute a deemed liquidation event under our charter, including any proposed merger or sale of the Company. Although the Series A and Series A-1 Preferred Stock holders have no rights to influence our day-to-day operations or vote on the election of directors, by virtue of their voting rights in the context of a deemed liquidation event, the holders of our Series A and Series A-1 Preferred Stock will be able to significantly influence the outcome of the vote on any such extraordinary transaction that is required to be submitted to a vote of our stockholders. This right may adversely affect the market price of our common stock by:

Delaying, deferring or preventing a change in control of the Company;

Impeding a merger, consolidation, takeover or other business combination involving the Company; or

Discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of the Company in a hostile transaction.

***We do not anticipate paying cash dividends in the foreseeable future.***

Our business requires significant funding. We currently plan to invest all available funds and future earnings in the development and growth of our business and do not anticipate paying any cash dividends on our common stock in the foreseeable future. As a result, capital appreciation, if any, of our common stock will be your sole source of potential gain for the foreseeable future.

***Provisions of our certificate of incorporation and bylaws and Delaware law might discourage, delay or prevent a change of control of the Company or changes in our management and, as a result, depress the trading price of our common stock.***

## Edgar Filing: RXi Pharmaceuticals Corp - Form 10-K

Our certificate of incorporation and bylaws contain provisions that could discourage, delay or prevent a change of control of the Company or changes in our management that the stockholders of the Company may deem advantageous. These provisions:

Authorize the issuance of blank check preferred stock that our Board of Directors could issue to increase the number of outstanding shares and to discourage a takeover attempt;

Prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;

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Provide that the Board of Directors is expressly authorized to adopt, alter or repeal our bylaws; and

Establish advance notice requirements for nominations for election to our Board of Directors or for proposing matters that can be acted upon by stockholders at stockholder meetings.

Although we believe these provisions collectively provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our Board of Directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management team by making it more difficult for stockholders to replace members of our Board of Directors, which is responsible for appointing the members of our management.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

**ITEM 1B. *UNRESOLVED STAFF COMMENTS***

None.

**ITEM 2. *PROPERTIES***

On December 17, 2013, we entered into a lease (the **Lease**) with 257 Simarano Drive, LLC, Brighton Properties, LLC, Robert Stubblebine 1, LLC and Robert Stubblebine 2, LLC to lease office and laboratory space in the building known as the **Main Building** located at 257 Simarano Drive, Marlborough, Massachusetts, covering approximately 7,581 square feet. The premises are used by the Company for office and laboratory space. The term of the Lease commenced on April 1, 2014 and continues for five years, expiring on March 31, 2019. The base rent for the premises during the first year of the Lease is \$107,709.50 per annum, payable monthly. Each year thereafter, the base rent shall increase by approximately 3% over the base rent from the prior year.

We believe that our facilities are suitable for our current and future needs.

**ITEM 3. *LEGAL PROCEEDINGS***

Although we are not currently involved in any legal proceedings, from time to time, we may become a party to various legal actions and complaints arising in the ordinary course of business.

**ITEM 4. *MINE SAFETY DISCLOSURES***

Not applicable.



**Table of Contents****PART II.****ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES****Market Information**

Our common stock is listed on the NASDAQ Capital Market under the symbol RXII. On July 23, 2013, we effected a 1- for-30 reverse stock split. The share prices in the table below are shown on a post-split basis. The following table shows the high and low per-share sale prices of our common stock for the periods indicated:

	<b>High</b>	<b>Low</b>
<b>2013</b>		
First Quarter	\$ 10.74	\$ 2.10
Second Quarter	8.67	5.10
Third Quarter	6.23	3.23
Fourth Quarter	3.60	2.55
<b>2014</b>		
First Quarter	\$ 6.84	\$ 2.82
Second Quarter	4.44	2.60
Third Quarter	3.98	1.93
Fourth Quarter	2.30	1.40

**Holders**

At March 23, 2015, there were approximately 166 holders of record of our common stock. Because many of our shares are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of individual stockholders represented by these holders of record.

**Dividends**

We have never paid any cash dividends and do not anticipate paying any cash dividends on our common stock in the foreseeable future. We expect to retain future earnings, if any, for use in our development activities and the operation of our business. The payment of any future dividends will be subject to the discretion of our Board of Directors and will depend, among other things, upon our results of operations, financial condition, cash requirements, prospects and other factors that our Board of Directors may deem relevant.

**Securities Authorized for Issuance Under Equity Compensation Plans**

We intend to file with the SEC a definitive proxy statement, which we refer to herein as the Proxy Statement, not later than 120 days after the close of the fiscal year ended December 31, 2014. The information required by this item relating to our equity compensation plans is incorporated herein by reference to the information contained under the section captioned "Equity Compensation Plan Information" of the Proxy Statement.

**Unregistered Sales of Securities**

No sales or issues of unregistered securities occurred that have not previously been disclosed in a Quarterly Report on Form 10-Q or in a Current Report on Form 8-K.

**Repurchases of Equity Securities**

We did not repurchase any shares of our common stock during fiscal 2014 or fiscal 2013.

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### **ITEM 6. SELECTED FINANCIAL DATA**

As a smaller reporting company, we are not required to provide this information.

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

*The following discussion of our financial condition and results of operations should be read in conjunction with our financial statements and the notes to those financial statements included in Item 8 of this Annual Report on Form 10-K. This discussion contains forward-looking statements that involve significant risks and uncertainties. As a result of many factors, such as those set forth under Risk Factors and elsewhere in this Annual Report on Form 10-K, our actual results may differ materially from those anticipated in these forward-looking statements. Please refer to the discussion under the heading Forward-Looking Statements above.*

#### **Overview**

RXi Pharmaceuticals Corporation ( **RXi**, **we**, **our** or the **Company** ) is a biotechnology company focused on discovering and developing innovative therapies addressing high unmet medical needs, primarily in the areas of dermatology and ophthalmology. Our development programs are based on our siRNA technology and immunotherapy agents. Our clinical development programs include, but are not limited to, our proprietary, self-delivering RNAi (sd-rxRNA®) compounds for the treatment of dermal and retinal scarring and an immunomodulating agent, Samcyprone , for the treatment of such disorders as alopecia areata, warts and cutaneous metastases of melanoma. In addition to these clinical programs, we have a pipeline of discovery and preclinical product candidates in our core therapeutic areas, as well as in other areas of interest. The Company's pipeline, coupled with our extensive patent portfolio, provides for the advancement to further discover and develop innovative therapies either on our own or in collaboration with strategic partners.

Our first clinical product candidate is RXI-109, a self-delivering RNAi compound (sd-rxRNA) developed for the reduction of dermal scar formation. RXI-109 is designed to reduce the expression of connective tissue growth factor ( **CTGF** ), a critical regulator of several biological pathways involved in fibrosis, including scar formation in the skin. RXI-109 is currently being developed to prevent or reduce dermal scarring following surgery or trauma, as well as for the management of hypertrophic scars and keloids. Hypertrophic scars are abnormal scars that are raised above the normal skin surface and can be reddened or darker than the existing skin tone. These scars result in part from an increased level of collagen and are less elastic than the surrounding skin. Keloids are also raised and reddened or darkened scars resulting from increased collagen production, but keloids often spread beyond the original site of skin injury and may continue to grow in size. Keloids can result from skin trauma as common as an ear piercing or vaccination and may grow to cover large areas.

Based on the safety profile shown in our two Phase 1 clinical trials, in November 2013, the Company started its first Phase 2a study (Study 1301) in subjects who had pre-existing hypertrophic scars present on their lower abdomen for at least one year. In this study, the subjects underwent scar revision surgery, after which they were treated with RXI-109 on one end of the scar and placebo on the opposite end of the scar. In this first Phase 2a study, treatment was limited; three intradermal doses over a period of two weeks. Enrollment in this study has been completed and subjects will continue to be monitored after this two-week treatment period according to the Study 1301 protocol. The 3-month observations support a clinical effect of RXI-109 in hypertrophic scars and have provided guidance on a dosing regimen. From this early data, the Company also determined that initiating treatment two-weeks post-surgery is more beneficial than initiating treatment immediately and that there may be a benefit to extending the treatment window farther into the proliferation phase of healing. With these observations, the Company will be able to optimize the

dosing regimens for our current and future clinical trials.

In April 2014, the Company began its second Phase 2a study (Study 1401) to evaluate RXI-109 for treatment to prevent the recurrence of keloids in subjects undergoing a keloidectomy (removal of a keloid). In



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this study, subjects with two keloids of similar size and location are eligible for the study. After keloidectomy, the lesions are closed and one is treated with RXI-109, and the other is treated with placebo. Enrollment has completed and subjects will be followed for several months after the end of treatment.

The Company's third Phase 2a study (Study 1402) for RXI-109 was initiated in July 2014 to evaluate RXI-109 for the reduction of recurrence of hypertrophic scars following elective scar revision surgery. Subjects with either one long hypertrophic scar, or two scars comparable in length, anatomical location and characteristics will be enrolled and be eligible to receive scar revision surgery. For a single scar, a portion of the revised scar segment will be treated with RXI-109 and a comparably sized length on the opposite end of the revised scar segment will be left untreated. If two scars are revised, one revised scar segment will be treated with RXI-109 and one scar will be left untreated after revision surgery. Subjects in Study 1402 have entered on a rolling basis, of which enrollment is more than 50% complete, and will be evaluated to month nine. This study incorporates the findings from Study 1301 regarding dosing regimen and includes six doses, initiating two weeks after surgery, thus extending the dosing period. Results from this study will help to further define the dose and treatment duration to be used in the formal Phase 2b dose finding studies and ultimately in Phase 3 pivotal studies.

In December 2014, the Company entered into an assignment and exclusive license agreement with Hapten Pharmaceuticals, LLC ( "**Hapten** ") under which we acquired from Hapten certain patent rights and related assets and rights, including an investigational new drug application ( "**IND** ") and clinical data for Hapten's Samcyprone gel products for therapeutic and prophylactic use. Samcyprone is a proprietary topical formulation of diphenylcyclopropenone ( "**DPCP** "), an immunomodulation agent that works by initiating a T-cell response. Typically, patients treated with DPCP are initially sensitized with a single, high concentration of drug and subsequently treated with low, non-irritant concentrations. Use of high concentrations of DPCP during the sensitization dose results in hyper-sensitizing the patient to subsequent challenge doses. In contrast, the use of Samcyprone allows sensitization using a much lower concentration of DPCP, avoiding hyper-sensitization to challenge doses. This should result in an improved safety and tolerability profile while maintaining the known efficacy of DPCP.

Samcyprone is being evaluated for the treatment of alopecia areata, warts and cutaneous metastases of malignant melanoma. A Phase 2a trial to evaluate the efficacy and safety of Samcyprone for the treatment of viral warts has been completed and investigator-sponsored trials for the treatment of cutaneous metastases of various cancers including melanoma and alopecia areata are underway. The Company is currently evaluating next steps for Samcyprone and expects to initiate a second Phase 2a clinical trial for the treatment of warts by the end of 2015.

While focusing our efforts on our RXI-109 and Samcyprone clinical programs, we also continue to advance our preclinical and discovery development programs, both on our own and through collaborations with academic and corporate third parties. In the preclinical stage, the Company has a clinical program for ocular indications with RXI-109 which includes retinal and corneal scarring. Toxicology studies for RXI-109 in the eye to support an IND are currently in progress and the Company is working toward filing an IND in mid-2015 for RXI-109 as a potential therapeutic for the scarring component of retinal diseases in the eye, such as age-related macular degeneration. Current areas of focus in the discovery stage of our ophthalmology franchise include a grant-funded program for discovery of sd-rxRNA compounds for novel targets for oncology indications specifically including retinoblastoma, and other exploratory efforts to identify potential sd-rxRNA lead compounds and targets from the RNAi-related assets acquired from OPKO Health, Inc. in March 2013. Within our dermatology franchise, the Company has selected collagenase and tyrosinase as new discovery stage targets for our self-delivering RNAi platform. For each of these two targets, we have identified potent sd-rxRNA compounds that target MMP1 or tyrosinase for further evaluation.

On April 22, 2014, the Company entered into a purchase agreement (the "**Prior Purchase Agreement** ") with Lincoln Park Capital Fund, LLC ( "**LPC** "), pursuant to which and subject to the terms and conditions contained in the Prior

Purchase Agreement, the Company had the right to sell to LPC up to \$20,000,000 in shares

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of the Company's common stock over a 30-month term. The Prior Purchase Agreement was terminable, among other circumstances, by mutual agreement of LPC and the Company at any time. The Company and LPC executed a termination agreement dated December 18, 2014, whereby the parties mutually agreed to terminate the Prior Purchase Agreement effective immediately. The Company sold a total of \$2.0 million in shares of common stock under the Prior Purchase Agreement and received net proceeds of approximately \$1.9 million after deducting commissions and other offering expenses of approximately \$0.1 million.

On December 18, 2014, the Company entered into a purchase agreement (the **Purchase Agreement**) with LPC, pursuant to which the Company has the right to sell to LPC up to \$10,800,000 in shares of the Company's common stock, subject to certain limitations and conditions set forth in the Purchase Agreement. The Company intends to use the net proceeds from this offering for working capital, to fund the development of the Company's therapeutic programs, as well as for other general corporate purposes. Subsequent to year end, the Company sold a total of 50,000 shares of common stock to LPC under the Purchase Agreement for proceeds of \$0.07 million. There have been no other purchases to date.

## **Research and Development**

To date, our research programs have focused on identifying product candidates for diseases for which we intend to develop a therapeutic drug. Since we commenced operations, research and development has comprised a significant proportion of our total operating expenses and is expected to comprise the majority of our spending for the foreseeable future.

There are risks in any new field of drug discovery that preclude certainty regarding the successful development of a product. We cannot reasonably estimate or know the nature, timing and costs of the efforts necessary to complete the development of, or the period in which material net cash inflows are expected to commence from, any product candidate. Our inability to make these estimates results from the uncertainty of numerous factors, including but not limited to:

Our ability to advance product candidates into preclinical research and clinical trials;

The scope and rate of progress of our preclinical program and other research and development activities;

The scope, rate of progress and cost of any clinical trials we commence;

The cost of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;

Clinical trial results;

The terms and timing of any collaborative, licensing and other arrangements that we may establish;

The cost and timing of regulatory approvals;

The cost of establishing clinical and commercial supplies of our product candidates and any products that we may develop;

The cost and timing of establishing sales, marketing and distribution capabilities;

The effect of competing technological and market developments; and

The effect of government regulation and insurance industry efforts to control healthcare costs through reimbursement policy and other cost management strategies.

Failure to complete any stage of the development of our product candidates in a timely manner could have a material adverse effect on our operations, financial position and liquidity.

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**License Agreements**

We have entered into licensing relationships with academic institutions, research foundations and commercial entities, and may seek to enter into additional licenses with pharmaceutical and biotechnology companies. We also may enter into strategic alliances to expand our intellectual property portfolio and to potentially accelerate our development programs by gaining access to technology and funding, including equity sales, license fees and other revenues. For each product that we develop that is covered by the patents licensed to us, including our material licenses discussed elsewhere in this Annual Report on Form 10-K, we are obligated to make additional payments upon the attainment of certain specified product development milestones.

See Business Intellectual Property and Note 11 to our financial statements in Item 8 of this Annual Report on Form 10-K for information on our material license agreements.

**Critical Accounting Policies and Estimates**

The discussion and analysis of our financial condition and results of operations is based upon our financial statements, which have been prepared in accordance with United States generally accepted accounting principles ( **GAAP** ). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, including those related to the impairment of long-lived assets, certain accrued expenses and stock-based compensation. We base our estimates on historical experience and various other assumptions that are believed to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions and could have a material impact on our reported results. While our significant accounting policies are more fully described in the Notes to our financial statements included elsewhere in this Annual Report on Form 10-K, we believe the following accounting policies to be the most critical in understanding the judgments and estimates we use in preparing our financial statements.

***Research and Development Expenses***

Research and development costs are charged to expense as incurred and relate to salaries, employee benefits, facility-related expenses, supplies, stock-based compensation related to employees and non-employees involved in the Company's research and development, external services, other operating costs and overhead related to our research and development departments, costs to acquire technology licenses and expenses associated with preclinical activities and our clinical trials. Payments made by the Company in advance for research and development services not yet provided and/or for materials not yet received are recorded as prepaid expenses. Accrued liabilities are recorded related to those expenses for which vendors have not yet billed us with respect to services provided and/or materials that we have received.

Preclinical and clinical trial expenses relate to third-party services, subject-related fees at the sites where our clinical trials are being conducted, laboratory costs, analysis costs, toxicology studies and investigator fees. Costs associated with these expenses are generally payable upon the passage of time or when certain milestones are achieved. Expense is recorded during the period incurred or in the period in which a milestone is achieved. In order to ensure that we have adequately provided for preclinical and clinical expenses during the proper period, we maintain an accrual to cover these expenses. These accruals are assessed on a quarterly basis and are based on such assumptions as expected total cost, the number of subjects and clinical trial sites and length of the study. Actual results may differ from these estimates and could have a material impact on our reported results. Our historical accrual estimates have not been materially different from our actual costs.

***Stock-based Compensation***

We follow the provisions of Financial Accounting Standards Board ( **FASB** ) Accounting Standards Codification ( **ASC** ) Topic 718, *Compensation – Stock Compensation* ( **ASC 718** ), which requires the measurement and recognition of compensation expense for all stock-based payment awards made to employees,

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officers and non-employee directors, including stock options. Stock compensation expense based on the grant date fair value estimated in accordance with the provisions of ASC 718 is recognized as an expense over the requisite service period. Determining the amount of stock-based compensation to be recorded requires us to develop highly subjective estimates to be used in calculating the grant-date fair value of stock options. We use the Black-Scholes option pricing model to value our option grants and determine the related compensation expense. The use of the model requires us to make estimates of the following assumptions:

*Expected volatility* Due to our limited trading history, we are responsible for estimating volatility and currently use the expected volatilities of similar entities. We have considered a number of factors in making our determination as to entities that are considered similar, such as the industry, stage of development, size of the company, and financial leverage.

*Expected term* We use the simplified method to estimate the expected term assumption. The simplified method is based on the vesting period and the contractual term for each grant, or for each vesting-tranche for awards with graded vesting.

*Risk-free interest rate* The yield on zero-coupon U.S. Treasury securities for a period that is commensurate with the expected term assumption is used as the risk-free interest rate.

*Dividend Yield* We utilize a dividend yield of zero based on the fact that we have never paid cash dividends and currently have no intention to pay cash dividends.

For stock options granted as consideration for services rendered by non-employees, the Company recognizes compensation expense in accordance with the requirements of FASB ASC Topic 505-50, *Equity Based Payments to Non-Employees*. Non-employee option grants that do not vest immediately upon grant are recorded as an expense over the requisite service period of the underlying stock options. At the end of each financial reporting period prior to vesting, the value of these options, as calculated using the Black-Scholes option-pricing model, will be re-measured using the fair value of the Company's common stock and the non-cash compensation recognized during the period will be adjusted accordingly. Since the fair value of options granted to non-employees is subject to change in the future, the amount of the future compensation expense will include fair value re-measurements until the stock options are fully vested.

**Results of Operations**

The following data summarizes our results of operations for the following periods indicated, in thousands:

	<b>For the Years Ended December 31,</b>	
	<b>2014</b>	<b>2013</b>
Revenue	\$ 71	\$ 399
Research and development expenses	(5,680)	(17,651)
General and administrative expenses	(3,217)	(3,697)
Operating loss	(8,826)	(20,949)
Net loss	(8,800)	(20,925)
Net loss applicable to common stockholders	\$ (12,930)	\$ (29,535)

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

**Revenue**

We generate revenue through government grants. The following table summarizes our total revenues from government grants, for the periods indicated, in thousands:

	<b>For the Years Ended December 31,</b>	
	<b>2014</b>	<b>2013</b>
Grant revenues	\$ 71	\$ 399



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Total revenues were approximately \$71,000 for the year ended December 31, 2014, compared with \$399,000 for the year ended December 31, 2013. The decrease of \$328,000, or 82%, was due to the reduced number of the Company's outstanding government grants and a reduction of work related to the grants during the year ended December 31, 2014 as compared with the same period in the prior year.

We had \$47,000 of deferred revenue at December 31, 2014, which consists of receipt of grant awards from the government, which we have not yet recognized, pursuant to our revenue recognition policies, as the work has not been completed. For the foreseeable future, we expect our revenue to continue to be derived primarily from government grants and we expect the amount of our grant revenue to fluctuate from period to period.

***Operating Expenses***

The following table summarizes our total operating expenses, for the periods indicated, in thousands:

	<b>For the Years Ended December 31,</b>	
	<b>2014</b>	<b>2013</b>
Research and development expenses	\$ 5,680	\$ 17,651
General and administrative expenses	3,217	3,697
<b>Total operating expenses</b>	<b>\$ 8,897</b>	<b>\$ 21,348</b>

**Research and Development Expenses**

Research and development expenses consist of compensation-related costs for our employees dedicated to research and development activities, fees related to our Scientific Advisory Board members, expenses related to our ongoing research and development efforts primarily related to our clinical trials, drug manufacturing, outside contract services, licensing and patent fees and laboratory supplies and services for our research programs. We expect research and development expenses to increase as we expand our discovery, preclinical and clinical activities.

Total research and development expense was approximately \$5,680,000 for the year ended December 31, 2014, compared with \$17,651,000 for the year ended December 31, 2013. The decrease of \$11,971,000, or 68%, was primarily due to a decrease of \$12,250,000 in expense related to the fair value of common stock issued in exchange for patent and technology rights and a decrease of \$114,000 in employee stock-based compensation expense offset by an increase of \$355,000 in research and development expenses driven by the costs to support the Company's three Phase 2a clinical trials and an increase of \$38,000 in non-employee stock-based compensation related to the change in the fair value of stock options.

**General and Administrative Expenses**

General and administrative expenses consist primarily of compensation-related costs for our employees dedicated to general and administrative activities, legal fees, audit and tax fees, consultants, professional services and general corporate expenses.

General and administrative expense was approximately \$3,217,000 for the year ended December 31, 2014, compared with \$3,697,000 for the year ended December 31, 2013. The decrease of \$480,000, or 13%, was primarily due to a

decrease of \$423,000 in general and administrative expenses primarily due to a decrease in professional services as compared to the prior year due to such transactions as the Company's completion of a reverse split and Nasdaq Listing application in 2013, a decrease in bonus expense, a decrease in Delaware franchise tax as a result of the Company's reduction in authorized common stock approved by stockholders in 2014 and a decrease of \$57,000 in employee stock-based compensation expense.

**Table of Contents*****Series A and Series A-1 Preferred Stock Dividends***

The following table summarizes our Series A and Series A-1 Preferred Stock transactions for the periods indicated, in thousands:

	<b>For the Years Ended December 31,</b>	
	<b>2014</b>	<b>2013</b>
Series A and Series A-1 Preferred Stock dividends	\$ 4,130	\$ 8,610

Series A and Series A-1 Preferred Stock dividends were approximately \$4,130,000 for the year ended December 31, 2014, compared with \$8,610,000 for the year ended December 31, 2013. The decrease of \$4,480,000, or 52%, was due to changes in the Company's closing common stock price on the dividend payment dates and the number of preferred shares earning dividends each quarter.

The rights and preferences of the Series A and Series A-1 Preferred Stock and the calculation of the dividend payable, are described further in Notes 7 and 8 to our financial statements in Item 8 of this Annual Report on Form 10-K.

**Liquidity and Capital Resources**

We had cash and cash equivalents of approximately \$8.5 million as of December 31, 2014, compared with cash, cash equivalents and short-term investments of approximately \$14.4 million as of December 31, 2013.

On April 22, 2014, the Company entered into a purchase agreement (the **Prior Purchase Agreement**) with Lincoln Park Capital Fund, LLC ( **LPC** ), pursuant to which and subject to the terms and conditions contained in the Prior Purchase Agreement, the Company had the right to sell to LPC up to \$20,000,000 in shares of the Company's common stock over a 30-month term. The Prior Purchase Agreement was terminable, among other circumstances, by mutual agreement of LPC and the Company at any time. The Company and LPC executed a termination agreement dated December 18, 2014, whereby the parties mutually agreed to terminate the Prior Purchase Agreement effective immediately. The Company sold a total of \$2.0 million in shares of common stock under the Prior Purchase Agreement and received net proceeds of approximately \$1.9 million after deducting commissions and other offering expenses of approximately \$0.1 million.

On December 18, 2014, the Company entered into a purchase agreement (the **Purchase Agreement**) with LPC, pursuant to which the Company has the right to sell to LPC up to \$10,800,000 in shares of the Company's common stock, subject to certain limitations and conditions set forth in the Purchase Agreement. The Company intends to use the net proceeds from this offering for working capital, to fund the development of the Company's therapeutic programs, as well as for other general corporate purposes. Subsequent to year end, the Company sold a total of 50,000 shares of common stock to LPC under the Purchase Agreement for proceeds of \$0.07 million. There have been no other purchases to date.

We believe that our existing cash and cash equivalents, along with our equity facility with LPC, should be sufficient to fund our operations into at least the third quarter of fiscal 2016. We have generated significant losses to date, have not generated any product revenue to date and may not generate product revenue in the foreseeable future, or ever. We expect to incur significant operating losses as we advance our product candidates through the drug development and regulatory process. In the future, we will be dependent on obtaining funding from third parties, such as proceeds from

the issuance of debt, sale of equity, funded research and development programs and payments under partnership and collaborative research and business development agreements, in order to maintain our operations and meet our obligations to licensors. There is no guarantee that debt, additional equity or other funding will be available to us on acceptable terms, or at all. If we fail to obtain additional funding when needed, we would be forced to scale back or terminate our operations or to seek to merge with or to be acquired by another company.

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***Net Cash Flow from Operating Activities***

Net cash used in operating activities was approximately \$7,758,000 for the year ended December 31, 2014 and was primarily due to the Company's net loss and decreases in accrued expenses and other current liabilities. Net cash used in operating activities was approximately \$6,311,000 for the year ended December 31, 2013 and was primarily due to the Company's net loss and increases in accrued expenses and other current liabilities. In addition, net cash used in operating activities is adjusted for other non-cash items to reconcile net loss to net cash used in operating activities. The decrease of \$12,405,000 in non-cash items year over year is primarily related to the non-cash expense for the fair value of common stock issued in exchange for technology. The other non-cash adjustments consist primarily of stock-based compensation and depreciation and amortization.

***Net Cash Flow from Investing Activities***

For the year ended December 31, 2014, net cash of \$2,917,000 provided by investing activities was primarily due to the maturity of \$8,000,000 in short-term investments offset by the purchase of \$5,000,000 of short-term investments and fixed asset purchases of \$95,000. Net cash used in investing activities of \$3,093,000 for the year ended December 31, 2013 was primarily due to the purchase of \$9,000,000 and \$78,000 in fixed asset purchases offset by the maturity of \$6,000,000 in short-term investments.

***Net Cash Flow from Financing Activities***

Net cash provided by financing activities was approximately \$1,947,000 for the year ended December 31, 2014 and was primarily due to net proceeds of \$1,886,000 received in connection with the equity facility in place with LPC. For the year ended December 31, 2013, net cash provided by financing activities was approximately \$15,667,000 and was primarily due to net proceeds of \$15,651,000 received from the issuance of approximately 3.8 million shares of our common stock in a private offering.

**Off-Balance Sheet Arrangements**

In connection with certain license agreements, we are required to indemnify the licensor for certain damages arising in connection with the intellectual property rights licensed under the agreement. In addition, we are a party to a number of agreements entered into in the ordinary course of business that contain typical provisions that obligate us to indemnify the other parties to such agreements upon the occurrence of certain events. These indemnification obligations are considered off-balance sheet arrangements in accordance with ASC Topic 460, *Guarantors' Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others*. To date, we have not encountered material costs as a result of such obligations and have not accrued any liabilities related to such obligations in our financial statements. See Note 11 to our financial statements for further discussion of these indemnification agreements.

**Recently Issued Accounting Standards**

See Note 3 to our financial statements in Item 8 of this Annual Report on Form 10-K for a description of recent accounting pronouncements applicable to our business.

**ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

As a smaller reporting company, we are not required to provide this information.



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**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

Board of Directors and Stockholders

RXi Pharmaceuticals Corporation

Marlborough, Massachusetts

We have audited the accompanying balance sheets of RXi Pharmaceuticals Corporation (the Company) as of December 31, 2014 and 2013, and the related statements of operations, convertible preferred stock and stockholders equity(deficit) and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company at December 31, 2014 and 2013 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.

/s/ BDO USA, LLP

Boston, Massachusetts

March 30, 2015



Table of Contents**RXi PHARMACEUTICALS CORPORATION****BALANCE SHEETS**

(Amounts in thousands, except share data)

	<b>December 31, 2014</b>	<b>December 31, 2013</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 8,496	\$ 11,390
Restricted cash	50	50
Short-term investments		3,000
Prepaid expenses and other current assets	442	303
Total current assets	8,988	14,743
Equipment and furnishings, net of accumulated depreciation of \$702 and \$632, in 2014 and 2013, respectively	183	177
Other assets	18	18
Total assets	\$ 9,189	\$ 14,938
<b>LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 285	\$ 163
Accrued expenses and other current liabilities	1,002	1,795
Deferred revenue	47	118
Total current liabilities	1,334	2,076
Commitments and contingencies (Note 6)		
Convertible preferred stock (Note 7):		
Series A convertible preferred stock, \$0.0001 par value, 15,000 shares authorized; 5,110 and 7,920 shares issued and outstanding at December 31, 2014 and 2013, respectively (at liquidation value)	5,110	7,920
Stockholders' equity (Note 8):		
Preferred stock, \$0.0001 par value; 10,000,000 authorized		
Series A-1 convertible preferred stock, \$0.0001 par value, 10,000 shares authorized; 1,578 and 2,054 shares issued and outstanding at December 31, 2014 and 2013, respectively (at liquidation value)	1,578	2,054
Common stock, \$0.0001 par value, 100,000,000 shares authorized; 21,984,272 and 11,788,045 shares issued and outstanding at December 31, 2014 and 2013, respectively	2	1
Additional paid-in capital	48,047	40,969
Accumulated deficit	(46,882)	(38,082)

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Total stockholders' equity	2,745	4,942
Total liabilities, convertible preferred stock and stockholders' equity	\$ 9,189	\$ 14,938

See accompanying notes to financial statements.

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Table of Contents**RXi PHARMACEUTICALS CORPORATION****STATEMENTS OF OPERATIONS**

(Amounts in thousands, except share and per share data)

	<b>Years Ended December 31,</b>	
	<b>2014</b>	<b>2013</b>
<b>Revenues:</b>		
Grant revenues	\$ 71	\$ 399
<b>Operating Expenses:</b>		
Research and development expenses (1)	5,680	17,651
General and administrative expenses (1)	3,217	3,697
Total operating expenses	8,897	21,348
Operating loss	(8,826)	(20,949)
Interest income, net	17	24
Other income, net	9	
Loss from continuing operations before income taxes	(8,800)	(20,925)
Provision for income taxes		
Net loss	\$ (8,800)	\$ (20,925)
Series A and A-1 convertible preferred stock dividends	(4,130)	(8,610)
Net loss applicable to common stockholders	\$ (12,930)	\$ (29,535)
<b>Net loss per common share applicable to common stockholders (Note 2):</b>		
Basic and diluted	\$ (0.79)	\$ (2.88)
Weighted average common shares: basic and diluted	16,362,905	10,263,954

(1) Non-cash stock-based compensation expenses included in operating expenses are as follows:

Research and development	\$ 836	\$ 912
General and administrative	\$ 1,010	\$ 1,067

See accompanying notes to financial statements.

**Table of Contents****RXi PHARMACEUTICALS CORPORATION****STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT)**

(Amounts in thousands, except share data)

	<b>Series A Convertible Preferred Stock</b>		<b>Series A-1 Convertible Preferred Stock</b>		<b>Common Stock</b>		<b>Additional Paid-in Capital</b>	<b>Accumulated Deficit</b>	<b>Total</b>
	<b>Shares Issued</b>	<b>Amount</b>	<b>Shares Issued</b>	<b>Amount</b>	<b>Shares Issued</b>	<b>Amount</b>			
Balance at December 31, 2012	9,726	\$ 9,726		\$	5,289,007	\$	\$ 11,317	\$ (17,157)	\$ (5,840)
Issuance of common stock, net of offering costs of \$727					3,765,230	1	15,650		15,651
Issuance of common stock in exchange for patent and technology rights					1,666,666		12,250		12,250
Stock-based compensation expense							1,979		1,979
Cash paid in lieu of fractional shares for 1:30 reverse stock split					(2,807)		(12)		(12)
Common stock issued upon exercise of stock options					2,000		5		5
Issuance of common stock under employee stock purchase plan					11,265		28		28
Exchange of Series A convertible preferred stock into Series A-1 convertible preferred stock	(2,000)	(2,000)	2,000	2,000					2,000

Conversions of Series A and Series A-1 convertible preferred stock into common stock	(434)	(434)			1,056,684		434		434
Fair value of Series A and Series A-1 convertible preferred stock dividends							(8,610)		(8,610)
Dividends issued on Series A and Series A-1 convertible preferred stock	628	628	54	54			7,928		7,982
Net loss								(20,925)	(20,925)
Balance at December 31, 2013	7,920	7,920	2,054	2,054	11,788,045	1	40,969	(38,082)	4,942
Stock-based compensation expense							1,846		1,846
Issuance of common stock, net of offering costs of \$114					700,000		1,886		1,886
Issuance of common stock under employee stock purchase plan					32,515		61		61
Exchange of Series A convertible preferred stock into Series A-1 convertible preferred stock	(3,000)	(3,000)	3,000	3,000					3,000
Conversions of Series A and Series A-1 convertible preferred stock into common stock	(166)	(166)	(3,716)	(3,716)	9,463,712	1	3,881		166
Fair value of Series A and							(4,130)		(4,130)

Series A-1 convertible preferred stock dividends										
Dividends issued on Series A and Series A-1 convertible preferred stock	356	356	240	240			3,534		3,774	
Net loss								(8,800)	(8,800)	

Balance at December 31, 2014	5,110	\$ 5,110	1,578	\$ 1,578	21,984,272	\$ 2	\$ 48,047	\$ (46,882)	\$ 2,745	
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See accompanying notes to financial statements.

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Table of Contents**RXi PHARMACEUTICALS CORPORATION****STATEMENTS OF CASH FLOWS**

(Amounts in thousands)

	<b>Years Ended December 31,</b>	
	<b>2014</b>	<b>2013</b>
Cash flows from operating activities:		
Net loss	\$ (8,800)	\$ (20,925)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	87	99
Gain on disposal of equipment	(10)	
Non-cash share-based compensation expense	1,846	1,979
Fair value of common stock issued in exchange for patent and technology rights		12,250
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(139)	(89)
Accounts payable	122	(253)
Accrued expenses and other current liabilities	(793)	1,028
Deferred revenue	(71)	(400)
<b>Net cash used in operating activities</b>	<b>(7,758)</b>	<b>(6,311)</b>
Cash flows from investing activities:		
Change in restricted cash		3
Purchase of short-term investments	(5,000)	(9,000)
Maturities of short-term investments	8,000	6,000
Cash paid for purchase of equipment and furnishings	(95)	(78)
Proceeds from disposal of equipment and furnishings	12	
Cash paid for lease deposit		(18)
<b>Net cash provided by (used in) investing activities</b>	<b>2,917</b>	<b>(3,093)</b>
Cash flows from financing activities:		
Net proceeds from the issuance of common stock	1,886	15,651
Proceeds from exercise of stock options		5
Proceeds from issuance of common stock in connection with employee stock purchase plan	61	28
Cash paid in lieu of fractional shares for 1:30 reverse stock split		(12)
Repayments of capital lease obligations		(5)
<b>Net cash provided by financing activities</b>	<b>1,947</b>	<b>15,667</b>
<b>Net (decrease) increase in cash and cash equivalents</b>	<b>(2,894)</b>	<b>6,263</b>
Cash and cash equivalents at the beginning of period	11,390	5,127

Cash and cash equivalents at the end of period	\$	8,496	\$	11,390
<b>Supplemental disclosure of non-cash investing and financing activities:</b>				
Exchange of Series A convertible preferred stock into Series A-1 convertible preferred stock	\$	3,000	\$	2,000
Conversion of Series A and Series A-1 convertible preferred stock into common stock	\$	3,882	\$	434
Fair value of Series A and Series A-1 convertible preferred stock dividends	\$	4,130	\$	8,610
Series A and Series A-1 convertible preferred stock dividends	\$	596	\$	682

See accompanying notes to financial statements.



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**RXi PHARMACEUTICALS CORPORATION**

**NOTES TO FINANCIAL STATEMENTS**

**1. Nature of Business**

RXi Pharmaceuticals Corporation ( **RXi**, **we**, **our** or the **Company** ) is a biotechnology company focused on discovering and developing innovative therapies addressing high unmet medical needs, primarily in the areas of dermatology and ophthalmology. Our development programs are based on our siRNA technology and immunotherapy agents. Our clinical development programs include, but are not limited to, our proprietary, self-delivering RNAi (sd-rxRNA<sup>®</sup>) compounds for the treatment of dermal and retinal scarring and an immunomodulating agent, Samcyprone , for the treatment of such disorders as alopecia areata, warts and cutaneous metastases of melanoma. In addition to these clinical programs, we have a pipeline of discovery and preclinical product candidates in our core therapeutic areas, as well as in other areas of interest. The Company s pipeline, coupled with our extensive patent portfolio, provides for the advancement to further discover and develop innovative therapies either on our own or in collaboration with strategic partners.

**2. Summary of Significant Accounting Policies**

*Basis of Presentation* The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ( **GAAP** ).

*Uses of Estimates in Preparation of Financial Statements* The preparation of financial statements in accordance with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and 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. Actual results could differ materially from these estimates.

*Cash and Cash Equivalents* The Company considers all highly liquid debt instruments with an original maturity of three months or less to be cash equivalents. Cash equivalents consist primarily of amounts invested in money market accounts and certificates of deposit.

*Restricted Cash* Restricted cash consists of certificates of deposit held by financial institutions as collateral for the Company s corporate credit cards.

*Short-term Investments* The Company s short-term investments consist of certificates of deposit with original maturities ranging from three months to one year.

*Concentrations of Credit Risk* Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash, cash equivalents and short-term investments. The Company maintains cash balances in several accounts with one bank, which at times are in excess of federally insured limits. The Company has established guidelines related to credit ratings and maturities intended to safeguard principal balances and maintain liquidity. The Company s investments are maintained in accordance with the Company s investment policy, which defines allowable investments, specifies credit quality standards and limits the exposure of any single issuer.

*Fair Value of Financial Instruments* The carrying amounts reported in the balance sheet for cash equivalents, restricted cash, short-term investments and accounts payable approximate their fair values due to their short-term nature or market rates of interest.

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*Equipment and Furnishings* Equipment and furnishings are stated at cost and depreciated using the straight-line method based on the estimated useful lives of the related assets. The Company provides for depreciation over the assets' estimated useful lives as follows:

Computer equipment	3 years
Machinery & equipment	5 years
Office furniture	5 years

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Depreciation and amortization expense for the years ended December 31, 2014 and 2013 was approximately \$87,000 and \$99,000, respectively.

*Impairment of Long-Lived Assets* The Company reviews long-lived assets for impairment on an annual basis, as of December 31, or on an interim basis if an event occurs that might reduce the fair value of such assets below their carrying values. An impairment loss would be recognized based on the difference between the carrying value of the asset and its estimated fair value, which would be determined based on either discounted future cash flows or other appropriate fair value methods. The Company believes no impairment existed as of December 31, 2014 and 2013.

*Revenue Recognition* The Company recognizes revenue when all of the following criteria are met: there is persuasive evidence of an arrangement, the fee is fixed or determinable, delivery has occurred or services have been rendered and collection of the related receivable is reasonably assured. The Company may generate revenue from product sales, license agreements, collaborative research and development arrangements, and government grants. To date the Company's principal source of revenue consists of government research grants. Revenue from a government grant is recognized over the respective contract periods as the services are performed. Monies received prior to the recognition of revenue are recorded as deferred revenue.

*Stock-based Compensation* The Company follows the provisions of the Financial Accounting Standards Board ( **FASB** ) Accounting Standards Codification ( **ASC** ) Topic 718, *Compensation - Stock Compensation* ( **ASC 718** ) which requires the measurement and recognition of compensation expense for all stock-based payment awards made to employees, officers and non-employee directors, including stock options. Stock compensation expense based on the grant date fair value estimated in accordance with the provisions of ASC 718 is recognized as an expense over the requisite service period.

For stock options granted as consideration for services rendered by non-employees, the Company recognizes compensation expense in accordance with the requirements of FASB ASC Topic 505-50, *Equity Based Payments to Non-Employees*. Non-employee option grants that do not vest immediately upon grant are recorded as an expense over the requisite service period of the underlying stock options. At the end of each financial reporting period prior to vesting, the value of these options, as calculated using the Black-Scholes option-pricing model, will be re-measured using the fair value of the Company's common stock and the non-cash compensation recognized during the period will be adjusted accordingly. Since the fair market value of options granted to non-employees is subject to change in the future, the amount of the future compensation expense will include fair value re-measurements until the stock options are fully vested.

*Research and Development Expenses* Research and development costs are charged to expense as incurred and relate to salaries, employee benefits, facility-related expenses, supplies, share-based compensation related to employees and non-employees involved in the Company's research and development, external services, other operating costs and overhead related to our research and development departments, costs to acquire technology licenses and expenses associated with preclinical activities and our clinical trials. Payments made by the Company in advance for research and development services not yet provided and/or for materials not yet received are recorded as prepaid expenses. Accrued liabilities are recorded related to those expenses for which vendors have not yet billed us with respect to services provided and/or materials that we have received.

Preclinical and clinical trial expenses relate to third-party services, subject-related fees at the sites where our clinical trials are being conducted, laboratory costs, analysis costs, toxicology studies and investigator fees. Costs associated with these expenses are generally payable on the passage of time or when certain milestones are achieved. Expense is recorded during the period incurred or in the period in which a milestone is achieved. In order to ensure that we have adequately provided for preclinical and clinical expenses during the proper period, we maintain an accrual to cover

these expenses. These accruals are assessed on a quarterly basis and are based on such assumptions as expected total cost, the number of subjects and clinical trial sites and length of the study. Actual results may differ from these estimates and could have a material impact on our reported results. Our historical accrual estimates have not been materially different from our actual costs.

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**Patents and Patent Application Costs** Although the Company believes that its patents and underlying technology have continuing value, the amount of future benefits to be derived from the patents is uncertain. Patent costs are, therefore, expensed as incurred.

**Income Taxes** The Company recognizes assets or liabilities for the deferred tax consequences of temporary differences between the tax basis of assets or liabilities and their reported amounts in the financial statements in accordance with FASB ASC 740, *Accounting for Income Taxes* ( **ASC 740** ). These temporary differences will result in taxable or deductible amounts in future years when the reported amounts of the assets or liabilities are recovered or settled. ASC 740 requires that a valuation allowance be established when management determines that it is more likely than not that all or a portion of a deferred asset will not be realized. The Company evaluates the realizability of its net deferred income tax assets and valuation allowances as necessary, at least on an annual basis. During this evaluation, the Company reviews its forecasts of income in conjunction with other positive and negative evidence surrounding the realizability of its deferred income tax assets to determine if a valuation allowance is required. Adjustments to the valuation allowance will increase or decrease the Company's income tax provision or benefit. The recognition and measurement of benefits related to the Company's tax positions requires significant judgment, as uncertainties often exist with respect to new laws, new interpretations of existing laws, and rulings by taxing authorities. Differences between actual results and the Company's assumptions or changes in the Company's assumptions in future periods are recorded in the period they become known.

**Comprehensive Loss** The Company's comprehensive loss is equal to its net loss for all periods presented.

**Net Loss per Share** The Company accounts for and discloses net loss per common share in accordance with FASB ASC Topic 260, *Earnings per Share*. Basic and diluted net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted average number of common shares outstanding. When the effects are not anti-dilutive, diluted earnings per share is computed by dividing the Company's net earnings by the weighted average number of common shares outstanding and the impact of all dilutive potential common shares.

The following table sets forth the potential common shares excluded from the calculation of net loss per common share because their inclusion would be anti-dilutive:

	<b>December 31,</b>	
	<b>2014</b>	<b>2013</b>
Options to purchase common stock	3,000,264	2,556,269
Common stock underlying Series A and Series A-1 convertible preferred stock	16,300,969	24,313,108
Warrants to purchase common stock	4,615	4,615
Total	19,305,848	26,873,992

### 3. Recent Accounting Pronouncements

In August 2014, the FASB issued Accounting Standards Update ( **ASU** ) 2014-15, *Presentation of Financial Statements – Going Concern (Topic 915): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. ASU 2014-15 states that in connection with preparing financial statements for each annual and interim reporting period, an entity's management should evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued (or within one year after the date that the financial statements are available

to be issued when applicable). ASU 2014-15 will be effective for annual and interim periods beginning on or after December 15, 2016, and will be effective for the Company beginning on January 1, 2017. Early adoption is permitted. The Company is currently evaluating the impact, if any, of the adoption of this update.

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In June 2014, the FASB issued ASU 2014-10, *Development Stage Entities (Topic 915) Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation*. ASU 2014-10 eliminates the concept of a development-stage entity in its entirety from current accounting guidance. Under current guidance, development-stage entities are required to present inception-to-date financial information in their annual statements. The new standard eliminates the concept of a development-stage entity from generally accepted accounting principles. Therefore, the current incremental reporting requirements for a development-stage entity, including inception-to-date information, will no longer apply. The new standard is effective for reporting periods beginning on or after December 15, 2014, and interim periods therein. The Company adopted this standard in June 2014. Other than the exclusion of the presentation of inception-to-date financial information, the adoption of this standard did not have a material impact on the Company's financial statements.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*. ASU 2014-09 states that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The new standard will be effective for annual and interim periods beginning on or after December 15, 2016, and will be effective for the Company beginning on January 1, 2017. Early adoption is not permitted. The Company is currently evaluating the method of adoption and the potential impact the update may have on our financial position and results of operations.

**4. Fair Value Measurements**

The Company follows the provisions of FASB ASC Topic 820, *Fair Value Measurements and Disclosures*, for the Company's financial assets and liabilities that are re-measured and reported at fair value at each reporting period and are re-measured and reported at fair value at least annually using a fair value hierarchy that is broken down into three levels. Level inputs are as defined as follows:

- Level 1      quoted prices in active markets for identical assets or liabilities.
- Level 2      other significant observable inputs for the assets or liabilities through corroboration with market data at the measurement date.
- Level 3      significant unobservable inputs that reflect management's best estimate of what market participants would use to price the assets or liabilities at the measurement date.

The Company categorized its cash equivalents, restricted cash and short-term investments as Level 2 hierarchy. The assets classified as Level 2 have initially been valued at transaction price and subsequently valued, at the end of each reporting period, using other market observable data. Observable market data points include quoted prices, interest rates, reportable trades and other industry and economic events. Financial assets measured at fair value on a recurring basis are summarized as follows, in thousands:

Description	December 31, 2014	Quoted Prices in		
		Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	\$ 4,000	\$	\$ 4,000	\$

Restricted cash	50	50
Total	\$ 4,050	\$ 4,050

Description	December 31, 2013	Quoted Prices in		
		Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	\$ 9,500	\$	\$ 9,500	\$
Restricted cash	50		50	
Short-term investments	3,000		3,000	
Total	\$ 12,550	\$	\$ 12,550	\$

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Accrued expenses and other current liabilities consist of the following, in thousands:

	<b>December 31,</b>	
	<b>2014</b>	<b>2013</b>
Employee compensation and benefits	\$ 528	\$ 627
Clinical development expenses	186	665
Professional fees	165	190
Research and development costs	118	130
Other	5	183
Total accrued expenses and other current liabilities	\$ 1,002	\$ 1,795

**6. Commitments and Contingencies***License Commitments*

The Company acquires assets under development and enters into research and development arrangements with third parties that often require milestone and royalty payments based on the progress of the asset through development stages. Milestone payments may be required, for example, upon approval of the product for marketing by a regulatory agency. In certain agreements, the Company is required to make royalty payments based upon a percentage of the sales of the products licensed pursuant to such agreements. Because of the contingent nature of these payments, they are not included in the table of contractual obligations shown below (see also Note 11).

These arrangements may be material individually, and in the unlikely event that milestones for multiple products covered by these arrangements were reached in the same period, the aggregate charge to expense could be material to the results of operations. In addition, these arrangements often give the Company the discretion to unilaterally terminate development of the product, which would allow the Company to avoid making the contingent payments; however, the Company is unlikely to cease development if the compound successfully achieves clinical testing objectives.

License agreements generally relate to the Company's obligations associated with our core technologies, RNAi and immunomodulators. The Company continually assesses the progress of its licensed technology and the progress of its research and development efforts as it relates to its licensed technology and may terminate with notice to the licensor at any time. In the event these licenses are terminated, no amounts will be due.

The Company's contractual license obligations that will require future cash payments as of December 31, 2014 are as follows, in thousands:

<b>Year Ending December 31,</b>	
2015	\$ 478
2016	150
2017	150

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2018	150
2019	150
Thereafter	530
Total	\$ 1,608

*Operating Leases*

The Company leases office and laboratory space for its corporate headquarters in Marlborough, Massachusetts. The lease for the space commenced on April 1, 2014 and will expire in March 2019. The monthly

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base rent for the premises during the first year was approximately \$9,000. Each year thereafter, the base rent shall increase by approximately 3% over the base rent from the prior year. The base rent includes the Company's pro rata share of the estimated annual real estate taxes and operating expenses.

Total rent expense under the Company's operating leases was \$107,500 and \$62,900 for the years ended December 31, 2014 and 2013, respectively.

At December 31, 2014, the Company's future minimum payments required under operating leases are as follows, in thousands:

<b>Year Ending December 31,</b>	
2015	\$ 119
2016	119
2017	117
2018	120
2019	30
Thereafter	
<b>Total</b>	<b>\$ 505</b>

The Company applies the disclosure provisions of FASB ASC Topic 460, *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others* ( **ASC 460** ), to its agreements that contain guarantee or indemnification clauses. The Company provides: (i) indemnifications of varying scope and size to certain investors and other parties for certain losses suffered or incurred by the indemnified party in connection with various types of third-party claims; and (ii) indemnifications of varying scope and size to officers and directors against third party claims arising from the services they provide to us. These indemnifications give rise only to the disclosure provisions of ASC 460. To date, the Company has not incurred costs as a result of these obligations and does not expect to incur material costs in the future. Accordingly, the Company has not accrued any liabilities in its financial statements related to these indemnifications.

## **7. Convertible Preferred Stock**

The Company has authorized up to 10,000,000 shares of preferred stock, \$0.0001 par value per share, for issuance. The Company's Board of Directors is authorized under the Company's Amended and Restated Articles of Incorporation, to designate the authorized preferred stock into one or more series and to fix and determine such rights, preferences, privileges and restrictions of any series of preferred stock, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, as shall be determined by the Company's Board of Directors upon its issuance. See also Note 8 to our financial statements for the rights and preferences of the Series A-1 convertible preferred stock ( **Series A-1 Preferred Stock** ).

### ***Series A Preferred Stock***

The Company currently has authorized a total of 15,000 shares of Series A convertible preferred stock ( **Series A Preferred Stock** ), \$0.0001 par value per share, for issuance.

### ***Accounting Treatment***

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The Series A Preferred Stock has been classified outside of permanent equity (within the mezzanine section between liabilities and equity on the balance sheets) as the Company may not be able to control the actions necessary to issue the maximum number of common shares needed to provide for a conversion in full of the then outstanding Series A Preferred Stock, at which time a holder of the Series A Preferred Stock may elect to redeem

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their preferred shares outstanding in the amount equal to the face value per share, plus unpaid accrued dividends. The Company's Series A-1 Preferred Stock has the same rights, privileges and preferences as the Series A Preferred Stock, but does not provide for any potential payment in cash in the event that the Company has insufficient shares of common stock authorized to honor conversions. Accordingly, the Series A-1 Preferred Stock is classified within permanent equity. The Series A-1 Preferred Stock is discussed further in Note 8.

*Dividends*

Holders of Series A Preferred Stock are entitled to receive cumulative mandatory dividends at the rate per share of seven percent (7%) of the face amount (\$1,000 per share) per annum, payable quarterly on each March 31, June 30, September 30 and December 31. Dividends shall be payable in additional shares of Series A Preferred Stock valued for this purpose at the face amount. In the event there are not sufficient authorized Series A Preferred Shares available to pay such a dividend, the dividend shall instead accrete to and increase the face value of the outstanding Series A Preferred Stock. The fair value of the Series A Preferred Stock dividend, which is included in the Company's net loss applicable to common stockholders, is calculated by multiplying the number of common shares that a preferred holder would receive upon conversion by the closing price of the Company's common stock on the dividend payment date.

The Company recorded Series A Preferred Stock dividends of \$2,399,000 and \$8,198,000 during the years ended December 31, 2014 and 2013, respectively.

*Conversion*

Each holder of shares of Series A Preferred Stock may, at any time and from time to time, convert each of its shares into a number of fully paid and non-assessable shares of common stock at the defined conversion rate. Each share of Series A Preferred Stock is convertible into 2,437.57 shares of common stock. In no event shall any holder of shares of Series A Preferred Stock have the right to convert shares of Series A Preferred Stock into shares of common stock to the extent that, after giving effect to such conversion, the holder, together with any of its affiliates, would beneficially own more than 9.999% of the then-issued and outstanding shares of common stock.

*Exchange Transaction*

On January 24, 2014, the Company entered into an exchange agreement (the **Exchange Agreement**) with Tang Capital Partners, L.P. (**TCP**) pursuant to which TCP exchanged a total of 3,000 shares of Series A Preferred Stock for a like number of shares of Series A-1 Preferred Stock.

On August 13, 2013, the Company entered into an exchange agreement (the **Prior Exchange Agreement**) with TCP pursuant to which TCP agreed to exchange a total of 2,000 shares of Series A Preferred Stock for a like number of shares of Series A-1 Preferred Stock.

In both transactions, the terms of the Series A-1 Preferred Stock were identical in all respects to the Series A Preferred Stock, other than the elimination of cash penalties that would potentially be due and payable upon the failure of the Company to have enough shares of common stock available to permit the conversion of Series A-1 Preferred Stock into common stock. The exchange transaction was recognized as a decrease in the face value of the Series A Preferred Stock and a corresponding increase in the face value of the Series A-1 Preferred Stock.

*Liquidation Preference*

The Liquidation Preference with respect to a share of Series A Preferred Stock means an amount equal to the face amount of the shares (\$1,000 per share) plus all accrued and unpaid dividends on the Series A Preferred Stock (as adjusted for any stock dividends, combinations, splits, recapitalizations and the like with respect to

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such shares). In the event of a liquidation, dissolution, or winding up, whether voluntary or involuntary, no distribution shall be made to the holders of any shares of capital stock of the Company (other than Senior Securities (as defined in the Certificate of Designations), pursuant to the rights, preferences and privileges thereof) unless prior thereto the holders of shares of Series A Preferred Stock have received the Liquidation Preference with respect to each share then outstanding.

*Voting*

The holders of Series A Preferred Stock do not have any right to elect directors and have only limited voting rights, which consist primarily of the right to vote under certain protective provisions set forth in the Certificate of Designations, regarding: (i) any proposed amendment to the Series A Preferred Stock or its right and preferences; and (ii) any proposed Deemed Liquidation Event as defined in the Certificate of Designations.

**8. Stockholders Equity**

***Series A-1 Preferred Stock***

The Company currently has authorized a total of 10,000 shares of Series A-1 Preferred Stock, \$0.0001 par value per share, for issuance. On January 24, 2014, the Company filed a Certificate of Increase with the Secretary of State of the State of Delaware amending the Company's previously filed Certificate of Designation for the Series A-1 Preferred Stock to increase the total number of shares of Series A-1 Preferred Stock authorized from 5,000 shares to 10,000 shares.

*Accounting Treatment*

The Series A-1 Preferred Stock has been classified as permanent equity as the Company is not required to effect a net cash settlement in the instance that the Company does not have enough shares of common stock available to permit the conversion of Series A-1 Preferred Stock into common stock.

*Dividends*

Holders of Series A-1 Preferred Stock are entitled to receive cumulative mandatory dividends at the rate per share of seven percent (7%) of the face amount (\$1,000 per share) per annum, payable quarterly on each March 31, June 30, September 30 and December 31. Dividends shall be payable in additional shares of Series A-1 Preferred Stock valued for this purpose at the face amount. In the event there are not sufficient authorized Series A-1 Preferred Shares available to pay such a dividend, the dividend shall instead accrete to and increase the face value of the outstanding Series A-1 Preferred Stock. The fair value of the Series A-1 Preferred Stock dividend, which is included in the Company's net loss applicable to common stockholders, is calculated by multiplying the number of common shares that a preferred holder would receive upon conversion by the closing price of the Company's common stock on the dividend payment date.

The Company recorded Series A-1 Preferred Stock dividends of \$1,731,000 and \$412,000 during the years ended December 31, 2014 and 2013, respectively.

*Conversion*

Each holder of shares of Series A-1 Preferred Stock may, at any time and from time to time, convert each of its shares into a number of fully paid and non-assessable shares of common stock at the defined conversion rate. Each share of

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Series A-1 Preferred Stock is convertible into 2,437.57 shares of common stock. In no event shall any holder of shares of Series A-1 Preferred Stock have the right to convert shares of Series A-1 Preferred Stock into shares of common stock to the extent that such issuance or sale or right to effect such conversion would result in the holder or any of its affiliates together beneficially owning more than 9.999% of the then issued and outstanding shares of common stock.

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*Exchange Transaction*

On January 24, 2014, the Company entered into the Exchange Agreement with TCP pursuant to which TCP exchanged a total of 3,000 shares of Series A Preferred Stock for a like number of shares of Series A-1 Preferred Stock.

On August 13, 2013, the Company entered into the Prior Exchange Agreement with TCP pursuant to which TCP agreed to exchange a total of 2,000 shares of Series A Preferred Stock for a like number of shares of Series A-1 Preferred Stock.

In both transactions, the terms of the Series A-1 Preferred Stock were identical in all respects to the Series A Preferred Stock, other than the elimination of cash penalties that would potentially be due and payable upon the failure of the Company to have enough shares of common stock available to permit the conversion of Series A-1 Preferred Stock into common stock. The exchange transaction was recognized as a decrease in the face value of the Series A Preferred Stock and a corresponding increase in the face value of the Series A-1 Preferred Stock.

*Liquidation Preference*

The Liquidation Preference with respect to a share of Series A-1 Preferred Stock means an amount equal to the face amount of the shares (\$1,000 per share) plus all accrued and unpaid dividends on the Series A-1 Preferred Stock (as adjusted for any stock dividends, combinations, splits, recapitalizations and the like with respect to such shares). In the event of a liquidation, dissolution, or winding up, whether voluntary or involuntary, no distribution shall be made to the holders of any shares of capital stock of the Company (other than Senior Securities (as defined in the Certificate of Designations), pursuant to the rights, preferences and privileges thereof) unless prior thereto the holders of shares of Series A-1 Preferred Stock have received the Liquidation Preference with respect to each share then outstanding. The liquidation preference of the Series A Preferred Stock is *pari passu* with the liquidation preference of the Series A-1 Preferred Stock.

*Voting*

The holders of Series A-1 Preferred Stock do not have any right to elect directors and have only limited voting rights, which consist primarily of the right to vote under certain protective provisions set forth in the Certificate of Designations, regarding: (i) any proposed amendment to the Series A-1 Preferred Stock or its right and preferences; and (ii) any proposed Deemed Liquidation Event as defined in the Certificate of Designations.

***Common Stock***

On July 10, 2014, the Company filed a Certificate of Amendment with the Secretary of State of the State of Delaware amending the Company's previously filed Amended and Restated Certificate of Incorporation to decrease the total number of shares of common stock authorized to 100,000,000. The decrease in the total number of shares of common stock authorized was approved by the Company's stockholders at the Company's Annual Meeting of Stockholders held on June 2, 2014.

On April 22, 2014, the Company entered into a purchase agreement (the **Prior Purchase Agreement**) with Lincoln Park Capital Fund, LLC ( **LPC** ), pursuant to which and subject to the terms and conditions contained in the Prior Purchase Agreement, the Company had the right to sell to LPC up to \$20 million in shares of the Company's common stock over a 30-month term. The Prior Purchase Agreement was terminable, among other circumstances, by mutual agreement of LPC and the Company at any time. The Company and LPC executed a termination agreement dated

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December 18, 2014, whereby the parties mutually agreed to terminate the Prior Purchase Agreement effective immediately. The Company sold a total of \$2.0 million in shares of common stock to LPC at a price of \$4.00 per share and previously issued 100,000 shares of common stock at a price of \$4.00 per share as a commitment fee, recorded as a cost of capital, under the Prior Purchase Agreement. As a result of this purchase, the Company received net proceeds of approximately \$1.9 million, after deducting commissions and other offering expenses of approximately \$0.1 million.

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On December 18, 2014, the Company entered into a purchase agreement (the **Purchase Agreement**) with LPC, pursuant to which the Company has the right to sell to LPC up to \$10.8 million in shares of the Company's common stock, subject to certain limitations and conditions set forth in the Purchase Agreement. Pursuant to the Purchase Agreement, the Company issued 100,000 shares of common stock at price per share of \$1.93 as a commitment fee under the Purchase Agreement, which was recorded as a cost of capital. The Company intends to use the net proceeds from this offering for working capital, to fund the development of the Company's development programs, as well as for other general corporate purposes.

On March 1, 2013, the Company entered into an asset purchase agreement with OPKO Health, Inc. (**OPKO**) pursuant to which the Company acquired substantially all of OPKO's RNAi-related assets, including patents, licenses, clinical and preclinical data and other related assets (the **OPKO Asset Purchase**). Upon the close of the OPKO Asset Purchase on March 12, 2013, the Company issued to OPKO 1,666,666 shares of common stock. The asset purchase agreement with OPKO is described further in Note 11.

On March 6, 2013, the Company entered into a securities purchase agreement with certain purchasers, pursuant to which the Company agreed to issue a total of 3,765,230 shares of common stock at a price of \$4.35 per share. The Company received net proceeds of \$15.7 million from the Offering, which closed on March 12, 2013, after deducting payment of commissions and other costs of \$0.7 million.

During the years ended December 31, 2014 and 2013, the Company issued 9,463,712 and 1,056,684 shares of common stock as a result of Series A and Series A-1 Preferred Stock conversions.

## **9. Stock-Based Compensation**

### *Stock Plans*

On January 23, 2012, the Company's Board of Directors and sole stockholder adopted the RXi Pharmaceuticals Corporation 2012 Long-Term Incentive Plan (the **2012 Incentive Plan**). Under the 2012 Incentive Plan, the Company may grant incentive stock options, nonqualified stock options, cash awards, stock appreciation rights, restricted and unrestricted stock and stock unit awards and other stock-based awards. The Company's Board of Directors currently acts as the administrator of the Company's 2012 Incentive Plan. The administrator has the power to select participants from among the key employees, directors and consultants of and advisors to the Company, establish the terms, conditions and vesting schedule, if applicable, of each award and to accelerate vesting or exercisability of any award.

As of December 31, 2014, an aggregate of 5,000,000 shares of common stock were reserved for issuance under the Company's 2012 Incentive Plan, including 3,000,264 shares subject to outstanding common stock options granted under the 2012 Incentive Plan and 1,997,736 shares available for future grants. Each option shall expire within ten years of issuance. Stock options granted by the Company to employees generally vest as to 12.5% of the shares on the six-month and first anniversary of the grant date and 25% of the shares at the end of each successive three-year period until fully vested.

### *Stock-Based Compensation*

The Company follows the provisions of ASC 718, which requires the measurement and recognition of compensation expense for all stock-based payment awards made to employees and non-employee directors including employee stock options. Stock compensation expense based on the grant date fair value estimated in accordance with the provisions of ASC 718 is recognized as an expense over the requisite service period.

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For stock options granted as consideration for services rendered by non-employees, the Company recognizes compensation expense in accordance with the requirements of FASB ASC Topic 505-50, *Equity Based Payments to Non-Employees*. Non-employee option grants that do not vest immediately upon grant are

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recorded as an expense over the requisite service period of the underlying stock options. At the end of each financial reporting period prior to vesting, the value of these options, as calculated using the Black-Scholes option-pricing model, will be re-measured using the fair value of the Company's common stock and the non-cash compensation recognized during the period will be adjusted accordingly. Since the fair value of options granted to non-employees is subject to change in the future, the amount of the future compensation expense will include fair value re-measurements until the stock options are fully vested.

The Company is currently using the Black-Scholes option-pricing model to determine the fair value of all its option grants. For option grants for the years ended December 31, 2014 and 2013, the following assumptions were used:

	<b>Year ended December 31,</b>	
	<b>2014</b>	<b>2013</b>
Risk-free interest rate	1.60% - 2.73%	0.71% - 2.19%
Expected volatility	97.91% - 107.01%	74.53% - 107.30%
Weighted average expected volatility	101.52%	76.27%
Expected life (in years)	5.20 - 10.00	5.20 - 10.00
Expected dividend yield	0.00%	0.00%

The weighted-average fair value of options granted during the years ended December 31, 2014 and 2013 was \$2.43 and \$4.05 per share, respectively.

The risk-free interest rate used for each grant was based upon the yield on zero-coupon U.S. Treasury securities with a term similar to the expected life of the related option. The Company's expected stock price volatility assumption is based upon the volatility of a composition of comparable companies. The expected life assumption for employee grants was based upon the simplified method provided for under ASC 718 and the expected life assumption for non-employees was based upon the contractual term of the option. The dividend yield assumption of zero is based upon the fact that the Company has never paid cash dividends and presently has no intention of paying cash dividends.

The following table summarizes the option activity of the Company:

	<b>Total Number of Shares</b>	<b>Weighted- Average Exercise Price Per Share</b>	<b>Weighted- Average Remaining Contractual Term</b>	<b>Aggregate Intrinsic Value</b>
Balance at December 31, 2013	2,556,269	\$ 3.47		
Granted	443,995	2.96		
Exercised				
Cancelled				
Balance at December 31, 2014	3,000,264	\$ 3.39	7.86 years	\$
Exercisable at December 31, 2014	1,739,455	\$ 3.39	7.60 years	\$

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Stock-based compensation expense for the years ended December 31, 2014 and 2013 was approximately \$1,846,000 and \$1,979,000, respectively. Of this, the Company recognized approximately \$81,000 and \$43,000 of expense related to non-employee stock options for the same period. There is no income tax benefit as the Company is currently operating at a loss and an actual income tax benefit may not be realized.

The intrinsic value of stock options exercised was \$2,000 for the year ended December 31, 2013. No options were exercised during the year ended December 31, 2014.

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As of December 31, 2014, the compensation expense for all unvested stock options in the amount of approximately \$2,700,000 will be recognized in the Company's results of operations over a weighted average period of 2.02 years.

*Employee Stock Purchase Plan*

On June 7, 2013, the Compensation Committee approved an employee stock purchase plan ( **ESPP** ), which was subsequently approved by the Company's stockholders at the Company's 2014 Annual Meeting of Stockholders. The ESPP allows employees to contribute a percentage of their cash earnings, subject to certain maximum amounts, to be used to purchase shares of the Company's common stock on each of two semi-annual purchase dates. The purchase price is equal to 90% of the market value per share on either (a) the date of grant of a purchase right under the ESPP or (b) the date on which such purchase right is deemed exercised, whichever is lower.

As of December 31, 2014, an aggregate of 113,333 shares of common stock were reserved for issuance under the Company's ESPP, of which 43,780 shares of common stock have been issued under the ESPP and 69,553 shares are available for future issuances.

The Company is currently using the Black-Scholes option-pricing model to determine the fair value of the ESPP stock rights. For stock rights issued in the years ended December 31, 2014 and 2013, the following assumptions were used:

	<b>Year Ended December 31,</b>	
	<b>2014</b>	<b>2013</b>
Risk-free interest rate	0.06% - 0.09%	0.09%
Expected volatility	94.99% - 103.36%	88.68%
Weighted average expected volatility	100.39%	88.68%
Expected life (in years)	0.50	0.50
Expected dividend yield	0.00	0.00%

The weighted average fair value of stock purchase rights granted as part of the ESPP was \$1.20 and \$2.04 for the years ended December 31, 2014 and 2013.

The risk-free interest rate used was based upon the yield on zero-coupon U.S. Treasury securities with a term similar to the expected life of the related option. The Company's expected volatility is based upon the volatility of a composition of comparable companies for the expected term. The expected life assumption was based upon the purchase period and the dividend yield assumption of zero is based upon the fact that the Company has never paid cash dividends and presently has no intention of paying cash dividends.

The Company recorded \$28,800 and \$10,200 of stock-based compensation expense for the year ended December 31, 2014 and 2013, respectively, related to the ESPP.

**Table of Contents****10. Income Taxes**

The components of federal and state income tax expense are as follows (in thousands):

	<b>Year Ended December 31,</b>	
	<b>2014</b>	<b>2013</b>
Current		
Federal	\$	\$
State		
Total current		
Deferred		
Federal	(2,727)	(9,123)
State	(583)	(2,002)
Total deferred	(3,310)	(11,125)
Valuation allowance	3,310	11,125
Total income tax expense	\$	\$

The components of net deferred tax assets are as follows (in thousands):

	<b>As of December 31,</b>	
	<b>2014</b>	<b>2013</b>
Net operating loss carryforwards	\$ 9,805	\$ 6,590
Tax credit carryforwards	261	146
Stock based compensation	1,392	861
Licensing deduction deferral	6,367	6,864
Other timing differences	110	165
Gross deferred tax assets	17,935	14,626
Valuation allowance	(17,935)	(14,626)
Net deferred tax asset	\$	\$

The Company's deferred tax assets at December 31, 2014 and 2013 consisted primarily of its net operating loss carryforwards, deferred compensation, tax credit carryforwards, Section 197 intangible assets capitalized for federal income tax purposes and certain accruals that for tax purposes are not deductible until future payment is made.

The Company has incurred net operating losses since inception. At December 31, 2014, the Company had federal and state net operating loss carryforwards of approximately \$46.8 million, which are available to reduce future taxable income expiring through 2034. Based on an assessment of all available evidence including, but not limited to the Company's limited operating history in its core business and lack of profitability, uncertainties of the commercial



viability of its technology, the impact of government regulation and healthcare reform initiatives, and other risks normally associated with biotechnology companies, the Company has concluded that it is more likely than not that these net operating loss carryforwards and credits will not be realized and, as a result, a full deferred income tax valuation allowance has been recorded against these assets.

Under the provisions of the Internal Revenue Code, certain substantial changes in the Company's ownership may result in a limitation on the amount of net operating loss carryforwards and research and development credit carryforwards which could be utilized annually to offset future taxable income and taxes payable.

The Company files income tax returns in the United States, Massachusetts and New Jersey. The Company is subject to tax examinations for Federal and state purposes for tax years 2012 through 2014. The Company has

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not recorded any uncertain tax positions as of December 31, 2014 or 2013. The Company does not believe there will be any material changes in its unrecognized tax positions over the next 12 months. RXi has not incurred any interest or penalties. In the event that the Company is assessed interest or penalties at some point in the future, they will be classified in the financial statements as general and administrative expenses.

**11. License Agreements**

As part of its business, the Company enters into licensing agreements with third parties that often require milestone and royalty payments based on the progress of the asset through development stages. Milestone payments may be required, for example, upon approval of the product for marketing by a regulatory agency. In certain agreements, the Company is required to make royalty payments based upon a percentage of the sales of the products licensed pursuant to such agreements.

The expenditures required under these arrangements may be material individually in the event that the Company develops product candidates covered by the intellectual property licensed under any such arrangement, and in the unlikely event that milestones for multiple products covered by these arrangements were reached in the same period, the aggregate charge to expense could be material to the results of operations. In addition, these arrangements often give the Company discretion to unilaterally terminate development of the product, which would allow the Company to avoid making the contingent payments; however, the Company is unlikely to cease development if the compound successfully achieves clinical testing objectives.

*Advirna.* We have entered into agreements with Advirna, or their surviving entity, pursuant to which Advirna assigned to us its existing patent and technology rights related to sd-rxRNA technology in exchange for our agreement to pay Advirna an annual maintenance fee of \$100,000. Pursuant to the terms of the agreement, in the first quarter of 2014 we paid to Advirna and recorded research and development expense of \$350,000 for a one-time milestone payment upon the issuance of the first patent with valid claims covering the assigned technology. Additionally, we will be required to pay a 1% royalty to Advirna on any licensing revenue received by us with respect to future licensing of the assigned Advirna patent and technology rights. We also granted back to Advirna a license under the assigned patent and technology rights for fields of use outside human therapeutics.

Our rights under the Advirna agreement will expire upon the later of: (i) the expiration of the last-to-expire of the patent rights (as defined) included in the Advirna agreement; or (ii) the abandonment of the last-to-be abandoned of such patents, unless earlier terminated in accordance with the provisions of the agreement.

We may terminate the Advirna agreement at any time upon 90 days' written notice to Advirna, and Advirna may terminate the agreement upon 90 days' prior written notice in the event that we cease using commercially reasonable efforts to research, develop, license or otherwise commercialize the patent rights or royalty-bearing products (as defined), provided that we may refute such claim within such 90-day period by showing budgeted expenditures for the research, development, licensing or other commercialization consistent with other technologies of similar stage of development and commercial potential as the patent rights or royalty-bearing products. Further, either party at any time may provide to the other party written notice of a material breach of the agreement. If the other party fails to cure the identified breach within 90 days after the date of the notice, the aggrieved party may terminate the agreement by written notice to the party in breach.

*OPKO.* In March 2013, we acquired from OPKO substantially all of its RNAi-related assets, which included patents and patent applications, licenses, clinical and preclinical data and other related assets. In exchange for the assets that we purchased from OPKO, we issued to OPKO 1,666,666 shares of our common stock and agreed to pay, if applicable: (i) up to \$50 million in development and commercialization milestones for the successful development and

commercialization of each Qualified Drug (as defined in the Asset Purchase Agreement with OPKO); and (ii) royalty payments equal to: (a) a mid-single-digit percentage of Net Sales (as defined in the Asset Purchase Agreement) with respect to each Qualified Drug sold for an ophthalmologic use during the applicable Royalty Period (as defined in the Asset Purchase Agreement); and (b) a low-single-digit percentage

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of Net Sales with respect to each Qualified Drug sold for a non-ophthalmologic use during the applicable Royalty Period (collectively, the Royalty Payments ). The Company recorded research and development expense of \$12,250,000 during the year ended December 31, 2013 to recognize the fair value of the common shares issued to OPKO in exchange for the RNAi-related assets acquired by the Company.

*Hapten.* On December 17, 2014, the Company entered into an assignment and exclusive license agreement, (the **Assignment and License Agreement** ) with Hapten Pharmaceuticals, LLC ( **Hapten** ) under which Hapten agreed, effective at a closing that was subject to the satisfaction of certain closing conditions which occurred in February 2015, to sell and assign to us certain patent rights and related assets and rights, including an investigational new drug application and clinical data, for Hapten s Samcyprone gel products for therapeutic and prophylactic use. Samcyprone is a proprietary gel formulation of diphenylcyclopropenone ( **DPCP** ), an immunomodulation agent that works by initiating a T-cell response. Hapten has been developing Samcyprone for the treatment of alopecia areata, warts and cutaneous metastases of malignant melanoma.

Under the Assignment and License Agreement, Hapten will receive at closing an upfront payment from us, payable in cash and stock, and will be entitled to receive: (i) future milestone payments tied to the achievement of certain clinical and commercial objectives (all of which payments may be made at our option in cash or through the issuance of common stock); and (ii) escalating royalties based on product sales by us and any sublicensees. The Assignment and License Agreement with Hapten is described further in Note 12.

## **12. Subsequent Events**

Subsequent to the balance sheet date and up to March 30, 2015, a total of 50,000 shares of common stock were sold to LPC pursuant to the Purchase Agreement, with proceeds received from such transactions totaling \$65,000.

Subsequent to the balance sheet date and up to March 30, 2015, the Company issued 8,987,326 shares of common stock as a result of Series A and A-1 Preferred Stock conversions.

On February 4, 2015, the Company closed the Assignment and License Agreement with Hapten. Pursuant to the Assignment and License Agreement, the Company paid \$100,000 in cash to Hapten as consideration for a license fee and issued 200,000 shares of common stock at a share price of \$1.14 as additional consideration.

On March 20, 2015, the Company entered into an exchange agreement with TCP pursuant to which TCP exchanged a total of 2,000 shares of Series A Preferred Stock for a like number of shares of Series A-1 Preferred Stock. The terms of the Series A-1 Preferred Stock are identical in all respects to the Series A Preferred Stock, other than the elimination of cash penalties that would potentially be due and payable upon the failure of the Company to have enough shares of common stock available to permit the conversion of Series A Preferred Stock into common stock. This exchange transaction will be recognized as a decrease in the face value of the Series A Preferred Stock and a corresponding increase in the face value of the Series A-1 Preferred Stock.

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**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**

Based on an evaluation as of the end of the period covered by this report, Dr. Geert Cauwenbergh, our Chief Executive Officer and acting Chief Financial Officer, has concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) were effective as of the end of the period covered by this report to ensure that information that we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms.

Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives, and Dr. Cauwenbergh has concluded that these controls and procedures are effective at the reasonable assurance level. We believe that a control system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the control 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.

**Management's Annual Report on Internal Control Over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

There are inherent limitations in the effectiveness of any system of internal control, including the possibility of human error and the circumvention or overriding of controls. Accordingly, even effective internal controls can provide only reasonable assurances with respect to financial statement preparation. Further, because of changes in conditions, the effectiveness of internal control may vary over time.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2014. In making this assessment, management used the criteria set forth in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Based on our assessment, the Company's Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2014, our internal control over financial reporting is effective.

This Annual Report on Form 10-K provides only management's report. As a smaller reporting company, we are not required to provide an attestation report by our independent registered public accounting firm regarding internal control over financial reporting.

**Changes in Internal Control Over Financial Reporting**

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2014 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**ITEM 9B. *OTHER INFORMATION***

None.

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**PART III**

**ITEM 10. *DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE***

We will file a definitive proxy statement for our 2015 annual meeting of stockholders (the **Proxy Statement** ) not later than 120 days after the fiscal year end of December 31, 2014. The information required by this item is incorporated herein by reference to the information contained in the Proxy Statement.

**ITEM 11. *EXECUTIVE COMPENSATION***

The information required by this item is incorporated herein by reference to the information contained in the Proxy Statement.

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

The information required by this item is incorporated herein by reference to the information contained in the Proxy Statement.

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

The information required by this item is incorporated herein by reference to the information contained in the Proxy Statement.

**ITEM 14. *PRINCIPAL ACCOUNTANT FEES AND SERVICES***

The information required by this item is incorporated herein by reference to the information contained in the Proxy Statement.

**PART IV**

**ITEM 15. *EXHIBITS AND FINANCIAL STATEMENT SCHEDULES***

**Financial Statements**

Our financial statements are set forth in Item 8 to this Annual Report on Form 10-K.

**Financial Statement Schedules**

Certain schedules are omitted because they are not applicable, or are not required by smaller reporting companies.

## **Exhibits**

The exhibits listed on the Exhibit Index beginning on page II-4, which is incorporated herein by reference, are filed or furnished as part of this report or are incorporated into this report by reference.

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Table of Contents**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.

**RXi PHARMACEUTICALS  
CORPORATION**

By: / s / GEERT CAUWENBERGH  
**Geert Cauwenbergh, Dr. Med. Sc.**  
**President, Chief Executive Officer**

**and Chief Financial Officer**

Date: March 30, 2015

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.

<b>Signatures</b>	<b>Title</b>	<b>Date</b>
/ s / GEERT CAUWENBERGH	President, Chief Executive Officer,	March 30, 2015
Geert Cauwenbergh, Dr. Med. Sc.	Chief Financial Officer and Director (Principal Executive Officer and Principal Financial Officer)	
/ s / CAITLIN KONTULIS	Controller and Secretary	March 30, 2015
Caitlin Kontulis	(Principal Accounting Officer)	
/ s / KEITH L. BROWNLIE	Director	March 30, 2015
Keith L. Brownlie		
/ s / ROBERT J. BITTERMAN	Director	March 30, 2015
Robert J. Bitterman		
/ s / H. PAUL DORMAN	Director	March 30, 2015
H. Paul Dorman		
/ s / CURTIS A. LOCKSHIN	Director	March 30, 2015

Curtis A. Lockshin, Ph.D.

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**Table of Contents****Exhibits****EXHIBIT INDEX**

<b>Exhibit</b>		<b>Incorporated by Reference Herein</b>	
<b>Number</b>	<b>Description</b>	<b>Form</b>	<b>Date</b>
2.1	Contribution Agreement, dated as of September 24, 2011, between RXi Pharmaceuticals Corporation (formerly RNCS, Inc.) and Galena Biopharma, Inc. (formerly RXi Pharmaceuticals Corporation).	Amendment No. 1 to the Registration Statement on Form S-1 (File No. 333-177498)	December 8, 2011
2.2	Securities Purchase Agreement, dated as of September 24, 2011, among RXi Pharmaceuticals Corporation (formerly RNCS, Inc.), Galena Biopharma, Inc. (formerly RXi Pharmaceuticals Corporation), Tang Capital Partners, LP and RTW Investments, LLC.	Amendment No. 1 to the Registration Statement on Form S-1 (File No. 333-177498)	December 8, 2011
2.3	Asset Purchase Agreement, dated March 1, 2013, between RXi Pharmaceuticals Corporation and OPKO Health, Inc. +	Quarterly Report on Form 10-Q (File No. 000-54910)	March 15, 2013
3.1	Amended and Restated Certificate of Incorporation of RXi Pharmaceuticals Corporation.	Amendment No. 4 to the Registration Statement on Form S-1 (File No. 333-177498)	February 7, 2012
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of RXi Pharmaceuticals Corporation.	Current Report on Form 8-K (File No. 000-54910)	July 22, 2013
3.3	Certificate of Designations, Preferences and Rights of Series A Convertible Preferred Stock of RXi Pharmaceuticals Corporation.	Amendment No. 4 to Registration Statement Form S-1 (File No. 333-177498)	February 7, 2012
3.4	Certificate of Designations, Preferences and Rights of Series A-1 Convertible Preferred Stock of RXi Pharmaceuticals Corporation.	Quarterly Report on Form 10-Q (File No. 000-54910)	August 14, 2013
3.5	Certificate of Increase, filed with the Secretary of State of the State of Delaware on January 24, 2014.	Current Report of Form 8-K (File No. 000-54910)	January 24, 2014
3.6	Amended and Restated Bylaws of RXi Pharmaceuticals Corporation.	Quarterly Report on Form 10-Q (File	May 14, 2012

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		No. 333-177498)	
4.1	Secured Convertible Promissory Note, dated September 24, 2011 of RXi Pharmaceuticals Corporation (formerly RNCS, Inc.), issued to Tang Capital Partners, LP.	Registration Statement on Form S-1 (File No. 333-177498)	October 25, 2011

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Exhibit	Incorporated by Reference Herein		
Number	Description	Form	Date
4.2	Secured Convertible Promissory Note, dated September 24, 2011 of RXi Pharmaceuticals Corporation (formerly RNCS, Inc.), issued to RTW Investments, LLC.	Registration Statement on Form S-1 (File No. 333-177498)	October 25, 2011
10.1	Employment Agreement, dated September 24, 2011, between RXi Pharmaceuticals Corporation (formerly, RNCS, Inc.) and Pamela Pavco, Ph.D.*	Current Report on Form 8-K of Galena Biopharma, Inc. (File No. 001-33958)	September 26, 2011
10.2	Patent and Technology Assignment Agreement between RXi Pharmaceuticals Corporation (formerly RNCS, Inc.) and Advirna, LLC, effective as of September 24, 2011.	Registration Statement on Form S-1 (File No. 333-177498)	October 25, 2011
10.3	RXi Pharmaceuticals Corporation 2012 Long Term Incentive Plan.*	Amendment No. 3 to the Registration Statement on Form S-1 (File No. 333-177498)	January 23, 2012
10.4	Form of Incentive Stock Option Award under the Company's 2012 Long Term Incentive Plan, as amended.*	Registration Statement on Form S-1 (File No. 333-191236)	September 18, 2013
10.5	Form of Non-qualified Stock Option Award under the Company's 2012 Long Term Incentive Plan, as amended.*	Registration Statement on Form S-1 (File No. 333-191236)	September 18, 2013
10.6	Form of Restricted Stock Unit Award under the Company's 2012 Long Term Incentive Plan, as amended.*	Registration Statement on Form S-1 (File No. 333-191236)	September 18, 2013
10.7	Amendment to RXi Pharmaceuticals Corporation Long-Term Incentive Plan.*	Registration Statement on Form S-1 (File No. 333-191236)	September 18, 2013
10.8	RXi Pharmaceuticals Corporation Employee Stock Purchase Plan.*	Registration Statement on Form S-1 (File No. 333-191236)	September 18, 2013
10.9	Form of Indemnification Agreement.*	Amendment No. 3 to the Registration Statement on	January 23, 2012

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Form S-1 (File  
No. 333-177498)

10.10	Employment Agreement, dated April 27, 2012, between RXi Pharmaceuticals Corporation and Geert Cauwenbergh, Dr. Med. Sc.*	Current Report on Form 8-K (File No. 333-177498)	May 3, 2012
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<b>Exhibit</b>		<b>Incorporated by Reference Herein</b>	
<b>Number</b>	<b>Description</b>	<b>Form</b>	<b>Date</b>
10.11	Securities Purchase Agreement, dated as of March 6, 2013, among RXi Pharmaceuticals Corporation and the purchasers named therein.	Current Report on Form 8-K (File No. 000-54910)	March 7, 2013
10.12	Lease Agreement dated December 17, 2013 between RXi Pharmaceuticals Corporation and 257 Simarano Drive, LLC, Brighton Properties, LLC, Robert Stubblebine 1, LLC and Robert Stubblebine 2, LLC	Current Report on Form 8-K (File No. 000-54910)	December 20, 2013
10.13	Purchase Agreement, dated as of April 22, 2014, between RXi Pharmaceuticals Corporation and Lincoln Park Capital Fund, LLC	Current Report on Form 8-K (File No. 001-36304)	April 23, 2014
10.14	Purchase Agreement, dated as of December 18, 2014, between RXi Pharmaceuticals Corporation and Lincoln Park Capital Fund, LLC	Current Report on Form 8-K (File No. 001-36304)	December 19, 2014
10.15	Manufacturing and Distribution Agreement, dated November 14, 2013 between RXi Pharmaceuticals Corporation and Ethicor Pharmaceuticals Ltd. (+)	Annual Report on Form 10-K (File No. 000-54910)	March 28, 2014
23.1	Consent of BDO USA, LLP, an Independent Registered Public Accounting Firm.*****		
31.1	Sarbanes-Oxley Act Section 302 Certification of Chief Executive Officer and Chief Financial Officer.*****		
32.1	Sarbanes-Oxley Act Section 906 Certification of Chief Executive Officer and Chief Financial Officer.*****		
101	The following financial information from the Annual Report on Form 10-K of RXi Pharmaceuticals Corporation for the year ended December 31, 2014, formatted in XBRL (eXtensible Business Reporting Language): (1) Balance Sheets as of December 31, 2014 and December 31, 2013; (2) Statements of Operations for the years ended December 31, 2014 and 2013; (3) Statements of Convertible Preferred Stock and Statements of Stockholders' Equity for the years ended December 31, 2014 and 2013; (4) Statements of Cash Flows for the years ended December 31, 2014 and 2013; and (4) Notes to Financial Statements.		

\* Indicates a management contract or compensatory plan or arrangement.

\*\*\*\*\* Filed herewith.

+ Confidential treatment has been requested or granted for certain portions which have been blanked out in the copy of the exhibit filed with the Securities and Exchange Commission. The omitted information has been filed separately with the Securities and Exchange Commission.