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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2018

Or

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

For the transition period from _____ to _____

Commission File Number 001-36304

PHIO PHARMACEUTICALS CORP.
(Exact name of registrant as specified in its charter)

Delaware	**45-3215903**
(State or other jurisdiction of incorporation or organization)	**(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	**Name of exchange on which registered**
Common stock, par value $0.0001 per share	**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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). ☒ Yes ☐ No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) 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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

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

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

The aggregate market value of the voting and non-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 29, 2018, was $8,383,995. 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 Phio Pharmaceuticals Corp. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 22, 2019, Phio Pharmaceuticals Corp. had 22,299,132 shares of common stock, $0.0001 par value, outstanding.

TABLE OF CONTENTS

PHIO PHARMACEUTICALS CORP.
ANNUAL REPORT ON FORM 10-K
For the Fiscal Year Ended December 31, 2018

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, although not all forward-looking statements contain these words. 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 as a result of a number of important factors, including those identified in this Annual Report on Form 10-K under the heading “Risk Factors” and in other filings Phio Pharmaceuticals Corp. periodically makes with the Securities and Exchange Commission. Therefore, you should not rely on any of these forward-looking statements. Forward-looking statements contained in this Annual Report on Form 10-K speak as of the date hereof and Phio Pharmaceuticals Corp. 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 report.

PART I

Unless otherwise noted, (1) the term "Phio" refers to Phio Pharmaceuticals Corp. and our subsidiary, MirImmune, LLC and (2) the terms "Company," "we," "us" and "our" refer to the ongoing business operations of Phio and MirImmune, LLC, whether conducted through Phio or MirImmune, LLC.

ITEM 1. *BUSINESS*

Overview

Phio Pharmaceuticals Corp. is a biotechnology company developing the next generation of immuno-oncology therapeutics based on our self-delivering RNAi ("**sd-rxRNA®**") therapeutic platform. The Company's efforts are focused on developing sd-rxRNA therapeutic compounds to be used in the context of adoptive cell transfer by targeting checkpoints or other gene targets, or to be used in immunotherapy following intra-tumoral injections. We aim to maximize the power of our sd-rxRNA therapeutic compounds by weaponizing therapeutic immune effector cells to attack cancer, and to make tumors more susceptible to such attacks, and ultimately provide patients battling cancers with a powerful new treatment option that goes beyond current treatment modalities.

In January 2017, the Company entered into a Stock Purchase Agreement pursuant to which it acquired all of the issued and outstanding shares of capital stock of MirImmune Inc. ("**MirImmune**") for an aggregate of 275,036 shares of common stock of the Company and 1,118,224 shares of the Company's Series C Convertible Preferred Stock. With the approval of the Company's stockholders at the 2017 Annual Meeting of Stockholders, every ten shares of the Series C Convertible Preferred Stock issued and outstanding were automatically converted into one share of common stock.

Prior to the Company's acquisition of MirImmune, our principal activities consisted of the preclinical and clinical development of the Company's sd-rxRNA compounds and topical immunotherapy agent in the areas of dermatology and ophthalmology. In January 2018, after a thorough review of its business operations, development programs and financial resources, the Company made a strategic decision to focus its efforts solely on immuno-oncology to accelerate growth and support a potential return on investment for its stockholders. In connection with this decision, the Company completed all open clinical trials in dermatology and ophthalmology with RXI-109, our first sd-rxRNA clinical candidate, and Samcyprone®, and reported out on the results of those clinical studies in 2018. The Company intends to seek a partner and/or out-licensee for its dermatology program and its ophthalmology program to continue with their development. The Company's current business strategy solely focuses on the development of immuno-oncology therapeutics utilizing our proprietary sd-rxRNA technology.

On November 19, 2018, the Company changed its name from RXi Pharmaceuticals Corporation to Phio Pharmaceuticals Corp., which reflects the Company's transition from a platform company to one that is fully committed to develop groundbreaking immuno-oncology therapeutics.

Our development efforts are based on our broadly patented sd-rxRNA technology platform. Our sd-rxRNA compounds do not require a delivery vehicle to penetrate into tissues and cells and are designed to "silence," or down-regulate, the expression of a specific gene that may be over-expressed in a disease condition. We believe that our sd-rxRNA platform uniquely positions the Company in the field of immuno-oncology because of this and for the following reasons:

- Our sd-rxRNA compounds do not require facilitated delivery (mechanical or formulation);
- Can target multiple genes (i.e. multiple immunosuppression pathways) in a single therapeutic entity;
- Demonstrate efficient uptake of sd-rxRNA to immune cells;
- Silencing by sd-rxRNA has been shown to have a sustained, or long-term, effect *in vivo*;
- Favorable clinical safety profile of sd-rxRNA with local administration; and
- Can be readily manufactured under current good manufacturing practices.

On January 3, 2018, the Board of Directors of the Company approved a 1-for-10 reverse stock split of the Company's outstanding common stock, which was effected on January 8, 2018. All share and per share amounts have been retroactively adjusted for all periods presented to give effect to the reverse stock split, including reclassifying an amount equal to the reduction in par value to additional paid-in capital in the financial statements.

Our Development Pipeline

We currently have a pipeline of discovery and preclinical programs in three focus areas in which we are aligning our internal research and development efforts with extramural collaborations. The table below sets forth the Company's stage of development for product candidates in each of our three R&D focus areas:

TREATMENT	INDICATION	DISCOVERY	PRE-IND	CLINICAL
Checkpoint Inhibition in ACT (TILs)	Melanoma	RXI-762		
Checkpoint Inhibition in ACT (TILs)	Ovarian Cancer	RXI-762		
Checkpoint Inhibition in ACT (TILs)	Head & Neck	RXI-762		
Checkpoint Inhibition in ACT (TCRs)	Other	RXI-762		
Checkpoint Inhibition in ACT (T-cells)	Various	RXI-804		
Checkpoint Inhibition in ACT (other)	Various	RXI-804		
Cell Maturation in ACT	Various	Undisclosed		
Cell Metabolism in ACT	Various	Undisclosed		
Direct Tumor / TME target	Melanoma	Undisclosed		
Direct Tumor / TME target	Various	Undisclosed		
Direct Tumor / TME target	Various	Undisclosed		

Checkpoint Inhibition in Adoptive Cell Transfer

The Company has developed sd-rxRNA targeting PD-1, TIGIT and other undisclosed checkpoints in adoptive cell transfer ("**ACT**") for the treatment of solid tumors. RXI-762 and RXI-804, sd-rxRNA compounds that are designed to suppress the expression of immune checkpoint proteins PD-1 and TIGIT, respectively, which, when used in ACT, are expected to result in an improved efficacy to the targeted tumors. We expect to enter clinical development with RXI-762, our most advanced program, as part of an ACT therapy for solid tumors in melanoma by the end of 2019.

Our strategy includes advancing our sd-rxRNA compounds towards clinical development, both independently and with extramural collaborations. We plan to focus our internal resources on therapeutic areas where research and development is appropriate for the size and financial resources of the Company and to secure partners in therapeutic areas with the requisite expertise and resources to advance our product and research candidates through clinical development. We believe that this approach to our strategy will allow us to build upon these current collaborations to add additional partnerships to our immuno-oncology pipeline, support the Company with a shorter path to the clinic by allowing us to utilize and build upon already established protocols of our partners and provide us with the opportunity to expand our immuno-oncology programs and pipeline in multiple areas. We have established a number of collaborations with cancer research institutions and companies in this therapeutic area.

The Center for Cancer Immune Therapy ("**CCIT**") at Herlev Hospital is a leading European cancer center for use of tumor-infiltrating lymphocytes ("**TILs**") for ACT. CCIT has carried out numerous clinical trials based on a direct translation of the discoveries from the laboratory. Our collaboration with CCIT is evaluating the potential of our sd-rxRNA technology platform to enhance the function of TILs for use in the treatment for a number of cancer types, including melanoma and ovarian cancer. To date, CCIT has evaluated sd-rxRNA compounds targeting immune checkpoints in preclinical screening models of matched TIL/tumor cell pairs from melanoma and cancer patients. Results have shown a marked PD-1 reduction on the surface of TILs in a pilot rapid expansion protocol.

Iovance Biotherapeutics, Inc. is a biotechnology company focused on the development and commercialization of autologous cellular immunotherapies optimizing personalized, tumor-directed TILs. Our research collaboration with Iovance will evaluate the potential synergies with our novel sd-rxRNA therapeutic compounds and Iovance's autologous cell therapy based on TILs for the use in the treatment of cancer. Data from this collaboration has shown that a sd-rxRNA mediated knock-down of PD-1 was associated with phenotypic changes indicative of TIL activation. Our next steps with Iovance include further evaluation of the impact of sd-rxRNA mediated gene silencing on TIL tumor reactivity and implementation of optimized silencing protocols and scale-up thereof.

Cell Maturation and Metabolism in Adoptive Cell Transfer

We use our sd-rxRNA in T-cells and other immune cell types, such as natural killer ("**NK**") cells and dendritic cells, for targets other than immune checkpoints in order to weaponize and improve cell persistence and cell viability in the immunosuppressive tumor micro-environment. We believe this shows the broad applicability of our platform technology and that our potential impact in immuno-oncology is not limited to checkpoints and TILs.

We have shown that sd-rxRNAs are rapidly and efficiently taken up by immune effector cells without the use of transfection reagents. Using sd-rxRNA compounds against checkpoint inhibitors, we can suppress their expression levels up to 95% in immune cells, including T-cells and NK cells. Furthermore, we have demonstrated potent silencing activity as well as a phenotypic effect (enhanced degranulation activity) of NK cells treated with sd-rxRNA compounds targeting checkpoints. By treating NK cells *ex-vivo*, prior to ACT with sd-rxRNA reducing the expression of proteins such as Cbl-b and TIGIT, the anti-tumor response of these cells can be improved. Ongoing work expands these findings to include compounds for more specific NK targets, including NK specific inhibitory receptors, which could be used alone or in combination.

Through our collaboration with Medigene AG, a German biotechnology company developing highly innovative, complementary treatment platforms to target various types and stages of cancer, we are exploring the potential synergies of our sd-rxRNA technology in combination with Medigene's recombinant TCRs to develop modified T-cells with enhanced efficacy and/or safety with the ultimate goal to further improve Medigene's T-cell therapies for the treatment of cancer patients. In the studies completed, Medigene observed the reduction of PD-1 surface levels in T-cells transduced with TCRs and treated with our sd-rxRNA compound, RXI-762. While these studies utilized the Company's PD-1 targeting sd-rxRNA for proof of concept, there is also the potential to expand the collaboration to additional targets and the two complementing technologies could lead to synergistic effects that might further sharpen and improve the therapeutic effects of Medigene's receptor modified T-cells.

Direct Tumor and Tumor Micro-Environment

Our third focus area includes the use of our sd-rxRNA directly towards tumor and/or tumor micro-environment ("**TME**") targets. Impacting the tumor cells and/or TME through a direct use of sd-rxRNA, such as via intra-tumoral injection, could potentially become an important form of adjuvant therapy. We believe that this will also show that our contributions with our sd-rxRNA compounds in immuno-oncology are not limited to use with another company's cell platform. Additionally, the Company has shown that its sd-rxRNA compounds are safe and well-tolerated via intradermal injections and injections in the eye through its completed clinical trials with RXI-109 in dermatology and ophthalmology.

Our collaborative research agreement with Gustave Roussy, a leading comprehensive cancer center in France, concentrates on determining the feasibility of our sd-rxRNA platform to target the TME via intra-tumoral injection. The goal of our recent *in vivo* study with Gustave Roussy was to demonstrate sd-rxRNA compound delivery via intra-tumoral injection and demonstrate activity (silencing of gene expression) of sd-rxRNA compounds. Results from this study showed an 80—85% reduction of the target gene expression in a mouse model of melanoma via intra-tumoral injection.

Our sd-rxRNA Platform

Diseases are often related to the wrong protein being made, excessive amounts of a specific protein being made, or the correct protein being made but at the wrong location or time. Overall, RNA is involved in the synthesis, regulation and processing of proteins. RNA interference ("**RNAi**') is a biological process in which RNA molecules inhibit gene expression or translation into proteins by preventing certain RNA from being read. RNAi offers a novel approach to the drug development process because RNAi compounds can potentially be designed to target any one of the thousands of human genes, many of which are "undruggable" by other modalities. 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 first design of RNAi compounds to be pursued for the development of human therapeutics were short, double-stranded RNAs that included limited modifications, known as small-interfering RNA ("**siRNA**"). Since the initial discovery of RNAi, drug delivery has been the primary challenge in developing RNAi-based therapeutics. One conventional solution to the delivery problem involves encapsulation of siRNA into a lipid-based particle, such as a liposome, to improve circulation time and cellular uptake. We have developed an alternative approach where delivery and drug-like properties are built directly into the RNAi compound itself. These novel compounds are termed self-delivering RNAi compounds, or sd-rxRNA.

sd-rxRNAs are hybrid oligonucleotide compounds that the Company believes combines the beneficial properties of both conventional RNAi and antisense technologies. Traditional, single-stranded antisense compounds have favorable tissue distribution and cellular uptake properties. However, they do not have the intracellular potency that is a hallmark of double-stranded RNAi compounds. Conversely, the duplex structure and hydrophilic character of traditional RNAi compounds results in poor tissue distribution and cellular uptake. In an attempt to combine the best properties of both technologies, sd-rxRNA have a single-stranded phosphorothioate region, a short duplex region, and contain a variety of nuclease-stabilizing and lipophilic chemical modifications. The combination of these features allows sd-rxRNA to achieve efficient spontaneous cellular uptake and potent, long-lasting intracellular activity.

We believe that our next generation sd-rxRNA compounds offer significant advantages over siRNAs used by other companies developing RNAi therapeutics, which are highlighted by the following characteristics:

- Efficient cellular uptake in the absence of a delivery vehicle;
- Potent RNAi activity;
- More resistant to nuclease degradation than unmodified oligonucleotides;
- Able to suppress long non-coding RNAs, both in cytoplasm and the nucleus;
- Readily manufactured;
- Potentially more specific for the target gene; and
- Reduced immune side effects compared to classic siRNA.

The route by which our sd-rxRNA compounds are 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, or 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. 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, our chemically synthesized sd-rxRNA compounds are optimized for stability and efficacy and have unique properties that improve tissue and cell uptake.

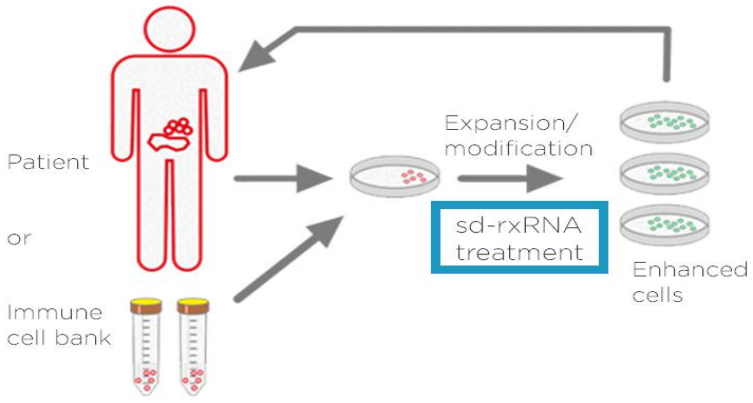
Our Adoptive Cell Transfer Approach

The self-delivering nature of our compounds makes sd-rxRNA ideally suited for use with ACT treatments and direct therapeutic use. In ACT, immune cells are isolated from specific patients or retrieved from allogeneic immune cell banks. The immune cells are then expanded and modified before being returned and used to treat the same patient. We believe our sd-rxRNA compounds are ideally suited to be used in combination with ACT, in order to make these immune cells more effective.

ACT includes a number of different types of immunotherapy treatments. These treatments all use immune cells, such as T-cells, that are grown in a lab to large numbers, followed by administering them to the body to fight the cancer cells. Sometimes, immune cells that naturally recognize a tumor are used, while other times immune cells are modified or "engineered" to make them recognize and kill the cancer cells. There are several types of ACT, including: a.) non-engineered cell therapy in which immune cells are grown from the patient's tumor or blood, such as TILS, or from donor blood or tissue such as NK cells, and b.) engineered immune cells in which these cells are genetically modified to recognize specific tumor proteins and to remain in an activated state (such as CAR T-cells and T-cell Receptors, or TCRs, and CAR NK cells).

Our approach to immunotherapy builds on well-established methodologies of ACT and involves the treatment of immune cells with our sd-rxRNA compounds during the expansion and modification phase. As shown below, immune cells are isolated from specific patients or retrieved from allogeneic immune cell banks and then expanded and sometimes processed to express tumor-binding receptors. Because our sd-rxRNA compounds do not require a delivery vehicle to penetrate into the cells, we are able to enhance these cells (for example by inhibiting the expression of immune checkpoint genes) by merely adding our sd-rxRNA compounds during the expansion process and without the need for genetic engineering. After enhancing these cells *ex vivo*, they are returned to the patient for treatment.

Our method introduces an important step in the *ex vivo* processing of immune cells. This step uses our sd-rxRNA technology to reduce or eliminate the expression of genes that make the immune cells less effective. For example, with our sd-rxRNA compounds, we can reduce the expression of immunosuppressive receptors or proteins by the therapeutic immune cells, potentially enabling them to overcome tumor resistance mechanisms and thus improving their ability to destroy the tumor cells. In various types of immune cells tested to date, sd-rxRNA treatment results in potent silencing while maintaining close to 100% transfection efficiency and nearly full cell viability.



We believe that a major advantage to our approach is that pre-treatment with our targeted compounds allows for multiple immune checkpoints to be attenuated within the same therapeutic cell, an improvement which could dramatically increase their tumor cell killing capability. In addition, these therapeutic immune cells may lack some known side effects associated with systemic checkpoint inhibitor therapies, while potentially improving efficacy over current immunotherapy approaches.

Additionally, one of the main issues with ACT is that the cells are very susceptible to the cancer signals that turn down the immune response and continuous activation of these cells causes them to become exhausted. These factors, among others, may reduce their efficacy and lifespan. A technology that can reprogram the immune cells using ACT, such as sd-rxRNA, is of key interest now in the immuno-oncology world.

Our Dermatology and Ophthalmology Programs

The Company intends to seek a partner and/or out-licensee for both its dermatology and ophthalmology programs, which includes RXI-109 and Samcyprone, to continue their development.

Dermatology – Hypertrophic Scarring

The Company's first RNAi clinical product candidate, RXI-109, is a sd-rxRNA that commenced human clinical trials in 2012. 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 and eye. Two Phase 1 clinical trials completed by the Company demonstrated the safety and tolerability of RXI-109 in ascending single and multi-doses and also provided the first evidence of clinical activity in a surgical setting. The Phase 1 clinical trials provided the desired profile to enable the initiation of a Phase 2a clinical trial. Positive results from Study 1402, our Phase 2a clinical trial with RXI-109 in hypertrophic scars, were reported in December 2017. The study met the primary effectiveness objective as shown by a statistically significant improved visual appearance of revised scars after scar revision surgery and treatment with RXI-109 versus control, as assessed by the investigator. The full study results showed that the product was safe and well tolerated for all dosage groups. Exploratory endpoint analysis furthermore showed that the cosmetic outcomes of RXI-109 treated scars were highly preferred over the untreated revised scars, by both investigators and patients. The study results show furthermore that RXI-109 was safe and well tolerated.

Dermatology – Warts

Samcyprone, the Company's second clinical candidate, is a proprietary topical formulation of the small molecule diphenylcyclopropenone ("**DPCP**"), an immunomodulator that works by initiating a T-cell response.

In May 2018, the Company announced results from its Phase 2 clinical trial with Samcyprone in cutaneous warts. The primary effectiveness objectives were met as shown by high levels of immunotherapeutic response and therapeutic response. The immunotherapeutic response rate – a prerequisite for therapeutic response – was 97.7% across all 88 subjects enrolled in the study. From a therapeutic response viewpoint, with once weekly dosing for up to 10 weeks, more than 70% of all warts showed a positive wart response rate, i.e. reduction of wart size of more than 50%. Complete wart clearance throughout the study was 54% for all warts, and up to 71.4% for certain wart types (non-plantar warts). The study results show furthermore that Samcyprone was safe and well tolerated.

Dermatology – Uneven Skin Tone and Pigmentation

Cosmetics are compounds that affect the appearance of the skin and make no preventative or therapeutic claims. These compounds may be developed more rapidly than therapeutics, therefore the path to market may be much shorter and less expensive. RXI-231, an sd-rxRNA compound targeting tyrosinase ("**TYR**"), was selected by the Company for cosmetic development. TYR is a 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 TYR can play a key role in the management of skin conditions including cutaneous hyperpigmentation disorders such as lentigines (freckles, age spots and liver spots) and possibly melanoma.

Three studies were performed under the consumer testing program with RXI-231. The first two studies in volunteers determined that the RXI-231 gel formulation did not cause irritation and sensitization when applied to the skin. The third study investigated the potential of RXI-231 to impact a skin melanin content (pigmentation) increase induced by UV exposure in a study design similar to one well documented in peer-reviewed journal articles and used by various cosmetic companies. Specific spectroscopic results showed that application of RXI-231 containing gel, as compared to a vehicle gel, can reduce a change of skin tone triggered by UV. These results not only validate our preclinical data about the effect of RXI-231 on skin pigmentation, but also provide important information on the capabilities of our proprietary topical formulation for the use of our sd-rxRNA based cosmetic ingredients in the consumer care space.

Ophthalmology – Retinal Scarring

As in dermal scarring, RXI-109 can also be used to target CTGF in the eye, where CTGF is known to be involved in retinal scarring. Building on the work in our dermal clinical program, the Company initiated a Phase 1/2 clinical trial to evaluate the safety and clinical activity of RXI-109 in reducing the progression of retinal scarring. In August 2018, the Company announced positive results from our Phase 1/2 clinical trial to evaluate the safety and clinical activity of RXI-109 in reducing the progression of retinal scarring in subjects with wet age-related macular degeneration with evidence of subretinal fibrosis. Each subject in the study received four doses of RXI-109 by intraocular injection at one-month intervals for a total dosing period of three months. The primary objective was met as shown by the absence of dose-limiting and serious toxicities, and only mild to moderate procedure related adverse events. None of the adverse events were drug related. In addition, comprehensive ocular examinations showed no indications of inflammation nor any other tolerability issues related to the treatment. The secondary objective of the study was also met with improved or stable disease in the study eyes of several subjects.

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

Patents and Patent Applications

We are actively seeking protection for our intellectual property and are prosecuting a number of patents and pending patent applications covering our compounds and technologies, including our sd-rxRNA technology. A combined summary of these patents and patent applications is set forth below in the following table:

	Pending Applications	Issued Patents
United States	24	40
Canada	11	3
Europe	16	37
Japan	11	11
Other Markets	18	10

Our RNAi portfolio includes 94 issued patents, 23 of which cover our self-delivering RNAi platform. There are 16 patent families broadly covering both the composition and methods of use of our self-delivering platform technology and uses of our sd-rxRNAs targeting immune checkpoint, cellular differentiation and metabolism targets for *ex vivo* cell-based cancer immunotherapies, as well as uses of our sd-rxRNAs targeting CTGF for the treatment of fibrotic disorders (including RXI-109 for the treatment of dermal and ocular fibrosis). These patents are scheduled to expire between 2029 and 2038. Furthermore, there are 75 patent applications, encompassing what we believe to be important new RNAi compounds and their use as therapeutics and/or cosmetics, 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 2038, not including any patent term extensions that may be afforded under the Federal Food, Drug, and Cosmetic Act ("**FFDCA**") (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).

The Samcyprone portfolio includes 1 issued patent and 5 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 2036, not including any patent term extensions that may be afforded under the FFDCA (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

We have secured exclusive and non-exclusive rights to develop therapeutics by licensing key RNAi technologies, Samcyprone 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 field for new technologies that could be in-licensed to further enhance our intellectual property portfolio and unique position in the RNAi and immuno-oncology space.

Advirna LLC. In September 2011, we entered into an agreement with Advirna, LLC ("**Advirna**") pursuant to which Advirna assigned to us its existing patent and technology rights related to sd-rxRNA technology in exchange for our agreement to issue to Advirna common stock equal to 5% of the Company's fully-diluted shares, pay an annual maintenance fee of $100,000 and pay a one-time milestone payment of $350,000 upon the issuance of the first patent with valid claims covering the assigned technology. The common shares of the Company were issued to Advirna in 2012 upon the completion of the spin-out from our former parent company and the one-time milestone payment was paid in 2014. Additionally, we will be required to pay a 1% royalty to Advirna on any license 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.

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) 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.

Hapten Pharmaceuticals, LLC. In December 2014, the Company entered into an Assignment and License Agreement with Hapten Pharmaceuticals, LLC ("**Hapten**") under which Hapten agreed 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 products for therapeutic and prophylactic use. Under the Assignment and License Agreement, and upon the closing of the agreement which occurred in February 2015, Hapten received a one-time upfront cash payment of $100,000 and we issued to Hapten 2,000 shares of common stock of the Company. 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.

We have certain customary diligence obligations under the Assignment and License Agreement requiring us to use commercially reasonable efforts to develop and commercialize one or more products covered by the Assignment and License Agreement, which obligations, if not performed, could result in rights assigned or licensed to us reverting back to Hapten.

In addition to the license agreements listed above, the Company has entered into and may enter into other license agreements that may benefit us as we develop our therapeutic pipelines.

Other Licensing Agreements

OPKO Health, Inc. In March 2013, the Company entered into an Asset Purchase Agreement (the "**Asset Purchase Agreement**") with OPKO Health, Inc. ("**OPKO**"), in which we acquired 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 16,667 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 therein) and (ii) royalty payments equal to: (a) a mid-single-digit percentage of "Net Sales" (as defined therein) with respect to each Qualified Drug sold for an ophthalmologic use during the applicable "Royalty Period" (as defined therein) 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.

We have certain customary diligence obligations under the Asset Purchase Agreement requiring us to use commercially reasonable efforts to develop and commercialize one or more products covered by the Asset Purchase Agreement, which obligations, if not performed, could result in assets transferred and rights assigned or licensed to us reverting back to OPKO.

Thera Neuropharma, Inc. In May 2016, Phio granted an exclusive license to Thera Neuropharma, Inc. ("**Thera**") to the Company's novel and proprietary sd-rxRNA platform to develop therapeutics for neurodegenerative diseases. Under the terms of the agreement, Thera will be responsible for all research, development, manufacturing, regulatory and commercialization activities for the licensed products. Thera's initial focus will be on sd-rxRNA compounds targeting superoxide dismutase 1 (SOD1) for use in developing innovative treatments for amyotrophic lateral sclerosis (ALS), commonly known as Lou Gehrig's disease. Upon execution of the license agreement, Phio was issued shares of common stock of Thera and was granted a five-year warrant to purchase additional shares of common stock of Thera pursuant to the terms of the license agreement. The Company is eligible to receive future cash, additional equity and royalties based on the achievement of certain milestones.

Research and Development

Our research and development expense primarily consists 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 including laboratory supplies and services for our research programs, our clinical trials, drug manufacturing, outside contract services, licensing fees and patent fees.

Total research and development expense for the years ended December 31, 2018 and 2017 was $4,326,000 and $5,370,000, respectively.

Acquired In-Process Research and Development

Assets purchased in an asset acquisition transaction are expensed as in-process research and development unless the assets acquired have an alternative future use. Acquired in-process research and development payments are immediately expensed and include upfront payments, as well as transaction fees and subsequent milestone payments. Development costs incurred after the acquisition are expensed as incurred.

The Company did not complete an asset acquisition transaction during the year ended December 31, 2018 that would require the recording of acquired in-process research and development expense. Total acquired in-process research and development expense for the year ended December 31, 2017 was $4,696,000, and related to the fair value of consideration given, which includes transaction costs, liabilities assumed and cancellation of notes receivable, and the deferred tax impact of the Company's acquisition of MirImmune.

Competition

The biotechnology and pharmaceutical industries, including the immuno-oncology field, are a constantly evolving landscape with rapidly advancing technologies and significant competition. There are a number of competitors in the immuno-oncology field including large and small pharmaceutical and biotechnology companies, academic institutions, government agencies and other private and public research organizations.

A variety of cell-based autologous and allogeneic approaches are being researched and developed, including but not limited to: CAR-T cell, TCR T-cell, GammaDelta T-cell, CAR-NK cell, NK cell, NKT cell and CTL. We believe that competitors in this field include, but are not limited to Adicet Bio, Allogene Therapeutics, Atara Bio, Autolus, Baylor College of Medicine, Bellicum Pharmaceuticals, bluebird bio, Celyad, Celgene, Cell Medica, Cellectis Therapeutics, Cellularity, CiMaas, CRISPR Therapeutics, Fate Therapeutics, Formula Therapeutics, Fortress Biotech, GAIA Biomedicine, Glycostem Therapeutics, Immatics, Iovance Biotherapeutics, Intrexon, Janssen Pharmaceuticals (with Nanjing Legend), Juno Therapeutics (Celgene), Kite Pharma (Gilead), MediGene, Mustang Bio, NantKwest, Neon Therapeutics, Novartis, Precigen, Refuge Biotechnologies Inc, Sorrento Therapeutics, Tactiva Therapeutics, TC Biopharm and Ziopharm Oncology.

A number of technological approaches to modulating gene expression in the field of immuno-oncology have been identified and are being researched and developed, including but not limited to: Antisense oligodeoxynucleotides (ASO), RNA interference (RNAi), zinc-finger nucleases (ZFNs), transcription activator-like effector nucleases (TALENs), messenger RNA (mRNA), and genetic engineering techniques such as Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) and various others. We believe that competitors in this field include, but are not limited to BioNTech, Cellectis, CRISPR Therapeutics, Dicerna Pharmaceuticals, Editas Medicine, eTherna Immunotherapies, Horizon Discovery, Intellia Therapeutics, Kymera Therapeutics, miRagen Therapeutics, Moderna Therapeutics, Noxxon Pharma, Obsidian Therapeutics, OliPass Corporation, OncoSec Medical System, Oncotelic, PTC Therapeutics, Sangamo Therapeutics, Sirnaomics, Stemirna Therapeutics, Takara Bio and Sangamo Therapeutics.

Government Regulation

The United States and many other 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 U.S. Food and Drug Administration ("**FDA**") regulates pharmaceutical and biologic products under the FFDCA, 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 protocols, manufacturing information, analytical data and other information submitted to the FDA in an investigational new drug ("**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 ("**NDA**"), or, in the case of a biologic, a biologics license application ("**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 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 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.

Employees

As of March 22, 2019, we had nine full-time employees. None of our employees are represented by a labor union or covered by a collective bargaining agreement nor have we experienced any work stoppages.

Corporate Information

We were incorporated in the state of Delaware in 2011 as RXi Pharmaceuticals Corporation. On November 19, 2018, the Company changed its name to Phio Pharmaceuticals Corp., to reflect its transition from a platform company to one that is fully committed to developing groundbreaking immuno-oncology therapeutics. Our executive offices are located at 257 Simarano Drive, Suite 101, Marlborough, MA 01752, and our telephone number is (508) 767-3861.

The Company's website address is *http://www.phiopharma.com*. We make available on our website, free of charge, copies of our annual reports on Form 10-K, our quarterly reports on Form 10-Q and our current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after these reports are filed electronically with, or otherwise furnished to, the Securities and Exchange Commission (the "**SEC**"). We also make available on our website the charters of our audit committee, compensation committee, and nominating and corporate governance committee, as well as our corporate code of ethics and conduct.

You may read and copy any materials the Company files with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding Phio and other issuers that file electronically with the SEC. The SEC's website address is *http://www.sec.gov*. The contents of these websites are not incorporated by reference into this report and should not be considered to be part of this report.

ITEM 1A. *RISK FACTORS*

Risks Relating to Our Business and Industry

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

Our research and development efforts and our future success is based on our sd-rxRNA technology platform. The use of RNA interference is a relatively new scientific discovery and the first regulatory approval of an RNAi therapeutic recently occurred in August 2018. The scientific evidence to support the feasibility of developing drugs based on these discoveries is limited. We may spend large amounts of money trying to develop our sd-rxRNA technology 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. If we are not successful in developing a product candidate using our sd-rxRNA technology, we may not be able to identify and successfully implement an alternative product development strategy.

We have limited experience in operating our current business in the area of immuno-oncology.

We have only a limited operating history with our current business strategy on which a decision to invest in our Company can be based. Prior to the Company's acquisition of MirImmune Inc. in January 2017, the Company's efforts were focused on the development of therapeutics in the areas of dermatology and ophthalmology. We are currently conducting multiple discovery and preclinical research studies using our sd-rxRNA technology for use in developing immuno-oncology therapeutics and we have limited experience as a company in developing such immuno-oncology technologies. Because of the number of companies and intense competition in immuno-oncology, we may not have the ability to successfully overcome many of the risks and uncertainties that companies face in this field.

We made a strategic decision to focus our development solely on immuno-oncology, and the anticipated benefits of our new strategic focus may not be realized.

We acquired MirImmune, a privately-held immuno-oncology company, in the past year and are undertaking to divest our current dermatology and ophthalmology programs. In January 2018, the Company completed a thorough review of its business operations, development programs and financial resources and announced its strategic decision to solely focus the Company's development portfolio on the field of immuno-oncology. There is no assurance that the Company will be able to consummate any strategic transactions for the dermatology and ophthalmology programs or that we will be able to be successful in implementing our new focus as an immuno-oncology product development company.

If we are not successful in identifying and developing product candidates, we will not be able to commence clinical trials in humans or obtain approval for our product candidates.

Our sd-rxRNA technology has been subject to only limited clinical testing with our first product candidate, RXI-109, for dermatologic and ophthalmic uses. We have identified lead compounds for preclinical development with our sd-rxRNA technology in immuno-oncology but have not yet commenced clinical testing. We may not be able to advance these or future product candidates through the preclinical stage into clinical trials. Additionally, we may not be able to identify data that would support entering these or future candidates into clinical trials. Furthermore, even if we successfully enter into clinical studies in immuno-oncology, the results from preclinical testing of a drug candidate may not predict the results that will be achieved in human clinical trials. There is no assurance that we will be able to successfully develop any product candidate(s), and we may focus our efforts and resources on product candidates that may prove to be unsuccessful.

We are dependent on the success of our product candidates, which may not receive regulatory approval or be successfully commercialized.

We have no commercial products and currently generate no revenue from product 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. 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. Preliminary observations made in early stages of clinical trials with small numbers of subjects are inherently uncertain. Initial clinical trial results are not necessarily indicative of results that will be obtained when full data sets are analyzed or in subsequent clinical trials.

While there have been a number of immunotherapy drugs approved by the FDA, there have been no FDA drug approvals using the approach that we are taking. We will be subjected to thorough regulatory review by the FDA, and there is limited experience in this area with a few precedents. The FDA may require additional information from the Company regarding our current or planned clinical 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 any of our product candidates, and we may spend large amounts of money trying to resolve these issues and may never succeed in doing so.

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;
- Effects of our drug candidates not having 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 FDA could impose a unique regulatory regime for our therapeutics.

The compounds we intend to develop may represent a new class of drug, and even though the first RNAi therapeutic was approved in August 2018, 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.

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 product candidates that we are developing are based on new technologies and therapeutic approaches. For example, RNAi products may be more expensive to manufacture than traditional small molecule drugs, which may make them costlier than competing small molecule drugs. Additionally, RNAi products do not readily cross the so-called blood brain barrier, are rapidly eliminated from circulating blood 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 our technologies. 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 technologies, 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 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 fields we are pursuing 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, formulations, 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 our technologies 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 the 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 applications 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.

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

The biotechnology and pharmaceutical industries, including immuno-oncology, have intense competition and contain a high degree of risk. We face a number of competitors that have substantially greater experience and greater research and development capabilities, staffing, financial, manufacturing, marketing, technical and other resources than us, and we may not be able to successfully compete with them. These companies include large and small pharmaceutical and biotechnology companies, academic institutions, government agencies and other private and public research organizations.

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. Some of our competitors may develop and commercialize products that are introduced to market earlier than our product candidates or on a more cost-effective basis. 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, on a cost-effective basis or otherwise, any products for which we are able to obtain approval may not be successful.

Our competitors also compete with us in acquiring technologies complementary to our sd-rxRNA technology. We may face competition with respect to product efficacy and safety, ease of use and adaptability to modes of administration, acceptance by physicians, timing and scope of regulatory approvals, reimbursement coverage, price and patent position, including dominant patent positions of others. If we are not able to successfully obtain regulatory approval or commercialize our product candidates, we may not be able to establish market share and generate revenues from our technology.

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

We do not have the facilities or expertise to manufacture supplies of any of our potential product candidates. Accordingly, we will be dependent upon contract manufacturers to obtain supplies, and we will need to either develop, contract for, or otherwise arrange for the necessary manufacturers for these supplies. If for any reason we are unable to obtain the supplies for our product candidates from our current manufacturer, we would have to seek to obtain it from another major 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. 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. 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 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 primarily to hospitals, oncologists and clinics, which 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 standards 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, including drugs in our clinical pipeline, 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 costs. 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 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, and any revisions to this legislation, 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 the Secretary 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.

With the current U.S. administration and Congress, there may be additional legislative changes, including repeal and replacement of certain provisions of the Affordable Care Act. It remains to be seen, however, precisely what new legislation will provide, when it will be enacted and what impact it will have on the availability of healthcare and containing or lowering the cost of healthcare. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain marketing approval and may affect our overall financial condition and ability to develop product candidates.

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 the principal members of our executive team, the loss of whose services could make it difficult for us to manage our business successfully and achieve our business objectives. While we have entered into employment agreements with each of our executive officers, they could leave at any time, in addition to our other employees, who are all “at will” employees. Our ability to identify, attract, retain and integrate additional qualified key personnel is also critical to our success. 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 Financial Condition

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 will likely be sufficient to fund our currently planned operations for at least the next 12 months. However, we have generated significant losses to date, have not generated any product revenue 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 drug development and the regulatory process. In the future, we may need to issue equity or incur debt in order to fund our planned expenditures, as well as to make acquisitions and other investments. We cannot assure you that equity or debt financing will be available to us on acceptable terms, or at all. If we cannot, or are limited in the ability to, issue equity, incur debt 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 is not limited to the following:

- To conduct research and development to successfully develop our 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 personnel;
- 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.

If we fail to obtain additional funding when needed, we may ultimately be unable to continue to develop and potentially commercialize our product candidates, and we may be forced to scale back or terminate our operations or seek to merge with or be acquired by another company.

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 current stockholders' 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 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 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 do not include any adjustments to, or classification of, recorded asset amounts and classification of liabilities that might be necessary 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.

Risks Relating to Our Securities

The price of our common stock has been and may continue to be volatile.

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.

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. 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 the rights of existing stockholders or reduce the value of our outstanding preferred stock or common stock. In particular, rights granted to holders of certain series 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.

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 limited experience with respect to acquiring other companies and 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, in January 2017, the Company acquired 100% of the outstanding capital stock of MirImmune. The assets and development programs acquired from MirImmune were at an early stage of development and will require 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 such assets, and a failure to successfully develop such assets could diminish our prospects.

To finance future acquisitions, we may choose to issue shares of our common stock or preferred stock as consideration, which would dilute current stockholders' 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.

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 the sole source of potential gain for our stockholders for the foreseeable future.

We may not be able to regain compliance with the continued listing requirements of The Nasdaq Capital Market.

On November 12, 2018, we received written notice (the "**Notification Letter**") from the Nasdaq Stock Market ("**Nasdaq**") notifying us that we are not in compliance with the minimum bid price requirements set forth in Nasdaq Listing Rule 5550(a)(2) for continued listing on The Nasdaq Capital Market. Nasdaq Listing Rule 5550(a)(2) requires listed securities to maintain a minimum bid price of $1.00 per share, and Listing Rule 5810(c)(3)(A) provides that a failure to meet the minimum bid price requirement exists if the deficiency continues for a period of 30 consecutive business days. Based on the closing bid price of our common stock for the 30 consecutive business days prior to the date of the Notification Letter, we no longer meet the minimum bid price requirement.

The Notification Letter does not impact our listing on The Nasdaq Capital Market at this time. The Notification Letter states that we have 180 calendar days, or until May 13, 2019, to regain compliance with Nasdaq Listing Rule 5550(a)(2). To regain compliance, the bid price of our common stock must have a closing bid price of at least $1.00 per share for a minimum of 10 consecutive business days at any time prior to May 13, 2019. In the event that we do not regain compliance by May 13, 2019, we may be eligible for additional time to reach compliance with the minimum bid price requirement. However, if we fail to regain compliance with the minimum bid price listing requirement or fail to maintain compliance with all other applicable continued listing requirements and Nasdaq determines to delist our common stock, the delisting could adversely impact us by, among other things, reducing the liquidity and market price of our common stock; reducing the number of investors willing to hold or acquire our common stock; limiting our ability to issue additional securities in the future; and limiting our ability to fund our operations.

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.

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;
- 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.

On January 22, 2019, the Company executed a First Amendment (the "**First Amendment**") to the Lease. The First Amendment extended the Lease term commencing on April 1, 2019 for five years (the "**Extension Term**"). The base rent for the premises during the first year of the Extension Term is $124,864.78 per annum, payable monthly. Each year thereafter, the base rent shall increase by approximately 3% over the base rent from the prior year. With six months' advance notice, either party may terminate the lease on March 31, 2021, paying the non-terminating party six months' rent as a penalty or on March 31, 2022, paying the non-terminating party three months' rent as a penalty.

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

ITEM 3. ***LEGAL PROCEEDINGS***

From time to time, we may become a party to various legal proceedings and complaints arising in the ordinary course of business. There are none deemed to be material at this time.

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

Not applicable.

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 "PHIO."

Holders

At March 22, 2019, there were approximately 60 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

See Item 12 to this Annual Report on Form 10-K for additional information about the securities authorized for issuance under our equity compensation plans.

Recent Sales of 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.

Purchases of Equity Securities by the Issuer and Affiliated Purchases

We did not repurchase any shares of our common stock during the years ended December 31, 2018 or 2017.

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 consolidated financial statements and the notes to those consolidated 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

Phio Pharmaceuticals Corp. is a biotechnology company developing the next generation of immuno-oncology therapeutics based on our self-delivering RNAi ("**sd-rxRNA®**") therapeutic platform. The Company's efforts are focused on developing sd-rxRNA therapeutic compounds to be used in the context of adoptive cell transfer by targeting checkpoints or other gene targets, or to be used in immunotherapy following intra-tumoral injections. We aim to maximize the power of our sd-rxRNA therapeutic compounds by weaponizing therapeutic immune effector cells to attack cancer, and to make tumors more susceptible to such attacks, and ultimately provide patients battling cancers with a powerful new treatment option that goes beyond current treatment modalities.

Prior to the Company's acquisition of MirImmune, Inc. ("**MirImmune**"), our principal activities consisted of the preclinical and clinical development of the Company's sd-rxRNA compounds and topical immunotherapy agent in the areas of dermatology and ophthalmology. In January 2018, after a thorough review of its business operations, development programs and financial resources, the Company made a strategic decision to focus its efforts solely on immuno-oncology to accelerate growth and support a potential return on investment for its stockholders. In connection with this decision, the Company completed all open clinical trials in dermatology and ophthalmology with RXI-109, our first sd-rxRNA clinical candidate, and Samcyprone®, and reported out on the results of those clinical studies in 2018. The Company intends to seek a partner and/or out-licensee for its dermatology program and its ophthalmology program to continue with their development. The Company's current business strategy solely focuses on the development of immuno-oncology therapeutics utilizing our proprietary sd-rxRNA technology.

On November 19, 2018, the Company changed its name from RXi Pharmaceuticals Corporation to Phio Pharmaceuticals Corp., which reflects the Company's transition from a platform company to one that is fully committed to develop groundbreaking immuno-oncology therapeutics.

Our development efforts are based on our broadly patented sd-rxRNA technology platform. Our sd-rxRNA compounds do not require a delivery vehicle to penetrate into tissues and cells and are designed to "silence," or down-regulate, the expression of a specific gene that may be over-expressed in a disease condition. We believe that our sd-rxRNA platform uniquely positions the Company in the field of immuno-oncology because of this and for the following reasons:

- Our sd-rxRNA compounds do not require facilitated delivery (mechanical or formulation);
- Can target multiple genes (i.e. multiple immunosuppression pathways) in a single therapeutic entity;
- Demonstrate efficient uptake of sd-rxRNA to immune cells;
- Silencing by sd-rxRNA has been shown to have a sustained, or long-term, effect *in vivo*;
- Favorable clinical safety profile of sd-rxRNA with local administration; and
- Can be readily manufactured under current good manufacturing practices.

On January 3, 2018, the Board of Directors of the Company approved a 1-for-10 reverse stock split of the Company's outstanding common stock, which was effected on January 8, 2018. All share and per share amounts have been retroactively adjusted for all periods presented to give effect to the reverse stock split, including reclassifying an amount equal to the reduction in par value to additional paid-in capital in the financial statements.

Checkpoint Inhibition in Adoptive Cell Transfer

The Company has developed sd-rxRNA targeting PD-1, TIGIT and other undisclosed checkpoints in adoptive cell transfer ("**ACT**") for the treatment of solid tumors. RXI-762 and RXI-804, sd-rxRNA compounds that are designed to suppress the expression of immune checkpoint proteins PD-1 and TIGIT, respectively, which, when used in ACT, are expected to result in an improved efficacy to the targeted tumors. We expect to enter clinical development with RXI-762, our most advanced program, as part of an ACT therapy for solid tumors in melanoma by the end of 2019.

The Center for Cancer Immune Therapy (CCIT) at Herlev Hospital is a leading European cancer center for use of tumor-infiltrating lymphocytes ("**TILs**") for ACT. CCIT has carried out numerous clinical trials based on a direct translation of the discoveries from the laboratory. Our collaboration with CCIT is evaluating the potential of our sd-rxRNA technology platform to enhance the function of TILs for use in the treatment for a number of cancer types, including melanoma and ovarian cancer. To date, CCIT has evaluated sd-rxRNA compounds targeting immune checkpoints in preclinical screening models of matched TIL/tumor cell pairs from melanoma and cancer patients. Results have shown a marked PD-1 reduction on the surface of TILs in a pilot rapid expansion protocol.

Iovance Biotherapeutics, Inc. is a biotechnology company focused on the development and commercialization of autologous cellular immunotherapies optimizing personalized, tumor-directed TILs. Our research collaboration with Iovance will evaluate the potential synergies with our novel sd-rxRNA therapeutic compounds and Iovance's autologous cell therapy based on TILs for the use in the treatment of cancer. Data from this collaboration has shown that a sd-rxRNA mediated knock-down of PD-1 was associated with phenotypic changes indicative of TIL activation. Our next steps with Iovance include further evaluation of the impact of sd-rxRNA mediated gene silencing on TIL tumor reactivity and implementation of optimized silencing protocols and scale-up thereof.

Cell Maturation and Metabolism in Adoptive Cell Transfer

We use our sd-rxRNA in T-cells and other immune cell types, such as natural killer ("**NK**") cells and dendritic cells, for targets other than immune checkpoints in order to weaponize and improve cell persistence and cell viability in the immunosuppressive tumor micro-environment. We believe this shows the broad applicability of our platform technology, and that our potential impact in immuno-oncology is not limited to checkpoints and TILs.

We have shown that sd-rxRNAs are rapidly and efficiently taken up by immune effector cells without the use of transfection reagents. Using sd-rxRNA compounds against checkpoint inhibitors, we can suppress their expression levels up to 95% in immune cells, including T-cells and NK cells. Furthermore, we have demonstrated potent silencing activity as well as a phenotypic effect (enhanced degranulation activity) of NK cells treated with sd-rxRNA compounds targeting checkpoints. By treating NK cells *ex-vivo*, prior to ACT with sd-rxRNA reducing the expression of proteins such as Cbl-b and TIGIT, the anti-tumor response of these cells can be improved. Ongoing work expands these findings to include compounds for more specific NK targets, including NK specific inhibitory receptors, which could be used alone or in combination.

Through our collaboration with Medigene AG, a German biotechnology company developing highly innovative, complementary treatment platforms to target various types and stages of cancer, we are exploring the potential synergies of our sd-rxRNA technology in combination with Medigene's recombinant TCRs to develop modified T-cells with enhanced efficacy and/or safety with the ultimate goal to further improve Medigene's T-cell therapies for the treatment of cancer patients. In the studies completed, Medigene observed the reduction of PD-1 surface levels in T-cells transduced with TCRs and treated with our sd-rxRNA compound, RXI-762. While these studies utilized the Company's PD-1 targeting sd-rxRNA for proof of concept, there is also the potential to expand the collaboration to additional targets and the two complementing technologies could lead to synergistic effects that might further sharpen and improve the therapeutic effects of Medigene's receptor modified T-cells.

Direct Tumor and Tumor Micro-Environment

Our third focus area includes the use of our sd-rxRNA directly towards tumor and/or tumor micro-environment ("**TME**") targets. Impacting the tumor cells and/or TME through a direct use of sd-rxRNA, such as via intra-tumoral injection, could potentially become an important form of adjuvant therapy. We believe that this will also show that our contributions with our sd-rxRNA compounds in immuno-oncology are not limited to use with another company's cell platform. Additionally, the Company has shown that its sd-rxRNA compounds are safe and well-tolerated via intradermal injections and injections in the eye through its completed clinical trials with RXI-109 in dermatology and ophthalmology.

Our collaborative research agreement with Gustave Roussy, a leading comprehensive cancer center in France, concentrates on determining the feasibility of our sd-rxRNA platform to target the TME via intra-tumoral injection. The goal of our recent *in-vivo* study with Gustave Roussy was to demonstrate sd-rxRNA compound delivery via intra-tumoral injection and demonstrate activity (silencing of gene expression) of sd-rxRNA compounds. Results from this study showed an 80—85% reduction of the target gene expression in a mouse model of melanoma via intra-tumoral injection.

Dermatology and Ophthalmology

The Company intends to seek a partner and/or out-licensee for both its dermatology and ophthalmology programs, which includes RXI-109 and Samcyprone, to continue their development. During 2018, the Company reported the results from its completed clinical trials in dermatology and ophthalmology with RXI-109 and Samcyprone.

- In December 2017, the Company announced positive results with RXI-109 in a Phase 2 open-label, multi-center, prospective, within-subject controlled study evaluating the effectiveness and safety of RXI-109 on the outcome of scar revision surgery for hypertrophic scars in healthy adults. The primary effectiveness objective was met as shown by a statistically significant improved visual appearance of revised scars after scar revision surgery and treatment with RXI-109 versus control, as assessed by the investigator. The full study results showed that the product was safe and well tolerated for all dosage groups. Exploratory endpoint analysis furthermore showed that the cosmetic outcomes of RXI-109 treated scars were highly preferred over the untreated revised scars, by both investigators and patients.

- In May 2018, the Company announced results from our Phase 2 clinical trial with Samcyprone in cutaneous warts. The primary effectiveness objectives were met as shown by high levels of immunotherapeutic response and therapeutic response. The immunotherapeutic response rate – a prerequisite for therapeutic response – was 97.7% across all 88 subjects enrolled in the study. From a therapeutic response viewpoint, with once weekly dosing for up to 10 weeks, more than 70% of all warts showed a positive wart response rate, i.e. reduction of wart size of more than 50%. Complete wart clearance throughout the study was 54% for all warts, and up to 71.4% for certain wart types (non-plantar warts). The study results show furthermore that Samcyprone was safe and well tolerated.

- In August 2018, the Company announced positive results from our Phase 1/2 clinical trial to evaluate the safety and clinical activity of RXI-109 in reducing the progression of retinal scarring. The trial was a multi-dose, dose escalation study conducted in subjects with wet age-related macular degeneration with evidence of subretinal fibrosis. Each subject in the study received four doses of RXI-109 by intraocular injection at one-month intervals for a total dosing period of three months. The primary objective was met as shown by the absence of dose-limiting and serious toxicities, and only mild to moderate procedure related adverse events. None of the adverse events were drug related. In addition, comprehensive ocular examinations showed no indications of inflammation nor any other tolerability issues related to the treatment. The secondary objective of the study was also met with improved or stable disease in the study eyes of several subjects.

On April 11, 2018, the Company closed a registered direct offering of 1,510,604 shares of the Company's common stock at a purchase price of $3.15 per share (the "**April 2018 Offering**") pursuant to the Securities Purchase Agreement dated as of April 9, 2018. In a concurrent private placement, the Company sold warrants (the "**April 2018 Warrants**") to purchase a total of 1,132,953 shares of common stock at a purchase price of $0.125 per underlying warrant share and with an exercise price of $3.15 per share (the "**Private Placement**"). Net proceeds to the Company from the April 2018 Offering and Private Placement were $4,210,000 after deducting placement agent fees and offering expenses paid by the Company. In connection with the April 2018 Offering and Private Placement, the Company issued warrants to purchase a total of 75,530 shares of common stock with an exercise price of $4.0546 per share to the placement agent, H.C. Wainwright & Co., LLC ("**HCW**").

On October 3, 2018, the Company closed an underwritten public offering (the "**October 2018 Offering**") of (i) 3,725,714 units (the "**Units**"), at a public offering price of $0.70 per Unit, with each Unit consisting of one share of common stock and one warrant (the "**October 2018 Warrants**") to purchase one share of common stock and (ii) 17,702,858 pre-funded units (the "**Pre-Funded Units**"), at a public offering price of $0.69 per Pre-Funded Unit, with each Pre-Funded Unit consisting of one pre-funded warrant (the "**Pre-Funded Warrants**") to purchase one share of common stock and one October 2018 Warrant. The October 2018 Warrants included in the Units and Pre-Funded Units are immediately exercisable at a price of $0.70 per share and expire seven years from the date of issuance. The Pre-Funded Warrants included in the Pre-Funded Units are immediately exercisable at a price per share of $0.01 and do not expire. Net proceeds from the October 2018 Offering were $13,193,000 after deducting underwriting discounts and commissions and offering expenses paid by the Company. Additionally, pursuant to the October 2018 Offering, the Company issued warrants to purchase up to 1,607,143 shares of common stock at an exercise price of $0.875 per share to the underwriter, HCW.

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 and 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 consolidated financial statements included elsewhere in this Annual Report, we believe the following accounting policies to be the most critical in understanding the judgments and estimates we use in preparing our financial statements.

Preclinical and Clinical Expenses

Preclinical and clinical trial expenses relate to estimates of costs incurred and fees connected with clinical trial sites, third-party clinical research organizations and other preclinical and clinical related activities and include such items as subject-related fees, laboratory work, investigator fees and analysis costs. 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 length of the study, timing of certain milestones and other information available to us.

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. 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 — The Company's expected stock price volatility assumption is based upon the Company's own implied volatility.

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.

The scope of ASC 718 was expanded to include share-based payment transactions for acquiring goods and services from non-employees.

Derivative Financial Instruments

During the normal course of business we may issue warrants to vendors as consideration to perform services. We may also issue warrants as part of a debt or equity financing. Warrants and other derivative financial instruments are accounted for either as equity or as an asset or liability, depending on the characteristics of each derivative financial instrument. Warrants classified as equity are measured at fair value and recorded as additional paid in capital in stockholders' equity at the date of issuance. No further adjustments to their valuation are made. Derivative financial instruments classified as an asset or liability are measured at fair value on the issuance date and are revalued on each subsequent balance sheet date. The changes in the fair value are recognized as current period income or loss.

Financial Operations Overview

Revenues

To date, we have primarily generated revenues through government grants. We have not generated any commercial product revenue.

In the future, we may generate revenue from a combination of government grants, research and development agreements, license fees and other upfront payments, milestone payments, product sales and royalties in connection with future strategic collaborators and partners. We expect that any revenue we generate will fluctuate from period to period as a result of the timing of the achievement of any preclinical, clinical or commercial milestones and the timing and amount of payments received relating to those milestones and the extent to which any of our product candidates are approved and successfully commercialized by us or strategic collaborators and partners. If the Company or any future partner fails to develop product candidates in a timely manner or obtain regulatory approval for them, then our ability to generate future revenue and our results of operations and financial position would be adversely affected.

Research and Development Expenses

Research and development expenses 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 our preclinical activities and clinical trials. Research and development expenses are charged to expense as incurred. 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 and expensed when the service has been performed or when the goods have been received.

Our research and development programs are focused on the development of the next generation of immuno-oncology therapeutics based on sd-rxRNA therapeutic platform. Prior to the Company's acquisition of MirImmune in January 2017, our research and development programs primarily focused on developing our sd-rxRNA compounds and our topical immunotherapy agent against therapeutically relevant targets in the fields of dermatology and ophthalmology. Since we commenced operations, research and development has composed a significant portion of our total operating expenses and is expected to compose 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 results of operations, financial position and liquidity.

Acquired In-Process Research and Development

Assets purchased in an asset acquisition transaction are expensed as in-process research and development unless the assets acquired have an alternative future use. Acquired in-process research and development payments are immediately expensed and include upfront payments, as well as transaction fees and subsequent milestone payments. Development costs incurred after the acquisition are expensed as incurred.

General and Administrative Expenses

General and administrative expenses relate to salaries, employee benefits, facility-related expenses, and stock-based compensation expense related to employees dedicated to general and administrative activities. Other general and administrative expenses include professional fees for legal, audit, tax and consulting services, as well as other general corporate expenses.

Other Income (Expense), net

Other income (expense) consists primarily of interest income and expense and various income or expense items of a non-recurring nature.

Results of Operations

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

	Years Ended December 31,		Dollar Change
	2018	2017	
Revenues	$ 138	$ 15	$ 123
Operating expenses	(7,502)	(14,077)	6,575
Operating loss	(7,364)	(14,062)	6,698
Income tax benefit	–	1,621	(1,621)
Net loss	$ (7,360)	$ (12,452)	$ 5,092

Comparison of the Years Ended December 31, 2018 and 2017

Revenues

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

	Years Ended December 31,		Dollar Change
	2018	2017	
Revenues	$ 138	$ 15	$ 123

Revenues for the year ended December 31, 2018 and 2017 related to the work performed by the Company as a sub-awardee under the government grant issued to our collaborator BioAxone Biosciences, Inc. from the National Institute of Neurological Disorders and Stroke. The grant provides funding for the development of a novel sd-rxRNA compound, BA-434, that targets PTEN for the treatment of spinal cord injury.

Operating Expenses

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

	Years Ended December 31,		Dollar Change
	2018	2017	
Research and development	$ 4,326	$ 5,370	$ (1,044)
Acquired in-process research and development	–	4,696	(4,696)
General and administrative	3,176	4,011	(835)
Total operating expenses	$ 7,502	$ 14,077	$ (6,575)

Research and Development Expenses

Research and development expenses for the year ended December 31, 2018 decreased 19% compared with the year ended December 31, 2017, primarily due to the completion of the work in the Company's dermatology and ophthalmology programs, including clinical trial-related and manufacturing-related expenses, and a decrease in payroll expenses due to a reduction in headcount as compared with the prior year period.

Acquired In-process Research and Development Expense

The Company did not complete an asset acquisition transaction during the year ended December 31, 2018 that would require the recording of acquired in-process research and development expense. Total acquired in-process research and development expense for the year ended December 31, 2017 was $4,696,000, and related to the fair value of consideration given, which includes transaction costs, liabilities assumed and cancellation of notes receivable, and the deferred tax impact of the Company's acquisition of MirImmune.

General and Administrative Expenses

General and administrative expenses for the year ended December 31, 2018 decreased 21% compared with the year ended December 31, 2017, primarily due to a decrease in payroll expenses due to a reduction in headcount as compared with the prior year period, as well as a decrease in professional fees for legal-related services.

Income Tax

The following table summarizes the Company's income tax for the periods indicated, in thousands:

	Years Ended December 31,		Dollar Change
	2018	2017	
Income tax benefit	$ –	$ 1,621	$ (1,621)

There was no income tax expense or benefit during the year ended December 31, 2018. For the year ended December 31, 2017, we recognized an income tax benefit of $1,621,000 for the tax-related impact of the Company's acquisition of MirImmune.

Liquidity and Capital Resources

On August 8, 2017, the Company entered into a purchase agreement (the "**LPC Purchase Agreement**") and a registration rights agreement with Lincoln Park Capital Fund, LLC ("**LPC**"), pursuant to which the Company has the right to sell to LPC up to $15,000,000 in shares of the Company's common stock, subject to certain limitations and conditions set forth therein, over the 30-month term of the LPC Purchase Agreement. During the year ended December 31, 2018, the Company sold 435,000 shares of common stock to LPC for net proceeds of approximately $1,312,000. In total, the Company has sold 495,000 shares of common stock to LPC for net proceeds of approximately $1,602,000.

On April 11, 2018, the Company closed on the April 2018 Offering and Private Placement of its common stock and the April 2018 Warrants. Net proceeds to the Company from the April 2018 Offering and Private Placement were $4,210,000 after deducting placement agent fees and offering expenses paid by the Company.

On October 3, 2018, the Company closed on the October 2018 Offering of its Units and Pre-Funded Units. Net proceeds from the October 2018 Offering were $13,193,000 after deducting underwriting discounts and commissions and offering expenses paid by the Company.

We had cash of $14,879,000 as of December 31, 2018, compared with $3,581,000 as of December 31, 2017. We have reported recurring losses from operations since inception and expect that we will continue to have negative cash flows from our operations for the foreseeable future. Historically, the Company's primary source of funding has been the sale of its securities. In the future, we will be dependent on obtaining funding from third parties, such as proceeds from the issuance of debt, sale of equity, or strategic opportunities, in order to maintain our operations. 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. We believe that our existing cash should be sufficient to fund our operations for at least the next twelve months.

The following table summarizes our cash flows for the periods indicated, in thousands:

	Years Ended December 31,	
	2018	**2017**
Net cash used in operating activities	$ (7,520)	$ (9,514)
Net cash used in investing activities	(5)	(103)
Net cash provided by financing activities	18,823	292
Net increase (decrease) in cash and restricted cash	$ 11,298	$ (9,325)

Net Cash Flow from Operating Activities

Net cash used in operating activities was $7,520,000 for the year ended December 31, 2018 compared with $9,514,000 for the year ended December 31, 2017. The decrease in cash used in operating activities of $1,994,000 was primarily attributable to a decrease in net loss offset by adjustments for non-cash expenses, principally acquired in-process research and development expense and deferred tax related to the Company's acquisition of MirImmune in the prior year.

Net Cash Flow from Investing Activities

Net cash used in investing activities was minimal for the year ended December 31, 2018, compared with $103,000 for the year ended December 31, 2017. The decrease in net cash flow from investing activities was primarily related to the purchase of laboratory equipment in the prior year offset by cash received in the MirImmune acquisition.

Net Cash Flow from Financing Activities

Net cash provided by financing activities was $18,823,000 for the year ended December 31, 2018, compared with $292,000 for the year ended December 31, 2017. The increase in net cash flow from financing activities was due to proceeds received by the Company from the issuance of common stock to LPC, the April 2018 Offering and Private Placement and the October 2018 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, "*Guarantor's 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 5 to our consolidated financial statements for further discussion of these indemnification agreements.

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

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

ITEM 8. *FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA*

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

Stockholders and Board of Directors
Phio Pharmaceuticals Corp.
Marlborough, Massachusetts

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Phio Pharmaceuticals Corp. (the "Company") and subsidiary as of December 31, 2018 and 2017, the related consolidated statements of operations, convertible preferred stock and stockholders' equity, and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company and subsidiary at December 31, 2018 and 2017, and the results of their operations and their cash flows for the years then ended**,** in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

/s/ BDO USA, LLP

We have served as the Company's auditor since 2011.

Boston, Massachusetts

March 27, 2019

PHIO PHARMACEUTICALS CORP.
CONSOLIDATED BALANCE SHEETS
(Amounts in thousands, except share data)

	Years Ended December 31,	
	2018	**2017**
ASSETS		
Current assets:		
Cash	$ 14,879	$ 3,581
Restricted cash	50	50
Prepaid expenses and other current assets	221	201
Total current assets	15,150	3,832
Property and equipment, net of accumulated depreciation of $981 and $900, in 2018 and 2017, respectively	172	248
Other assets	–	18
Total assets	$ 15,322	$ 4,098
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 550	$ 511
Accrued expenses	1,194	1,754
Total current liabilities	1,744	2,265
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Preferred stock, $0.0001 par value, 10,000,000 shares authorized	–	–
Common stock, $0.0001 par value, 100,000,000 shares authorized; 18,841,814 and 2,429,993 shares issued and outstanding at December 31, 2018 and December 31, 2017, respectively	2	–
Additional paid-in capital	99,487	80,384
Accumulated deficit	(85,911)	(78,551)
Total stockholders' equity	13,578	1,833
Total liabilities and stockholders' equity	$ 15,322	$ 4,098

See accompanying notes to consolidated financial statements.

PHIO PHARMACEUTICALS CORP.
CONSOLIDATED STATEMENTS OF OPERATIONS
(Amounts in thousands, except share and per share data)

	Years Ended December 31,	
	2018	**2017**
Revenues	$ 138	$ 15
Operating expenses:		
Research and development	4,326	5,370
Acquired in-process research and development	–	4,696
General and administrative	3,176	4,011
Total operating expenses	7,502	14,077
Operating loss	(7,364)	(14,062)
Total other income (expense), net	4	(11)
Loss before income taxes	(7,360)	(14,073)
Income tax benefit	–	1,621
Net loss	$ (7,360)	$ (12,452)
Net loss per share:		
Basic and diluted	$ (1.04)	$ (5.52)
Weighted average shares used in calculating:		
Basic and diluted net loss per share	7,044,718	2,257,754

See accompanying notes to consolidated financial statements.

PHIO PHARMACEUTICALS CORP.
CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY
(Amounts in thousands, except share data)

	Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated	
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Total
Balance at December 31, 2016	5,737	$ 3,525	–	$ –	1,300,318	$ –	$ 73,429	$ (66,099)	$ 10,855
Acquisition of MirImmune Inc.	–	–	1,118,224	–	275,036	–	2,824	–	2,824
Conversions of Series B convertible preferred stock into common stock	(5,737)	(3,525)	–	–	637,445	–	3,525	–	–
Conversion of Series C convertible preferred stock into common stock	–	–	(1,118,224)	–	111,822	–	–	–	–
Issuance of common stock under 2017 Lincoln Park Capital, LLC purchase agreement, net of offering costs of $74	–	–	–	–	105,000	–	290	–	290
Issuance of common stock under employee stock purchase plan	–	–	–	–	372	–	2	–	2
Stock-based compensation expense	–	–	–	–	–	–	314	–	314
Net loss	–	–	–	–	–	–	–	(12,452)	(12,452)
Balance at December 31, 2017	–	–	–	–	2,429,993	–	80,384	(78,551)	1,833
Cash paid in lieu of fractional shares for 1:10 reverse stock split	–	–	–	–	(31)	–	–	–	–
Issuance of common stock under 2017 Lincoln Park Capital, LLC purchase agreement	–	–	–	–	435,000	–	1,312	–	1,312
Issuance of common stock and warrants in connection with registered direct offering and private placement, net of offering costs of $690	–	–	–	–	1,510,604	–	4,210	–	4,210
Issuance of common stock, pre-funded warrants and warrants in connection with underwritten public offering, net of offering costs of $1,630	–	–	–	–	3,725,714	1	13,192	–	13,193
Issuance of common stock upon the exercise of pre-funded warrants	–	–	–	–	10,534,286	1	104	–	105
Issuance of common stock under employee stock purchase plan	–	–	–	–	2,946	–	3	–	3
Issuance of unvested, restricted stock	–	–	–	–	203,302	–	–	–	–
Stock-based compensation expense	–	–	–	–	–	–	282	–	282
Net loss	–	–	–	–	–	–	–	(7,360)	(7,360)
Balance at December 31, 2018	–	$ –	–	$ –	18,841,814	$ 2	$ 99,487	$ (85,911)	$ 13,578

See accompanying notes to consolidated financial statements.

PHIO PHARMACEUTICALS CORP.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Amounts in thousands)

	Years Ended December 31,	
	2018	**2017**
Cash flows from operating activities:		
Net loss	$ (7,360)	$ (12,452)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	81	70
Non-cash stock-based compensation expense	282	314
Acquired in-process research and development expense	–	4,696
Deferred taxes	–	(1,621)
Value of non-marketable equity securities recognized as revenue	–	9
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(2)	(51)
Accounts payable	39	(608)
Accrued expenses	(560)	129
Net cash used in operating activities	(7,520)	(9,514)
Cash flows from investing activities:		
Cash acquired in MirImmune Inc. acquisition	–	100
Cash paid for purchase of property and equipment	(5)	(203)
Net cash used in investing activities	(5)	(103)
Cash flows from financing activities:		
Proceeds from the issuance of common stock, net of offering costs	1,312	290
Proceeds from the issuance of common stock and warrants, net of offering costs	17,403	–
Proceeds from the issuance of common stock upon exercise of pre-funded warrants	105	–
Proceeds from the issuance of common stock in connection with the employee stock purchase plan	3	2
Net cash provided by financing activities	18,823	292
Net increase (decrease) in cash and restricted cash	11,298	(9,325)
Cash and restricted cash at the beginning of period	3,631	12,956
Cash and restricted cash at the end of period	$ 14,929	$ 3,631
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	$ 3	$ –
Supplemental disclosure of non-cash investing and financing activities:		
Conversions of Series B convertible preferred stock into common stock	$ –	$ 3,525
Conversion of Series C convertible preferred stock into common stock	$ –	$ 816
MirImmune Inc. acquisition:		
Cancellation of notes receivable	$ –	$ 150
Accounts payable assumed	$ –	$ 5
Fair value of securities issued	$ –	$ 2,824

See accompanying notes to consolidated financial statements.

1. Nature of Operations

Phio Pharmaceuticals Corp. is a biotechnology company developing the next generation of immuno-oncology therapeutics based on our self-delivering RNAi ("**sd-rxRNA®**") therapeutic platform. The Company's efforts are focused on developing sd-rxRNA therapeutic compounds to be used in the context of adoptive cell transfer by targeting checkpoints or other gene targets, or to be used in immunotherapy following intra-tumoral injections. We aim to maximize the power of our sd-rxRNA therapeutic compounds by weaponizing therapeutic immune effector cells to attack cancer, and to make tumors more susceptible to such attacks, and ultimately provide patients battling cancers with a powerful new treatment option that goes beyond current treatment modalities.

Prior to the Company's acquisition of MirImmune, Inc. ("**MirImmune**"), our principal activities consisted of the preclinical and clinical development of the Company's sd-rxRNA compounds and topical immunotherapy agent in the areas of dermatology and ophthalmology. In January 2018, after a thorough review of its business operations, development programs and financial resources, the Company made a strategic decision to focus its efforts solely on immuno-oncology to accelerate growth and support a potential return on investment for its stockholders. In connection with this decision, the Company completed all open clinical trials in dermatology and ophthalmology with RXI-109, our first sd-rxRNA clinical candidate, and Samcyprone®, and reported out on the results of those clinical studies in 2018. The Company intends to seek a partner and/or out-licensee for its dermatology program and its ophthalmology program to continue with their development. The Company's current business strategy solely focuses on the development of immuno-oncology therapeutics utilizing our proprietary sd-rxRNA technology.

On November 19, 2018, the Company changed its name from RXi Pharmaceuticals Corporation to Phio Pharmaceuticals Corp., which reflects the Company's transition from a platform company to one that is fully committed to develop groundbreaking immuno-oncology therapeutics.

On January 3, 2018, the Board of Directors of the Company approved a 1-for-10 reverse stock split of the Company's outstanding common stock, which was effected on January 8, 2018. All share and per share amounts in the financial statements have been retroactively adjusted for all periods presented to give effect to the reverse stock split, including reclassifying an amount equal to the reduction in par value to additional paid-in capital.

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**").

Principles of Consolidation

The consolidated financial statements include the accounts of Phio Pharmaceuticals Corp. and its wholly owned subsidiary, MirImmune, LLC. All material intercompany accounts have been eliminated in consolidation.

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.

Restricted Cash

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

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash. 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.

Property and Equipment

Property and equipment 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
Furniture & fixtures	5 years
Leasehold improvements	5 years

Depreciation and amortization expense for the years ended December 31, 2018 and 2017 was $81,000 and $70,000, respectively.

Derivative Financial Instruments

The Company follows the provisions of the Financial Accounting Standards Board ("**FASB**") Accounting Standards Codification ("**ASC**") Topic 815, "*Derivatives and Hedging*" ("**ASC 815**"). Financial instruments that meet the definition of a derivative are classified as an asset or liability and measured at fair value on the issuance date and are revalued on each subsequent balance sheet date. The changes in fair value are recognized as current period income or loss. Financial instruments that do not meet the definition of a derivative are classified as equity and measured at fair value and recorded as additional paid in capital in stockholders' equity at the date of issuance. No further adjustments to their valuation are made.

Fair Value of Financial Instruments

The carrying amounts reported in the balance sheet for restricted cash, accounts payable and accrued expenses approximate their fair values due to their short-term nature.

Impairment of Long-Lived Assets

The Company reviews long-lived assets for impairment 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, 2018. At December 31, 2017, the Company fully impaired its non-marketable securities and included impairment expense of $9,000 within total other income/expense on the consolidated statement of operations related to the impairment.

Research and Development Expenses

Research and development costs 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 its research and development departments, costs to acquire technology licenses and expenses associated with preclinical activities and its clinical trials. Research and development expenses are charged to expense as incurred. 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 and expensed when the service has been performed or when the goods have been received. Accrued liabilities are recorded related to those expenses for which vendors have not yet billed the Company with respect to services provided and/or materials that it has received.

Preclinical and clinical trial expenses relate to estimates of costs incurred and fees connected with clinical trial sites, third-party clinical research organizations and other preclinical and clinical related activities and include such items as subject-related fees, laboratory work, investigator fees and analysis costs. 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 the Company has adequately provided for preclinical and clinical expenses during the proper period, the Company maintains 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 length of the study, timing of certain milestones and other information available to us. Actual results may differ from these estimates and could have a material impact on the Company's reported results. The Company's historical accrual estimates have not been materially different from its actual costs.

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 research and development as incurred.

Acquired In-process Research and Development

Assets purchased in asset acquisition transactions are expensed as in-process research and development unless the assets acquired have an alternative future use. Acquired in-process research and development payments are immediately expensed and include upfront payments, as well as transaction fees and subsequent milestone payments. Development costs incurred after the acquisition are expensed as incurred.

Stock-based Compensation

The Company follows the provisions of the FASB ASC Topic 718, "*Compensation — Stock Compensation*" ("**ASC 718**"), which requires the measurement and recognition of compensation expense for all stock-based payment awards. 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.

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 the FASB ASC Topic 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 share attributable to common stockholders in accordance with the FASB ASC Topic 260, "*Earnings per Share."* Basic and diluted net loss per common share attributable to common stockholders is computed by dividing net loss attributable to common stockholders by the weighted average number of common shares outstanding. 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.

3. Recent Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update ("**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. On July 9, 2015, the FASB voted to delay the effective date of the new revenue standard by one year but to permit entities to choose to adopt the standard as of the original effective date. In March 2016, the FASB issued ASU 2016-08, *"Revenue from Contracts with Customers (Topic 606) – Principal Versus Agent Considerations,"* which improves the operability and understandability of the implementation guidance on principal versus agent considerations. In April 2016, the FASB issued ASU 2016-10, "*Revenue from Contracts with Customers* (*Topic 606*) *– Identifying Performance Obligations and Licensing*," which clarifies two aspects of the guidance on accounting for revenue contracts with customers: identifying performance obligations and the licensing implementation guidance. In May 2016, the FASB issued ASU 2016-12, "*Revenue from Contracts with Customers* (*Topic 606*) *– Narrow Scope Improvements and Practical Expedients*," which addresses collectability assessment, presentation of sales taxes, noncash consideration and completed contracts and contract modifications at transition. The amendments in these ASUs do not change the core principles for those areas. This standard became effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period. Early adoption is not permitted. The Company adopted this ASU in the first quarter of 2018. Since the Company has no significant revenue, this ASU had no immediate impact on its consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, "*Leases (Topic 842),*" ("**Topic 842**") which requires companies that are lessees to recognize a right-of-use asset and lease liability for most leases that do not meet the definition of a short-term lease. For income statement purposes, leases will continue to be classified as either operating or financing. This standard will result in extensive qualitative and quantitative disclosure changes. In July 2018, the FASB issued ASU 2018-10, "*Codification Improvements to Topic 842, Leases,*" which affects narrow aspects of the guidance issued in the amendments in ASU 2016-02, "*Leases*." The FASB further issued ASU 2018-11, "*Leases (Topic 842): Targeted Improvements*," in July 2018, which provides entities with an additional (and optional) transition method to adopt the new leases standard. This standard will be effective for annual reporting periods beginning after December 15, 2018, including interim periods within that reporting period.

The Company will adopt Topic 842 on January 1, 2019, using the modified retrospective approach as applied to leases existing as of or entered into after the adoption date. Topic 842 provides a number of optional practical expedients and accounting policy elections. The Company has elected the package of practical expedients to not reassess whether any expired or existing contracts are or contain leases, lease classification of existing or expiring leases and indirect costs for existing or expired leases. The Company has also elected the practical expedient to not separate lease and non-lease components and instead account for each separate lease component and non-lease components associated with that lease as a single lease component. Upon adoption of Topic 842, the Company expects that the standard will have a material effect on its financial statements. The Company continues to assess all of the effects of the impact of the adoption and expects that the most significant effects will primarily relate to the recognition of a right of use asset and corresponding lease liability on the balance sheet on the date of adoption, currently estimated at $30,000, and providing significant new disclosures around leasing activities. The Company does not expect the adoption of the new standard to have a significant impact on its consolidated statements of operations or cash flows.

In June 2018, the FASB issued ASU 2018-07, "*Compensation – Stock Compensation (Topic 718) – Improvements to Nonemployee Share-Based Payment Accounting*," which expands the scope of ASC 718 to include share-based payment transactions for acquiring goods and services from non-employees. The amendment specifies that ASC 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. This standard will be effective for annual reporting periods beginning after December 15, 2018, including interim periods within that reporting period. Early adoption is permitted, but no earlier than an entity's adoption date of Topic 606. The Company early adopted this ASU in the second quarter of 2018. The ASU had no material impact on the Company's consolidated financial statements.

In August 2018, the Securities and Exchange Commission issued Release No. 33-10532 that amends and clarifies certain financial reporting requirements. The principal change to the Company's financial reporting will be the inclusion of the annual disclosure requirement of changes in stockholders' equity in Rule 3-04 of Regulation S-X to interim periods. The Company will adopt this new rule beginning with our financial reporting for the quarter ended March 31, 2019. Upon adoption, the Company will include the consolidated statements of stockholders' equity with each quarterly filing on Form 10-Q.

4. Accrued Expenses

Accrued expenses consist of the following, in thousands:

	December 31,	
	2018	**2017**
Compensation and benefits	$ 437	$ 735
Clinical development expenses	107	261
Professional fees	170	167
Research and development costs	480	583
Other	–	8
Total accrued expenses	$ 1,194	$ 1,754

5. 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.

The Company's contractual license obligations that will require future cash payments as of December 31, 2018 are as follows, in thousands:

Year Ending December 31,		
2019	$	165
2020		165
2021		165
2022		100
2023		100
Thereafter		600
Total	$	1,295

Operating Leases

The Company leases office and laboratory space for its corporate headquarters and primary research facility in Marlborough, Massachusetts. The lease for the office and lab space will expire on March 31, 2019. Average monthly rental expense is approximately $10,300, which includes the Company's pro rata share of annual real estate taxes and operating expenses. The Company recognizes rental expense on its office space on a straight-line basis over the lease term. Differences between the straight-line rent expense and rent payments are classified as deferred rent.

Total rent expense under the Company's operating lease was approximately $120,000 and $115,000 for the years ended December 31, 2018 and 2017, respectively.

At December 31, 2018, the Company's future minimum payments required under operating leases are as follows, in thousands:

Year Ending December 31,		
2019	$	30
Total	$	30

The Company applies the disclosure provisions of the 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 consolidated financial statements related to these indemnifications.

6. MirImmune Inc. Acquisition

On January 6, 2017, the Company entered into a Stock Purchase Agreement (the "**Stock Purchase Agreement**") and completed its acquisition of MirImmune. Pursuant to the Stock Purchase Agreement, the Company acquired all of the issued and outstanding shares of capital stock of MirImmune for an aggregate of 275,036 shares of common stock of the Company and an aggregate of 1,118,224 shares of Series C Convertible Preferred Stock of the Company (the "**Series C Convertible Preferred Stock**").

The acquisition of MirImmune was assessed under the FASB ASC Topic 805, "*Business Combinations*" ("**ASC 805**"). Under ASC 805, the Company determined that the acquired assets did not constitute a business and that the transaction would be accounted for as an asset acquisition. Under ASC 805, the assets acquired were considered to have no alternative future uses, as determining the future economic benefit of the acquired assets at the date of acquisition was highly uncertain. The fair value of the assets was determined using the quoted market price of the Company's common stock on January 6, 2017, the date of the acquisition, and was fully expensed as in-process research and development.

Additionally, the Company assessed the MirImmune acquisition under ASC Topic 740, "*Income Taxes*" ("**ASC 740**"). The acquisition resulted in an income tax benefit of $1,621,000 and a corresponding increase to acquired in-process research and development expense resulting from the reduction in the Company's valuation allowance due to the deferred tax liability created as a result of the book and tax basis difference during the year ended December 31, 2017.

During the year ended December 31, 2017, the Company recorded $4,696,000 in in-process research and development expense related to the fair value of consideration given, which includes transaction costs, liabilities assumed and cancellation of notes receivable, and the deferred tax impact of the MirImmune acquisition.

The Company was restricted from converting any of the Series C Convertible Preferred Stock into common stock to the extent that such conversion was not approved by the Company's stockholders in accordance with the stockholder approval requirements of Nasdaq Marketplace Rule 5635. On June 9, 2017, with the approval of the Company's stockholders in accordance with the Nasdaq stockholder approval requirements, every ten shares of the Series C Convertible Preferred Stock outstanding were automatically converted into one share of common stock, such that there were no shares of Series C Convertible Preferred Stock issued or outstanding after the conversion.

Under the terms of the Stock Purchase Agreement, if certain development or commercial milestones are achieved within two years, the Company will be required to either (i) issue a number of shares of common stock (the "**Milestone Shares**") equal to the sum of 251,909 shares of common stock, plus an additional number of shares of common stock equal to 13% of the common stock issued upon exercise of any warrants issued under the Company's underwritten public offering completed in December 2016, but only to the extent that such warrants have been exercised prior to the milestone being achieved or (ii) pay the equivalent value of the Milestone Shares in cash.

The Company assessed the Milestone Shares under the FASB ASC Topic 480, "*Distinguishing Liabilities from Equity*" ("**ASC 480**"). The Company determined that liability accounting would be required for the Milestone Shares under ASC 480. The Company will record a liability related to the Milestone Shares if and when the milestones are achieved and the consideration becomes payable. At that time, the Company will record the cost of the Milestone Shares as in-process research and development expense. No milestones under the Stock Purchase Agreement have been met as of December 31, 2018 or 2017. Additionally, on January 6, 2019, the Company had not met the development or commercial milestones as set forth in the Stock Purchase Agreement and is no longer required to issue the Milestone Shares or pay the equivalent value of Milestone Shares in cash.

7. Stockholders' Equity

Lincoln Park Capital Fund, LLC — On August 8, 2017, the Company entered into a purchase agreement (the "**Purchase Agreement**") and a registration rights agreement with Lincoln Park Capital, LLC ("**LPC**"), pursuant to which the Company has the right to sell to LPC shares of the Company's common stock, subject to certain limitations and conditions set forth in the 2017 Purchase Agreement.

As a commitment fee for entering into the Purchase Agreement, the Company issued 45,000 shares of the Company's common stock to LPC at a value per share of $5.80, which was recorded as a cost of capital. During the year ended December 31, 2018, the Company sold 435,000 shares of common stock to LPC for net proceeds of approximately $1,312,000. During the year ended December 31, 2017, the Company sold 60,000 shares of common stock to LPC for net proceeds of approximately $290,000.

April 2018 Registered Direct Offering and Private Placement — On April 11, 2018, the Company closed a registered direct offering of 1,510,604 shares of the Company's common stock at a purchase price of $3.15 per share (the "**April 2018 Offering**") pursuant to the Securities Purchase Agreement dated as of April 9, 2018. In a concurrent private placement, the Company sold warrants (the "**April 2018 Warrants**") to purchase a total of 1,132,953 shares of common stock at a purchase price of $0.125 per underlying warrant share and with an exercise price of $3.15 per share (the "**Private Placement**"). Net proceeds to the Company from the April 2018 Offering and Private Placement were $4,210,000 after deducting placement agent fees and offering expenses paid by the Company. In connection with the April 2018 Offering and Private Placement, the Company issued warrants to purchase a total of 75,530 shares of common stock with an exercise price of $4.0546 per share to the placement agent, H.C. Wainwright & Co., LLC ("**HCW**") (the "**Placement Agent Warrants**")

The Company assessed the April 2018 Warrants and Placement Agent Warrants under the FASB ASC Topic 480, "*Distinguishing Liabilities from Equity*" ("**ASC 480**") and determined that the April 2018 Warrants and Placement Agent Warrants were outside the scope of ASC 480. The Company next assessed the April 2018 Warrants and Placement Agent Warrants under the FASB ASC Topic 815, "*Derivatives and Hedging*" ("**ASC 815**"). Under the related guidance, a reporting entity shall not consider a contract to be a derivative instrument if the contract is both (1) indexed to the entity's own stock and (2) classified in stockholders' equity. The Company determined that the April 2018 Warrants and Placement Agent Warrants were indexed to the Company's stock, as the agreements do not contain any exercise contingencies and the settlement amount equals the difference between the fair value of the Company's common stock price and the strike price. The Company also assessed the classification in stockholders' equity and determined the April 2018 Warrants and Placement Agent Warrants met all of the criteria for classification as equity under ASC 815. Based on this analysis, the Company determined that the April 2018 Warrants and Placement Agent Warrants would be classified in stockholders' equity.

October 2018 Underwritten Public Offering — On October 3, 2018, the Company closed an underwritten public offering (the "**October 2018 Offering**") of (i) 3,725,714 units (the "**Units**"), at a public offering price of $0.70 per Unit, with each Unit consisting of one share of common stock and one warrant (the "**October 2018 Warrants**") to purchase one share of common stock and (ii) 17,702,858 pre-funded units (the "**Pre-Funded Units**"), at a public offering price of $0.69 per Pre-Funded Unit, with each Pre-Funded Unit consisting of one pre-funded warrant (the "**Pre-Funded Warrants**") to purchase one share of common stock and one October 2018 Warrant. The October 2018 Warrants included in the Units and Pre-Funded Units are immediately exercisable at a price of $0.70 per share and expire seven years from the date of issuance. The Pre-Funded Warrants included in the Pre-Funded Units are immediately exercisable at a price per share of $0.01 and do not expire. Net proceeds from the October 2018 Offering were $13,193,000 after deducting underwriting discounts and commissions and offering expenses paid by the Company. Additionally, pursuant to the October 2018 Offering, the Company issued warrants to purchase up to 1,607,143 shares of common stock at an exercise price of $0.875 per share to the underwriter, HCW (the "**Underwriter Warrants**").

The Company assessed the October 2018 Warrants and Underwriter Warrants under the FASB ASC Topic 480, "*Distinguishing Liabilities from Equity*" ("**ASC 480**") and determined that the October 2018 Warrants and Underwriter Warrants were outside the scope of ASC 480. The Company next assessed the October 2018 Warrants and Underwriter Warrants under the FASB ASC Topic 815, "*Derivatives and Hedging*" ("**ASC 815**"). Under the related guidance, a reporting entity shall not consider a contract to be a derivative instrument if the contract is both (1) indexed to the entity's own stock and (2) classified in stockholders' equity. The Company determined that the October 2018 Warrants and Underwriter Warrants were indexed to the Company's stock, as the agreements do not contain any exercise contingencies and the settlement amount equals the difference between the fair value of the Company's common stock price and the strike price. The Company also assessed the classification in stockholders' equity and determined the October 2018 Warrants and Underwriter Warrants met all of the criteria for classification as equity under ASC 815. Based on this analysis, the Company determined that the October 2018 Warrants and Underwriter Warrants would be classified in stockholders' equity.

Warrants

The following table summarizes the Company's outstanding equity-classified warrants at December 31, 2018:

Summary of Warrants	Exercise prices	Number of Shares Underlying Warrants	Expiration
June 2015 Warrants	$ 52.00	130,007	June 2, 2020
December 2016 Warrants	$ 9.00	1,277,793	December 21, 2021
April 2018 Warrants	$ 3.15	1,132,953	May 31, 2023
Placement Agent Warrants	$ 4.0546	75,530	April 9, 2023
Pre-Funded Warrants	$ 0.01	7,168,572	No expiration
October 2018 Warrants	$ 0.70	21,428,572	October 3, 2025
Underwriter Warrants	$ 0.875	1,607,143	October 1, 2023
Total warrants outstanding		32,820,570	

During the year ended December 31, 2018, the Company received proceeds of $105,000 from the exercise of Pre-Funded Warrants for a total of 10,534,286 shares of common stock. There were no warrant exercises during the year ended December 31, 2017.

8. Net Loss per Share

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

	December 31,	
	2018	2017
Options to purchase common stock	141,677	50,156
Restricted stock units	137,500	–
Restricted stock	203,302	–
Warrants to purchase common stock	32,820,570	1,408,000
Total	33,303,049	1,458,156

9. Stock-based Compensation

Stock Plans

On January 23, 2012, the Company's Board of Directors and sole stockholder adopted the Phio Pharmaceuticals Corp. 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, 2018, an aggregate of 750,000 shares of common stock were reserved for issuance under the Company's 2012 Incentive Plan, including 141,677 shares subject to outstanding common stock options and 137,500 shares subject to unvested restricted stock units ("**RSUs**") granted under the 2012 Incentive Plan and 470,803 shares available for future grants. Stock options and RSUs granted by the Company to employees vest annually over 4 years after the grant date and, in the instance of stock options, expire within ten years of issuance.

Stock Options

The Company uses the Black-Scholes option-pricing model to determine the fair value of all its option grants. For valuing options granted during the years ended December 31, 2018 and 2017, the following assumptions were used:

	December 31,	
	2018	**2017**
Risk-free interest rate	2.70 – 2.93%	1.73 – 2.49%
Expected volatility	91.28 – 161.45%	82.99 – 123.01%
Weighted average expected volatility	159.55%	84.65%
Expected lives (in years)	5.50 – 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, 2018 and 2017 was $1.75 and $4.90 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 Company's own implied volatility. The expected life assumption for option grants is based upon the simplified method provided for under ASC 718. The dividend yield assumption 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 activity of the Company's stock option plan for the year ended December 31, 2018:

	Total Number of Shares	**Weighted-Average Exercise Price Per Share**	**Weighted-Average Remaining Contractual Term**	**Aggregate Intrinsic Value**
Balance at December 31, 2017	50,180	$ 192.30		
Granted	108,250	1.83		
Exercised	–	–		
Cancelled	(16,753)	27.25		
Balance at December 31, 2018	141,677	$ 66.29	8.17 years	$ –
Exercisable at December 31, 2018	38,274	$ 238.48	4.71 years	$ –

Stock-based compensation expense related to stock options for the year ended December 31, 2018 and 2017 was $112,000 and $314,000, respectively.

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.

As of December 31, 2018, the compensation expense for all unvested stock options in the amount of approximately $200,000 will be recognized in the Company's results of operations over a weighted average period of 3.04 years.

Restricted Stock Units

In addition to stock options to purchase shares of common stock, the Company may also grant RSUs. RSUs are generally subject to graded vesting and the satisfaction of service requirements, similar to our stock options. Upon vesting, each outstanding RSU will be exchanged for one share of the Company's common stock. The fair value of the RSUs awarded are based on the Company's closing stock price at the grant date and are expensed over the requisite service period.

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

	Number of Shares	Weighted-Average Grant Date Fair Value Per Share
Unvested units at December 31, 2017	–	$ –
Granted	151,250	1.79
Vested	–	–
Forfeited	(13,750)	1.79
Unvested units at December 31, 2018	137,500	$ 1.79

Stock-based compensation expense related to RSUs was $52,000 for the year ended December 31, 2018. There was no stock-based compensation expense related to RSUs for the year ended December 31, 2017.

As of December 31, 2018, the compensation expense for all unvested RSUs in the amount of approximately $194,000 will be recognized in the Company's results of operations over a weighted average period of 2.78 years.

Restricted Stock

On August 31, 2018, Geert Cauwenbergh, Dr. Med. Sc., the Company's former Chief Executive Officer, elected the right to receive, in lieu of cash, for the period from September 15, 2018 to December 31, 2018, up to 50% of his base salary and cash bonuses, if any, (collectively, the "**Compensation**") payable in the form of unvested, restricted shares of the Company's common stock. Such restricted shares will be received in the form of a series of grants made on each Company payroll date in lieu of cash payment of the Compensation and shall vest in full on January 1, 2019, subject to his continued employment through such date. On December 19, 2018, the Company and Dr. Cauwenbergh agreed to extend the applicable period of the election through February 28, 2019 and that all restricted stock issued during the election period will vest on March 1, 2019.

The fair value of the restricted stock is based on the Company's closing stock price on the date of grant and is expensed over the vesting period. For the year ended December 31, 2018, the Company granted 203,302 restricted shares of the Company's common stock in lieu of Compensation to Dr. Cauwenbergh. Stock-based compensation expense related to the restricted shares was $118,000 for the year ended December 31, 2018. There were no restricted stock issuances under this election during the year ended December 31, 2017.

Compensation Expense Related to Equity Awards

The Company recorded total stock-based compensation expense related to equity awards in the consolidated statement of operations for the years ended December 31, 2018 and 2017 as follows, in thousands:

	December 31,	
	2018	**2017**
Research and development	$ 40	$ 89
General and administrative	242	225
Total stock-based compensation	$ 282	$ 314

10. Income Taxes

For the years ended December 31, 2018 and 2017, all of the Company's loss before income taxes was generated in the United States.

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

	Years Ended December 31,	
	2018	**2017**
Current		
Federal	$ –	$ –
State	–	–
Total current	–	–
Deferred		
Federal	(1,555)	2,945
State	(639)	(1,568)
Total deferred	(2,194)	1,377
Valuation allowance	2,194	(2,998)
Total income tax expense (benefit)	$ –	$ (1,621)

The Company's acquisition of MirImmune resulted in an income tax benefit of $1,621,000 in 2017 and a corresponding increase to acquired in-process research and development expense resulting from the reduction in the Company's valuation allowance due to the deferred tax liability created as a result of the book and tax basis difference.

Reconciliation of the effective income tax rate to the U.S. statutory rate is as follows:

	Years Ended December 31,	
	2018	2017
Federal statutory rate	21%	(34)%
State income taxes, net of federal benefit	5.5	(6.5)
Non-deductible expenses	(1.2)	0.5
Income tax credits	4.3	(2.5)
Deferred rate change	–	62.5
Valuation allowance	(29.6)	(31.5)
Effective tax rate	–	(11.5)

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

	Years Ending December 31,	
	2018	2017
Net operating loss carryforwards	$ 16,957	$ 14,681
Tax credit carryforwards	1,556	1,322
Stock-based compensation	1,388	1,336
Licensing deduction deferral	3,059	3,393
Other timing differences	140	175
Gross deferred tax assets	23,100	20,907
Valuation allowance	(23,100)	(20,907)
Net deferred tax asset (liability)	$ –	$ –

The Company's deferred tax assets at December 31, 2018 and 2017 consisted primarily of its net operating loss carryforwards, deferred compensation, tax credit carryforwards, intangible assets capitalized for federal income tax purposes and certain accruals that for tax purposes are not deductible until future payment is made. The valuation allowance increased $2,194,000 and decreased $4,621,000 for the years ended December 31, 2018 and 2017, respectively, and is primarily attributable to an increase in net operating losses and tax credits.

On December 22, 2017, the President of the United States signed into law the Tax Cuts and Jobs Act tax reform legislation. This legislation makes significant changes in U.S. tax law including a reduction in the corporate tax rates, changes to net operating loss carryforwards and carrybacks, and a repeal of the corporate alternative minimum tax. The legislation reduced the U.S. corporate tax rate from the current rate of 34% to 21%. As a result of the enacted law, the Company was required to revalue deferred tax assets and liabilities at the enacted rate. This revaluation resulted in a decrease to the Company's net deferred tax assets of approximately $8,800,000 and a corresponding reduction of the same amount in the valuation allowance against these deferred tax assets in the fourth quarter of 2017. The Company concluded the tax accounting consideration associated with the Tax Cuts and Jobs Act and no material adjustments were recorded in the year ended December 31, 2018.

The Company has incurred net operating losses since inception. At December 31, 2018, the Company had federal and state net operating loss carryforwards of approximately $64,000,000 and $56,000,000, respectively, which are available to reduce future taxable income through 2038. In addition, the Company has federal and state research credits of $1,116,000 and $558,000, respectively, to offset future tax expense through 2038. 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 does not believe any substantial changes in ownership have occurred, however a detailed analysis would need to be conducted in order to be certain.

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 2018. The Company has not recorded any uncertain tax positions as of December 31, 2018 or 2017. The Company does not believe there will be any material changes in its unrecognized tax positions over the next 12 months. The Company 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 LLC. We have entered into an agreement with Advirna LLC ("**Advirna**"), pursuant to which Advirna assigned to us its existing patent and technology rights related to the sd-rxRNA technology. In exchange, the Company is obligated to pay Advirna an annual maintenance fee and paid a milestone payment upon the issuance of the first patent with valid claims covering the assigned technology in 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. To date, royalties owed to Advirna under the agreement have been minimal. 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 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.

Hapten Pharmaceuticals, LLC. We have entered into an Assignment and License Agreement (the "**Assignment and License Agreement**") with Hapten Pharmaceuticals, LLC ("**Hapten**") under which Hapten agreed 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 products for therapeutic and prophylactic use. Under 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. To date, no milestones have been met and no royalties have been earned under the Assignment and License Agreement with Hapten.

We have certain customary diligence obligations under the Assignment and License Agreement requiring us to use commercially reasonable efforts to develop and commercialize one or more products covered by the Assignment and License Agreement, which obligations, if not performed, could result in rights assigned or licensed to us reverting back to Hapten.

12. Subsequent Events

Subsequent to the balance sheet date, the Company received proceeds of approximately $32,100 from the exercise of Pre-Funded Warrants for a total of 3,214,286 shares of common stock.

On January 22, 2019, the Company executed a First Amendment (the "**First Amendment**") to the lease dated December 17, 2013 with 257 Simarano LLC (the "**Lease**"). The Lease covers approximately 7,581 of premises used by the Company for office and laboratory space located at 257 Simarano Drive, Marlborough, Massachusetts. The First Amendment extended the Lease term commencing on April 1, 2019 for five years (the "**Extension Term**"). The base rent for the premises during the first year of the Extension Term is $124,864.78 per annum, payable monthly. Each year thereafter, the base rent shall increase by approximately 3% over the base rent from the prior year. With six months' advance notice, either party may terminate the lease on March 31, 2021, paying the non-terminating party six months' rent as a penalty or on March 31, 2022, paying the non-terminating party three months' rent as a penalty. The Company will adopt Topic 842 on January 1, 2019 and expects that the Extension Term will increase the right of use asset and corresponding lease liability to be recognized on the balance sheet to a current estimation of approximately $600,000. The Company is continuing to assess all the effects of the impact of the adoption.

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

N/A.

ITEM 9A. *CONTROLS AND PROCEDURES*

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer, evaluated the effectiveness of disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) 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. 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. Based on the evaluation of our disclosure controls and procedures as of the end of the period covered by this report, management concluded that our disclosure controls and procedures were effective as of such date.

Remediation of Previous Material Weakness in Internal Control Over Financial Reporting

In connection with the preparation of our consolidated financial statements as of and for the year ended December 31, 2017, we identified a material weakness in our internal control over financial reporting related to our controls over accounting for income taxes. During the year ended December 31, 2018, the Company has executed on its remediation plan for this material weakness and the material weakness has been remediated.

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, 2018. 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 this assessment, management concluded that, as of December 31, 2018, our internal control over financial reporting was effective.

Attestation Report of the Registered Public Accounting Firm

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

During 2018, management implemented its remediation plan to address the control deficiency that led to the material weakness in internal control over financial reporting related to our controls over accounting for income taxes for the fiscal year ended December 31, 2017. As part of the remediation plan management executed on (i) implementing the increased involvement on a quarterly basis with our third-party tax accountants dedicated to determining the appropriate accounting for material and complex tax transactions in a timely manner, (ii) reviewing our tax accounting process to identify and implement enhanced tax accounting process and related internal control procedures and (iii) established additional training and education programs for financial personnel responsible for income tax accounting. There were no other changes in our internal control over financial reporting during the quarter ended December 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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

None.

PART III

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

The following table sets forth our directors and executive officers, their ages and the positions currently held by each person:

Name	Age	Position
Gerrit Dispersyn, Dr. Med. Sc.	44	President and Chief Executive Officer
Robert J. Bitterman	68	Chairman of the Board of Directors
Keith L. Brownlie	66	Director
Geert Cauwenbergh, Dr. Med. Sc.	65	Director
H. Paul Dorman	82	Director
Jonathan E. Freeman, Ph.D.	51	Director
Curtis A. Lockshin, Ph.D.	58	Director

Gerrit Dispersyn, Dr. Med. Sc. has served as our President and Chief Executive Office since March 2019 and was our President and Chief Operating Officer from November 2018 to March 2019, and our Chief Development Officer from April 2017 to November 2018. From 2014 to April 2017, Dr. Dispersyn was the Vice President, Global Head of Clinical Affairs at Integra Lifesciences Corporation, a medical technology company dedicated to limiting uncertainty for surgeons so they can concentrate on providing the best patient care. Prior to assuming this role, Dr. Dispersyn held the position of Vice President, Program Management & Clinical Affairs from 2008 to 2014. Prior to his roles at Integra Lifesciences Corporation, Dr. Dispersyn was employed by Barrier Therapeutics, Inc. where he held various roles, including Vice President, Product Development & Portfolio Management. He was also the founder of INGRESS LLC, a consultancy company providing R&D and clinical operations support to start-up companies. He received his Doctorate in Medical Sciences from Maastricht University, Faculty of Medicine (Netherlands), a post-graduate degree in Biomedical Imaging and a Master of Science degree in Biochemistry, both from the University of Antwerp, Belgium.

Robert J. Bitterman has served as a member and the Chairman of our Board of Directors since 2012. Mr. Bitterman founded Cutanea Life Sciences, Inc. in September 2005 as its President, Chief Executive Officer and director. Cutanea Life Sciences, Inc. focuses on the development and commercialization of proprietary technologies to treat diseased and aging skin and was successfully acquired by Maruho Company, LTD. in February 2012, where Mr. Bitterman has continued his role as President and Chief Executive Officer. Prior to his role at Cutanea Life Sciences, Inc., Mr. Bitterman has also held the position of President and Chief Executive Officer of Isolagen, Inc., President and General Manager of Dermik Laboratories and various positions of increasing responsibility in financial and commercial capacities within Aventis S.A. Mr. Bitterman holds an A.B. degree in Economics from The College of the Holy Cross and a Master of Business Administration degree from Boston University. He also holds a Doctor of Humane Letters (Honoris Causa) from the New York College of Podiatric Medicine and is a member of the Philadelphia Business Leaders Network. We believe Mr. Bitterman’s qualifications to serve as a member of our Board of Directors include his experience in executive leadership, in the pharmaceutical industry and in experience in early stage organizations having founded Cutanea Life Sciences, Inc.

Keith L. Brownlie has served as a member of our Board of Directors since 2012. Mr. Brownlie was employed by the accounting firm Ernst & Young LLP from 1974 to 2010. At Ernst & Young, he served as audit partner for numerous public companies and was the Life Sciences Industry Leader for the New York Metro Area. Mr. Brownlie co-founded the New Jersey Entrepreneur of the Year Program and was co-chair of the BIONJ/PABIO Annual Symposium. Since his retirement from Ernst &Young in 2010, Mr. Brownlie currently serves as a director and chairman of the audit committees of Soligenix, Inc. and Celldex Therapeutics, Inc. Mr. Brownlie also previously served as a director and as chairman of the audit committees of Cancer Genetics, Inc. and EpiCept Corporation, which merged with Immune Pharmaceuticals in August 2013. Mr. Brownlie received a B.S. in Accounting from Lehigh University and is a Certified Public Accountant. We believe Mr. Brownlie's qualifications to serve as a member of our Board of Directors include his significant financial expertise, his background in the biotechnology industry and his experience serving as a director of other public companies.

Geert Cauwenbergh, Dr. Med. Sc. has served as a member of our Board of Directors since 2012 and was our Chief Executive Officer from November 2018 to March 2019 and our President and Chief Executive Officer from April 2012 to November 2018. In March 2019, Dr. Cauwenbergh retired from his position as the Company's Chief Executive Officer and remained as a member of our Board of Directors. Dr. Cauwenbergh was appointed to the Board and was elected as President and Chief Executive Officer of the Company in 2012 and in March 2019 retired from his position as the Company's Chief Executive Officer. Prior to joining the Company, Dr. Cauwenbergh was active through his consulting company, Phases 123 LLC, in advising various small biotech and healthcare companies from June 2011 to April 2012. In addition, Dr. Cauwenbergh served as Chairman and Chief Executive Officer of Barrier Therapeutics, Inc., a publicly-traded biopharmaceutical company he founded in 2001 that focused on dermatology drug development, which was acquired by Stiefel Laboratories, Inc. in 2008. Prior to founding Barrier Therapeutics, Inc., Dr. Cauwenbergh was employed by Johnson & Johnson for 23 years where he held a number of ascending senior management positions, including Vice President of Research and Development for Johnson & Johnson's Skin Research Center. He currently serves as a director of Moberg Pharma AB and Cutanea Life Sciences, Inc. In 2005, Dr. Cauwenbergh was inducted into the New Jersey High-Tech Hall of Fame, and, from 2009 to 2010, he served as Chairman of the Board of Trustees of BioNJ. Dr. Cauwenbergh received his Doctorate in Medical Sciences from the Catholic University of Leuven, Faculty of Medicine (Belgium), where he also completed his masters and undergraduate work. We believe Dr. Cauwenbergh's qualifications to serve as a member of our Board of Directors include his extensive experience and knowledge in the biotechnology industry, his leadership background and his experience serving as a director of other biotechnology companies.

H. Paul Dorman has served as a member of our Board of Directors since 2013. Mr. Dorman currently serves as the Chairman and CEO of DFB Pharmaceuticals, a holdings company specializing in investing in and operating pharmaceutical businesses. From 1990 to 2012, Mr. Dorman also served as the Chairman and CEO of DPT Laboratories, a contract manufacturer and developer of pharmaceutical products. Prior to acquiring DPT Laboratories, Mr. Dorman was employed by Johnson & Johnson for 12 years, where he served in various positions, including Vice President and director. Prior to Johnson & Johnson, Mr. Dorman was employed by Baxter-Travenol, a large pharmaceuticals company. Mr. Dorman holds a B.S. degree in Mechanical Engineering from Tulane University and a Juris Doctor of Law from Loyola University. We believe Mr. Dorman's qualifications to serve as a member of our Board of Directors include his extensive experience in executive leadership and business experience in the pharmaceutical industry.

Jonathan E. Freeman, Ph.D. has served has a member of our Board of Directors since 2017. Dr. Freeman is the Chief Operating Officer of Anthos Therapeutics Inc., a clinical stage biopharmaceutical company focused on the commercialization of genetically and pharmacologically validated therapies for high-risk cardiovascular patient populations. Dr. Freeman currently serves as Senior Advisor to Blackstone Life Sciences, a private investment platform with capabilities to invest across the life-cycle of companies and products within the key life science sector. Prior to these roles, Dr. Freeman served as Chief Business Officer of Vedanta Biosciences, a private company pioneering an innovative class of therapies modulating interaction pathways between the human microbe and the host immune system, from 2017 to 2018. Prior to his role with Vedanta Biosciences, Dr. Freeman served as the Senior Vice President, Head of Strategy Development & Portfolio Management at Merck KGaA, a leading science and technology company in healthcare, life science and performance materials, from 2013 to 2016 and Head of Licensing, Global Business Development from 2008 to 2012. Dr. Freeman also was the Director of M&A at Baxter Healthcare from 2005 to 2008, and from 1999 to 2005 was Head of Licensing at Serono. Dr. Freeman holds a First Class Honours in Biochemistry and an M.A. from Cambridge University, a Ph.D. in cancer research from the Imperial Cancer Research Fund (now CRUK) and an MBA with a finance major from Webster, St. Louis. We believe Dr. Freeman's qualifications to serve as a member of our Board of Directors include his executive leadership experience, his experience in large and small biotechnology companies and his scientific background.

Curtis A. Lockshin, Ph.D. has served as a member of our Board of Directors since 2013. Dr. Lockshin currently serves as the Chief Scientific Officer of Xenetic Biosciences, Inc., a biopharmaceutical company focused on developing biologic drugs and novel oncology therapeutics. Prior to his appointment as Chief Scientific Officer, Dr. Lockshin served as the Vice President of Research and Operations from 2014 to 2017. From 2014 to July 2016, Dr. Lockshin served as Chief Executive Officer and director of SciVac Therapeutics, Inc., a company in the business of the development, production and marketing of biological products for human healthcare, and with the company's merger with VBI Vaccines, Inc. in July 2016, Dr. Lockshin served as Chief Technical Officer of the merged company until December 2016. In addition, Dr. Lockshin has served as President and Chief Executive Officer of Guardum Pharmaceuticals, LLC and was previously the Vice President of Corporate R&D Initiatives for OPKO Health, Inc. from October 2011 to February 2013. Dr. Lockshin is a director of the Ruth K. Broad Biomedical Research Foundation, a Duke University Support Corporation that supports basic research related to Alzheimer's disease and neurodegeneration via intramural, extramural and international grants and has previously served as director of ChromaDex, Inc. and Sorrento Therapeutics, Inc. Dr. Lockshin holds a S.B. degree in Life Sciences and a Ph.D. in Biological Chemistry from the Massachusetts Institute of Technology. We believe Dr. Lockshin's qualifications to serve as a member of our Board of Directors include his extensive industry knowledge, bringing critical scientific and research and development expertise to our Board of Directors, and management experience.

Board Leadership Structure and Role in Risk Oversight

The positions of Chairman of the Board of Directors (the "**Board**") and Chief Executive Officer are separated, which allows our Chief Executive Officer to focus on our day-to-day business, while allowing the Chairman of the Board to lead the Board in its fundamental role of providing advice to and independent oversight of management. Our Board recognizes the time, effort and energy that the Chief Executive Officer is required to devote to his position in the current business environment, as well as the commitment required to serve as our Chairman. Our Board also believes that this structure ensures a greater role for the independent directors in the oversight of our Company and active participation of the independent directors in setting agendas and establishing priorities and procedures for the work of our Board. Our Board believes its administration of its risk oversight function has not affected its leadership structure.

While our Bylaws do not require that our Chairman and Chief Executive Officer positions be separate, our Board believes that having separate positions and having an independent outside director serve as Chairman is the appropriate leadership structure for us at this time and demonstrates our commitment to good corporate governance. Our separated Chairman and Chief Executive Officer positions are augmented by our independent Board committees that provide appropriate oversight in the areas described below. At executive sessions of independent directors, these directors speak candidly on any matter of interest, which may be with or without the Chief Executive Officer present. The independent directors meet separately in executive session on at least an annual basis to discuss matters relating to the Company and the Board, without members of the management team present. We believe this structure provides consistent and effective oversight of our management and the Company.

The Board has overall responsibility for the oversight of the Company's risk management process, which is designed to support the achievement of organizational objectives, including strategic objectives, to improve long-term organizational performance and enhance stockholder value. Risk management includes not only understanding company-specific risks and the steps management implements to manage those risks, but also what level of risk is acceptable and appropriate for the Company. Management is responsible for establishing our business strategy, identifying and assessing the related risks and implementing appropriate risk management practices. The Board periodically reviews our business strategy and management's assessment of the related risk, and discusses with management the appropriate level of risk for the Company. The Board also delegates oversight to Board committees to oversee selected elements of risk as set forth below.

Board Committees

Audit Committee

The Audit Committee is composed of Messrs. Brownlie (Chairman) and Dorman and Dr. Freeman. The Audit Committee selects the Company's independent registered public accounting firm, approves its compensation, oversees and evaluates the performance of the independent registered public accounting firm, oversees the accounting and financial reporting policies and internal control systems of the Company, reviews the Company's interim and annual financial statements, independent registered public accounting firm reports and management letters and performs other duties, as specified in the Audit Committee Charter. All members of the Audit Committee satisfy the current independence and experience requirements of Rule 10A-3 of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**") and the current Nasdaq independence standards, and the Board has determined that Mr. Brownlie is an "audit committee financial expert," as the Securities and Exchange Commission (the "**SEC**") has defined that term in Item 407 of Regulation S-K.

Compensation Committee

The Compensation Committee is composed of Messrs. Bitterman (Chairman) and Brownlie and Dr. Lockshin. The Compensation Committee determines compensation levels for the Company's executive officers and directors, oversees administration of the Company's equity compensation plans and performs other duties regarding compensation for employees and consultants as the Board may delegate from time to time. Our Chief Executive Officer makes recommendations to the Compensation Committee regarding the corporate and individual performance goals and objectives relevant to executive compensation and executives' performance in light of such goals and objectives and recommends other executives' compensation levels to the Compensation Committee based on such evaluations. The Compensation Committee considers these recommendations and then makes an independent decision regarding officer compensation levels and awards. All members of the Compensation Committee satisfy the current Nasdaq independence standards, and each member of the Committee qualifies as an "outside director" and "non-employee director" as defined by Section 162(m) of the Code and Rule 16b-3 of the Exchange Act, respectively.

Nominating and Corporate Governance Committee

The Nominating and Corporate Governance Committee is comprised of Drs. Lockshin (Chairman) and Freeman and Messr. Dorman. The Nominating and Governance Committee reviews potential director nominees, recommends nominees to the Board, oversees the Company's corporate governance principles and develops and implements policies and processes regarding corporate governance matters. Drs. Lockshin and Freeman and Messr. Dorman satisfy the current Nasdaq independence standards.

A copy of the Company's Audit, Compensation and Nominating and Corporate Governance Committee charters are available on the Company's website at www.phiopharma.com.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our "officers" (as defined in Rule 16a-1(f) under the Exchange Act) and directors, and persons who own more than 10% of a registered class of our equity securities to file reports of beneficial ownership and changes in beneficial ownership with the SEC. Officers, directors and greater-than-10% stockholders (the "**Reporting Persons**") are required by SEC regulations to furnish us with copies of all reports filed under Section 16(a). Based solely on our review of copies of these reports and representations of such Reporting Persons, we believe that during fiscal year 2018, all Reporting Persons satisfied such applicable SEC filing requirements.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics that applies to all our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. Our Code of Business Conduct and Ethics, as well as other corporate governance materials, is located on our website at www.phiopharma.com. We intend to disclose future amendments to certain provisions of the Code of Business Conduct and Ethics, and waiver of the Code of Business Conduct and Ethics granted to executive officers and directors, on the website within four business days following the date of the amendment or waiver.

ITEM 11. ***EXECUTIVE COMPENSATION***

The following describes the compensation earned in fiscal 2018 and 2017 by each of the executive officers identified below in the Summary Compensation Table, who are referred to collectively as our "named executive officers". Our named executive officers with respect to the fiscal year that ended on December 31, 2018 are Geert Cauwenbergh, Dr. Med. Sc., former Chief Executive Officer and Gerrit Dispersyn, Dr. Med. Sc., current President and Chief Executive Officer. Pursuant to SEC rules, we are providing compensation information for Drs. Pavco and Eliseev because they served as our former Chief Development Officer and former Chief Business Officer, respectively, during the year ended December 31, 2017.

Name and principal position	Year	Salary ($)	Option awards ($)[1]	Stock awards ($)[1]	Non-equity incentive plan compensation ($)[2]	All other compensation ($)[3]	Total ($)
Geert Cauwenbergh, Dr. Med. Sc. [4]	2018	420,366[5]	36,099	37,590	115,775[5]	606	610,436
Former Chief Executive Officer	2017	416,000	5,928	–	156,000[5]	599	578,527
Gerrit Dispersyn, Dr. Med. Sc. [6]	2018	315,558	27,504	28,640	52,800	454	424,956
President and Chief Executive Officer	2017	186,346	44,555	–	44,097	275	275,273
Pamela Pavco, Ph.D. [7]	2018	–	–	–	–	–	–
Former Chief Development Officer	2017	196,471	3,155	–	–	228	199,854
Alexey Eliseev, Ph.D. [8]	2018	–	–	–	–	75,000	75,000
Former Chief Business Officer	2017	215,671	91,028	–	–	75,289	381,988

(1) The amounts shown reflect the grant date fair value of stock options and restricted stock units computed in accordance with Accounting Standards Codification ("**ASC**") 718 for the indicated year, adjusted to disregard the effects of any estimate of forfeitures related to service-based vesting. The assumptions we used in valuing the stock options and restricted stock units are described more fully in the "Management's Discussion and Analysis" section and the notes to the consolidated financial statements for the year ended December 31, 2018.

(2) The amounts shown reflect the annual cash bonus earned for performance for each respective year under the Company's Incentive Bonus Program. The annual cash bonus for fiscal year 2018 was paid in February 2019 and the annual cash bonus for fiscal year 2017 was paid in September 2018.

(3) Represents amounts for the dollar value of life insurance premiums paid, except as noted in footnote 8 below.

(4) Dr. Cauwenbergh became our President and Chief Executive Officer effective April 27, 2012. He retired from the Company on March 1, 2019.

(5) On August 31, 2018 and subsequently amended on December 19, 2018 and February 13, 2019, Dr. Cauwenbergh elected the right to receive, in lieu of cash, for the period from September 15, 2018 to February 28, 2019, up to 50% of his base salary and cash bonuses payable in the form of unvested restricted shares of the Company's common stock with such restricted shares to vest in full on June 1, 2019. Dr. Cauwenbergh received a total of 355,717 shares of restricted stock of the Company in lieu of cash compensation for: a.) $56,673 of base salary for the year ended December 31, 2018, b.) $78,000 of fiscal year 2017 bonus compensation paid in 2018 and c.) $57,887 of fiscal year 2018 bonus compensation paid in February 2019. Refer to footnote 9 in the Company's notes to the consolidated financial statements for the year ended December 31, 2018 for further details related to the restricted stock issued as of December 31, 2018.

(6) Dr. Dispersyn became our Chief Development Officer effective April 24, 2017 and served in this role until November 2018 when he was appointed President and Chief Operating Officer. On March 1, 2019, Dr. Dispersyn was appointed to President and Chief Executive Officer of the Company.

(7) Dr. Pavco became our Chief Development Officer effective September 11, 2011. She retired from the Company on May 19, 2017.

(8) Dr. Eliseev became our Chief Development Officer on January 6, 2017. He left the Company on September 15, 2017. The amount reflected under "All Other Compensation" also includes severance payments made to Dr. Eliseev in connection with his termination consistent with and subject to the conditions set forth in his employment agreement.

Outstanding Equity Awards at Fiscal Year-End

The following table shows information regarding outstanding equity awards as of December 31, 2018 for our named executive officers:

	Option Awards			
Name	**Number of Securities Underlying Unexercised Options Exercisable (#)**	**Number of Securities Underlying Unexercised Options Unexercisable (#)**	**Option Exercise Price ($)**	**Option Expiration Date**
Geert Cauwenbergh, Dr. Med. Sc.[1]	11,386	–	255.00	06/08/2022
	1,334	–	600.00	06/07/2023
	1,331	–	285.00	06/02/2024
	1,165	166	38.00	06/01/2025
	943	388	28.60	02/10/2026
	596	704	6.29	02/01/2027
	–	21,000	1.79	08/01/2028
Gerrit Dispersyn, Dr. Med. Sc.[2]	3,959	5,541	6.50	04/24/2027
	–	16,000	1.79	08/01/2028
Pamela Pavco, Ph.D.[3]	5,582	–	390.00	05/04/2022
	667	–	600.00	06/07/2023
	661	–	285.00	06/02/2024
	579	82	38.00	06/01/2025
	468	193	28.60	02/10/2026
	175	380	6.29	02/01/2027
Alexey Eliseev, Ph.D.	–	–	–	

	Stock Awards			
Name	**Number of Shares or Units of Stock That Have Not Vested (#)**	**Market Value of Shares or Units of Stock That Have Not Vested ($)**	**Equity Incentive Plan Awards: Number of Shares or Units of Stock That Have Not Vested (#)**	**Equity Incentive Plan Awards: Market Value of Shares or Units of Stock That Have Not Vested ($)[4]**
Geert Cauwenbergh, Dr. Med. Sc.[1]	–	–	21,000	6,930
Gerrit Dispersyn, Dr. Med. Sc.[2]	–	–	16,000	5,280

(1) The equity awards granted to Dr. Cauwenbergh prior to 2018 vest as to 25% of the award on the first anniversary of the grant date and as to the remaining 75% of the option in equal monthly installments over a three-year period thereafter. Subsequent to 2018, equity awards granted to Dr. Cauwenbergh vest in equal annual installments over four years. Each option award was granted ten years prior to the option expiration date.

(2) The equity awards granted to Dr. Dispersyn prior to 2018 vest in equal monthly installments over a four years. Subsequent to 2018, equity awards granted to Dr. Dispersyn vest in equal annual installments over four years. Each option award was granted ten years prior to the option expiration date.

(3) The option awards granted to Dr. Pavco vest in equal monthly installments over a four years. So long as Dr. Pavco remains on the Company's Scientific Advisory Board, options granted to her during her employment with the Company will continue to vest after her retirement. Each option award was granted ten years prior to the option expiration date.

(4) Value is based on the Company's common stock closing price of $0.33 on December 31, 2018.

Nonqualified Deferred Compensation Earnings

We do not have any nonqualified deferred compensation plans.

Employment and Change of Control Agreements

Gerrit Dispersyn, Dr. Med. Sc.

Dr. Dispersyn was appointed Chief Development Officer on April 24, 2017 before becoming the Company's President and Chief Operating Officer on November 14, 2018 and the Company's President and Chief Executive Officer on March 1, 2019. As President and Chief Executive Officer, Dr. Dispersyn will be entitled to receive an initial base salary of $380,000 per annum, as well as a performance bonus of up to 30% of his base salary, subject to the achievement of performance goals to be established annually. Dr. Dispersyn is also entitled to a grant by the Company of restricted stock units entitling him to receive shares of common stock equal to 2% of the outstanding shares of the Company's common stock, subject to the Company's stockholders' approving a sufficient increase of shares of common stock that may be offered pursuant to the Company's 2012 Long Term Incentive Plan at the Company's next Annual Meeting. Such restricted stock units will vest in equal annual installments over four years beginning with the effective date of Dr. Dispersyn's appointment as CEO and will become fully vested and exercisable on March 1, 2023. Otherwise, Dr. Dispersyn's April 24, 2017 employment agreement with the Company remains in full force and effect.

Dr. Dispersyn's employment agreement provides that, upon termination of Dr. Dispersyn's employment without "cause" (as defined therein) by us or by Dr. Dispersyn for "good reason" (as defined therein), he will be entitled to payment of: (1) any accrued but unpaid salary and unused vacation as of the date of his termination; (2) six months of salary from the date of termination; and (3) continued participation, at our expense, during the applicable six-month severance period in our sponsored group medical and dental plans. In the event his employment is terminated within twelve months following a "change of control" of the Company, he will be entitled to: (x) twelve months of salary from the date of termination; (y) accelerated vesting of any unvested stock options held by him as to 50% of the unvested option shares or the portion of the unvested option shares that would have vested over the following twenty-four months, whichever is greater; and (z) continued participation, at our expense, during the twelve-month severance period in our sponsored group medical and dental plans.

Geert Cauwenbergh, Dr. Med. Sc.

We previously entered into an employment agreement, dated April 27, 2012, with Dr. Cauwenbergh. He served as the Company's Chief Executive Officer until his retirement on March 1, 2019. Dr. Cauwenbergh was entitled to receive an initial base salary of $360,000 per annum. Pursuant to the employment agreement, he received an option to purchase up to 11,386 shares of common stock at an exercise price equal to the fair value of the underlying common stock on the date of grant. The option vested with respect to one quarter of the underlying shares on April 27, 2012, and then vested on a ratable basis monthly thereafter over the next three years such that the option became fully vested and exercisable on April 27, 2016. No retirement benefits were owed to Dr. Cauwenbergh by the Company upon his retirement.

Pamela Pavco, Ph.D.

We previously entered into an employment agreement, dated September 24, 2011, with Dr. Pavco. She served as the Company's Chief Development Officer until her retirement on May 19, 2017. Dr. Pavco was entitled to receive an initial annual salary of $300,000. Pursuant to the employment agreement, she received an option to purchase up to 5,582 shares of common stock at an exercise price equal to the fair value of the underlying common stock on the date of grant. The option vested in equal monthly installments over four years, beginning on October 24, 2011, such that the option became fully vested and exercisable on September 24, 2015. No retirement benefits were owed to Dr. Pavco by the Company upon her retirement. On May 22, 2017, Dr. Pavco was appointed to our Scientific Advisory Board. So long as she serves in that role, options awarded to her during her employment with the Company will continue to vest according to their terms.

Alexey Eliseev, Ph.D.

We previously entered into an employment agreement, dated January 6, 2017, with Dr. Eliseev. He served as the Company's Chief Business Officer until his termination on September 15, 2017. Dr. Eliseev was entitled to receive an initial salary of $300,000. Pursuant to the employment agreement, he received an option to purchase 17,439 shares of common stock at an exercise price equal to the fair value of the underlying common stock on the date of grant. The option was to vest in equal monthly installments over four years beginning on February 6, 2017, provided, in each case, that Dr. Eliseev remained in our continuous employ through such vesting date.

The employment agreement provided that if we were to terminate Dr. Eliseev's employment without "cause" (as defined in the employment agreement), he would be entitled to payment of (1) any accrued but unpaid salary and unused vacation as of the date of his termination; (2) six months of salary from the date of terminations; and (3) continued participation, at our expense, during the applicable six-month severance period in our sponsored group medical and dental plans. Effective September 15, 2017, Dr. Eliseev's employment with the Company ended and was treated as a termination without "cause". Dr. Eliseev received severance benefits totaling $150,000 consistent with and subject to the conditions set forth in the employment agreement.

Director Compensation

The following table shows the compensation paid in fiscal year 2018 to the Company's non-employee directors:

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)[1][2]	Total ($)
Robert J. Bitterman	35,000	17,900	52,900
Keith L. Brownlie	35,000	17,900	52,900
H. Paul Dorman	25,000	17,900	42,900
Jonathan E. Freeman, Ph.D.	25,000	17,900	42,900
Curtis A. Lockshin, Ph.D.	30,000	17,900	47,900

(1) The amounts shown reflect the grant date fair value computed in accordance with ASC 718 for the indicated year, adjusted to disregard the effects of any estimate of forfeitures related to service-based vesting. The assumptions we used in valuing the restricted stock units granted are described more fully in the "Management's Discussion and Analysis" section and the notes to the consolidated financial statements for the year ended December 31, 2018.

(2) As of December 31, 2018, the aggregate number of shares underlying stock options and restricted stock units by our non-employee directors is as follows: Robert J. Bitterman — 1,202 option awards and 10,000 restricted stock units, Keith L. Brownlie — 1,202 option awards and 10,000 restricted stock units, H. Paul Dorman — 1,035 option awards and 10,000 restricted stock units, Jonathan E. Freeman, Ph.D. — 350 option awards and 10,000 restricted stock units and Curtis A. Lockshin, Ph.D. — 1,035 option awards and 10,000 restricted stock units.

We compensate our non-employee directors for their service as a member of our Board. As our only director who was also an employee during the year ended December 31, 2018, Dr. Cauwenbergh received no separate compensation for Board service. Dr. Cauwenbergh's compensation is set forth above in the Summary Compensation Table.

Each non-employee director is entitled to receive an annual cash retainer of $25,000. The chairs of our Board and Audit Committee are entitled to receive an additional annual cash retainer of $10,000 and the chair of the Nominating and Corporate Governance Committee is entitled to receive an additional annual cash retainer of $5,000.

Each non-employee director is entitled to receive an annual restricted stock unit award for 10,000 shares of the Company's common stock, vesting annually over one year.

Non-employee directors are also reimbursed for their travel and reasonable out-of-pocket expenses incurred in connection with attending Board and committee meetings and in attending continuing education seminars, to the extent that attendance is required by the Board or the committee(s) on which that director serves.

The Compensation Committee and the Board reassess the appropriate level of equity compensation for non-employee directors on an annual basis. Future equity compensation payments will be determined on a year-by-year basis for the foreseeable future due to the volatility of the Company's stock price.

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

Securities Authorized for Issuance Under Equity Compensation Plans

The following table sets forth certain information, as of December 31, 2018, about the securities authorized for issuance under our equity compensation plans, which consisted of our 2012 Long Term Incentive Plan and our 2013 Employee Stock Purchase Plan:

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in First Column)
Equity compensation plans approved by security holders	279,177	$ 34.52	470,803
Equity compensation plans not approved by security holders	–	–	–
Total	279,177	$ 34.52	470,803

Beneficial Ownership

Based on information available to us and filings with the Securities and Exchange Commission ("**SEC**"), the following table sets forth certain information regarding the beneficial ownership (as defined by Rule 13d-3 under the Exchange Act) of our outstanding common stock for (i) each of our directors, (ii) each of our "named executive officers," as defined in the Executive Compensation section above, (iii) all of our directors and executive officers as a group and (iv) persons known to us to beneficially own more than 5% of our outstanding common stock. The following information is presented as of March 1, 2019 or such other date as may be reflected below.

Beneficial ownership and percentage ownership are determined in accordance with the rules of the SEC and include voting or investment power with respect to shares of stock. This information does not necessarily indicate beneficial ownership for any other purpose. Under these rules, shares of common stock issuable under stock options or warrants that are exercisable within 60 days of March 1, 2019 are deemed outstanding for the purpose of computing the percentage ownership of the person holding the options or warrants, but are not deemed outstanding for the purpose of computing the percentage ownership of any other person.

Unless otherwise indicated and subject to applicable community property laws, to our knowledge, each stockholder named in the following table possesses sole voting and investment power over their shares of common stock, except for those jointly owned with that person's spouse. Unless otherwise indicated below, the address of each person listed on the table is c/o Phio Pharmaceuticals Corp., 257 Simarano Drive, Suite 101, Marlborough, MA 01752.

Name and Address of Beneficial Owner	Shares Beneficially Owned	
	Number [1]	Percent of Class[2]
Greater than 5% Holders		
CVI Investments, Inc.[3] P.O. Box 309GT Ugland House South Church Street George Town, Grand Cayman KY1-1104 Cayman Islands	1,998,801	9.90%
Sabby Volatility Warrant Master Fund, Ltd.[4] c/o Ogier Fiduciary Services (Cayman) Limited 89 Nexus Way, Camana Bay Grand Cayman KY1-9007 Cayman Islands	1,814,619	9.99%
Directors, Director Nominees, Officers and Named Executive Officers:		
Gerrit Dispersyn, Dr. Med. Sc. [5]	5,100	*
Robert J. Bitterman[6]	1,830	*
Keith L. Brownlie[7]	1,202	*
Geert Cauwenbergh, Dr. Med. Sc.[8]	502,862	2.41%
H. Paul Dorman[9]	1,598	*
Jonathan E. Freeman, Ph.D. [10]	350	*
Curtis A. Lockshin, Ph.D.[11]	1,225	*
All current directors and executive officers as a group (seven persons)	514,167	2.46%

* Indicates less than 1%.

(1) Represents shares of common stock and shares of restricted stock held as of March 1, 2019 plus shares of common stock that may be acquired upon exercise of options, warrants and other securities exercisable or convertible within 60 days of March 1, 2019.

(2) Based on 20,879,132 shares of common stock that were issued and outstanding as of March 1, 2019. The percentage ownership and voting power for each person (or all directors and executive officers as a group) is calculated by assuming the exercise or conversion of all options, warrants and convertible securities exercisable or convertible within 60 days of March 1, 2019 held by such person and the non-exercise and non-conversion of all outstanding warrants, options and convertible securities held by all other persons.

(3) Based solely on information set forth in a Schedule 13G filed with the SEC on February 14, 2019.

(4) Based solely on information set forth in a Schedule 13G filed with the SEC on January 4, 2019.

(5) Consists of (a) 350 shares of common stock and (b) 4,750 shares of common stock issuable upon the exercise of options within 60 days of March 1, 2019.

(6) Consists of (a) 440 shares of common stock and (b) 1,202 shares of common stock issuable upon the exercise of options and 188 shares of common stock issuable upon the exercise of warrants exercisable within 60 days of March 1, 2019.

(7) Consists of 1,202 shares of common stock issuable upon the exercise of options exercisable within 60 days of March 1, 2019.

(8) Consists of (a) 482,042 shares of common stock and (b) 17,086 shares of common stock issuable upon the exercise of options and 3,734 shares of common stock issuable upon the exercise of warrants exercisable within 60 days of March 1, 2019.

(9) Consists of (a) 375 shares of common stock and (b) 1,035 shares of common stock issuable upon the exercise of options and 188 shares of common stock issuable upon the exercise of warrants exercisable within 60 days of March 1, 2019.

(10) Consists of 350 shares of common stock issuable upon the exercise of options exercisable within 60 days of March 1, 2019.

(11) Consists of (a) 130 shares of common stock and (b) 1,035 shares of common stock issuable upon the exercise of options and 60 shares of common stock issuable upon the exercise of warrants exercisable within 60 days of March 1, 2019.

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

Since the past two years, there has not been, nor is there currently proposed, any transaction or series of related transactions to which we were or will be a party in which the amount involved exceeded or will exceed $120,000 and in which the other parties included or will include any of our directors, executive officers, holders of 5% or more of our voting securities, or any member of the immediate family of any of the foregoing persons, other than compensation arrangements with directors and executive officers, which are described where required in "Directors, Executive Officers and Corporate Governance," "Executive Compensation," and the transactions described below.

Procedures for Review, Approval or Ratification of Transactions with Related Persons

Our Board of Directors has a policy to review and approve all transactions with directors, officers and holders of more than 5% of our voting securities and their affiliates. These policies and procedures are generally not in writing, but are evidenced by longstanding principles adhered to by our Board. The policy provides that, prior to Board of Director consideration of a transaction with such a related party, the material facts as to the related party's relationship or interest in the transaction must be disclosed to the Board of Directors, and the transaction will not be considered approved by the Board of Directors unless a majority of the directors who are not interested in the transaction (if applicable) approve the transaction. Furthermore, when stockholders are entitled to vote on a transaction with a related party, the material facts of the related party's relationship or interest in the transaction must be disclosed to the stockholders, who must approve the transaction in good faith.

Indemnification Agreements

We have entered into indemnification agreements with each of our executive officers and directors. These agreements provide that, subject to limited exceptions and among other things, we will indemnify each of our executive officers and directors to the fullest extent permitted by law and advance expenses to each indemnitee in connection with any proceeding in which a right to indemnification is available.

Stock Purchase Agreement

On January 6, 2017, the Company entered into a Stock Purchase Agreement (the "**Stock Purchase Agreement**") by and among the Company, Phio Merger Sub, LLC, a Delaware limited liability company and wholly owned subsidiary of the Company, MirImmune Inc., a Delaware corporation ("**MirImmune**"), the stockholders of MirImmune as set forth on the signature pages thereto (each a "**Seller**" and collectively, the "**Sellers**"), and Alexey Wolfson, Ph.D., in his capacity as the Sellers' Representative. Pursuant to the Stock Purchase Agreement, the Company acquired from the Sellers 100% of the issued and outstanding shares of capital stock of MirImmune for an aggregate of 275,036 shares of the Company's common stock and an aggregate of 1,118,224 shares of Series C Convertible Preferred Stock, par value $0.0001 per share (the "**Series C Convertible Preferred Stock**"). Such consideration represented in the aggregate a number of shares of capital stock equal to approximately 19.99% of the outstanding common stock immediately prior to the execution of the Stock Purchase Agreement, plus approximately 19.99% of the common stock underlying the Company's outstanding Series B Convertible Preferred Stock, par value $0.0001 per share (the "**Series B Convertible Preferred Stock**"), immediately prior to the execution of the Stock Purchase Agreement, which were previously issued in the Company's registered securities offering pursuant to a registration statement on Form S-1 (File No. 333-214199) (the "**Financing**"). On June 9, 2017, with the approval of the Company's stockholders in accordance with the stockholder approval requirements of Nasdaq Marketplace Rule 5635, every ten shares of the Company's Series C Convertible Preferred Stock outstanding were automatically converted into one share of common stock, such that no shares of Series C Convertible Preferred Stock remained issued or outstanding.

Under the terms of the Stock Purchase Agreement, if certain development or commercial milestones (the "**Milestones**") are achieved within two years of the Closing (as defined therein), the Company will be required to either: (i) issue to the Sellers a number of shares of common stock (the "**Milestone Shares**") equal to the sum of 251,909 shares of common stock (which represents 13% of the outstanding common stock and 13% of the common stock underlying the shares of Series B Convertible Preferred Stock, in each case as of immediately following the closing of the Financing), plus an additional number of shares of common stock equal to 13% of the common stock issued upon exercise of any warrants issued under the Financing, which would result in the issuance of a maximum of 166,111 additional shares of common stock, but only to the extent that such warrants have been exercised prior to the Milestones being achieved; or (ii) pay the equivalent value of the Milestone Shares in cash to the Sellers, subject to certain adjustments set forth in the Stock Purchase Agreement. The Company received shareholder approval in accordance with Rule 5635 of the Nasdaq Marketplace Rules at its 2017 Annual Meeting of Stockholders to issue the Milestone Shares, if necessary. As of January 9, 2019, two years from the Closing, the Company did not achieve the Milestones as defined in the Securities Purchase Agreement.

Pursuant to the Stock Purchase Agreement, we issued 81,781 shares of common stock and 332,499 shares of Series C Convertible Preferred Stock, which upon stockholder approval were converted into 33,249 shares of common stock, to Alexey Eliseev, Ph.D., a Seller in the agreement and co-founder of MirImmune. Dr. Eliseev was appointed the Chief Business Officer of the Company following the Company's acquisition of MirImmune until his termination on September 15, 2017. The approximate dollar value of such shares was equal to $0.8 million. As the Company did not achieve the Milestones within two years of the Closing, Dr. Eliseev is not eligible to receive Milestone Shares. In connection with the Stock Purchase Agreement Dr. Eliseev also executed and delivered a three-year non-compete agreement with the Company under which Dr. Eliseev agreed to not interfere with the Company's business or solicit the Company's employees or business contacts.

Director Independence

We believe that the Company benefits from having a strong and independent Board. For a director to be considered independent, the Board must determine that the director does not have any direct or indirect material relationship with the Company that would affect his or her exercise of independent judgment. On an annual basis, the Board reviews the independence of all directors under the applicable Nasdaq listing standards. The Company also considers each director's affiliations with the Company and members of management, as well as significant holdings of Company securities. This review considers all known relevant facts and circumstances in making an independence determination. Based on this review, the Board of Directors has made an affirmative determination that all directors, other than Dr. Cauwenbergh, are independent. It was determined that Dr. Cauwenbergh lacks independence because of his status as the Company's former Chief Executive Officer.

In addition, Nasdaq listing standards require that, subject to specified exceptions, each member of our Audit, Compensation and Nominating and Corporate Governance Committees be independent and that our Audit Committee members also satisfy independence criteria set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as amended.

For additional information regarding director independence and committee memberships, see "Item 10—Directors, Executive Officers and Corporate Governance".

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

The following is a summary of the fees billed to the Company by BDO USA, LLP for professional services rendered for the fiscal years ended December 31, 2018 and 2017. These fees are for work invoiced in the fiscal years indicated.

	2018	2017
Audit Fees:		
Consists of fees billed for professional services rendered for the audit of the Company's annual financial statements and the review of the interim financial statements included in the Company's quarterly reports (together, the "**Financial Statements**") and for services normally provided in connection with statutory and regulatory filings or engagements	$ 243,197	$ 255,664
Other Fees:		
Audit-Related Fees		
Consists of fees billed for assurance and related services reasonably related to the performance of the annual audit or review of the Financial Statements	–	–
Tax Fees		
Consists of fees billed for tax compliance, tax advice and tax planning	–	–
All Other Fees		
Consists of fees billed for other products and services not described above, which consisted of fees relating to: accounting policy and auditor consent	–	–
Total Other Fees	–	–
Total All Fees:	$ 243,197	$ 255,664

The Audit Committee reviews and pre-approves all audit and non-audit services performed by its independent registered public accounting firm, as well as the fees charged for such services. All fees incurred in fiscal years 2018 and 2017 for services rendered by BDO USA, LLP were approved in accordance with these policies. In its review of non-audit service fees, the Audit Committee considers, among other things, the possible impact of the performance of such services on the auditor's independence.

PART IV

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

Financial Statements

Our consolidated 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

Exhibit Number	Description	Incorporated by Reference Herein Form	Date
2.1	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)	May 15, 2013
2.2	Stock Purchase Agreement, dated January 6, 2017, by and among RXi Pharmaceuticals Corporation, RXi Merger Sub, LLC, MirImmune Inc., certain shareholders named therein and Alexey Wolfson, Ph.D., in his capacity as Sellers' Representative.	Current Report on Form 8-K (File No. 001-36304)	January 10, 2017
3.1	Amended and Restated Certificate of Incorporation of Phio Pharmaceuticals Corp.	Current Report on Form 8-K (File No. 001-36304)	November 19, 2018
3.2	Amended and Restated Bylaws of Phio Pharmaceutical Corp.	Current Report on Form 8-K (File No. 001-36304)	November 19, 2018
4.1	Form of Warrant.	Amendment No. 1 to the Registration Statement on Form S-1 (File No. 333-203389)	May 21, 2015
4.2	Form of Warrant.	Amendment No. 3 to the Registration Statement on Form S-1 (File No. 333-214199)	December 14, 2016
4.3	Form of Warrant	Current Report on Form 8-K (File No. 001-36304)	April 11, 2018
4.4	Form of Placement Agent Warrant	Current Report on Form 8-K (File No. 001-36304)	April 11, 2018
4.5	Form of Warrant	Amendment No. 1 to the Registration Statement on Form S-1 (File No. 333-221173)	September 28, 2018

4.6	Form of Pre-Funded Warrant	Amendment No. 1 to the Registration Statement on Form S-1 (File No. 333-221173)	September 28, 2018
10.1	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
10.2	RXi Pharmaceuticals Corporation 2012 Long Term Incentive Plan.*	Registration Statement on Form S-8 (File No. 333-177498)	August 24, 2018
10.3	Form of Restricted Stock Unit Award under the Company's 2012 Long Term Incentive Plan.*	Amendment No. 2 to the Registration Statement on Form S-1 (File No. 333-177498)	December 29, 2011
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	RXi Pharmaceuticals Corporation Employee Stock Purchase Plan.*	Registration Statement on Form S-8 (File No. 333-277013)	August 24, 2018
10.7	Form of Indemnification Agreement.*	Amendment No. 3 to the Registration Statement on Form S-1 (File No. 333-177498)	January 23, 2012
10.8	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
10.9	Employment Agreement, dated January 6, 2017, between RXi Pharmaceuticals Corporation and Alexey Eliseev, Ph.D.*	Annual Report on Form 10-K (File No. 001-36304)	March 30, 2017
10.10	Non-Competition Agreement, dated January 6, 2017, between RXi Pharmaceuticals Corporation and Alexey Eliseev, Ph.D.*	Annual Report on Form 10-K (File No. 001-36304)	March 30, 2017
10.11	Employment Agreement, dated April 24, 2017, between RXi Pharmaceuticals Corporation and Gerrit Dispersyn, Dr. Med. Sc.*	Post-effective Amendment No. 1 to the Registration Statement on Form S-1 (File No. 333-214199)	May 4, 2017
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	First Amendment to Lease dated January 22, 2019	Current Report on Form 8-K (File No. 001-36304)	January 28, 2019
10.14	Registration Rights Agreement, dated August 8, 2017, between RXi Pharmaceuticals Corporation and Lincoln Park Capital Fund, LLC.	Current Report on Form 8-K (File No. 001-36304)	August 9, 2017

10.15	Purchase Agreement, dated August 8, 2017, between RXi Pharmaceuticals Corporation and Lincoln Park Capital Fund, LLC.	Registration Statement on Form S-1 (File No. 333-220062)	August 18, 2017
10.16	Securities Purchase Agreement, dated April 9, 2018, by and between the Company and the Purchasers therein.	Current Report on Form 8-K (File No. 001-36304)	April 11, 2018
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, 2017, formatted in XBRL (eXtensible Business Reporting Language): (1) Consolidated Balance Sheets as of December 31, 2017 and 2016; (2) Consolidated Statements of Operations for the years ended December 31, 2017 and 2016; (3) Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity for the years ended December 31, 2017 and 2016; (4) Consolidated Statements of Cash Flows for the years ended December 31, 2017 and 2016; and (4) Notes to Consolidated 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.

ITEM 16. ***FORM 10-K SUMMARY***

None.

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.

PHIO PHARMACEUTICALS CORP.

By: /s/ Gerrit Dispersyn

Gerrit Dispersyn, Dr. Med. Sc.
President and Chief Executive Officer

Date: March 27, 2019

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.

Signatures	Title	Date
/s/ Gerrit Dispersyn Gerrit Dispersyn, Dr. Med. Sc.	President and Chief Executive Officer (Principal Executive Officer and Principal Financial Officer)	March 27, 2019
/s/ Caitlin Kontulis Caitlin Kontulis	Vice President of Finance and Administration and Secretary (Principal Accounting Officer)	March 27, 2019
/s/ Robert J. Bitterman Robert J. Bitterman	Director	March 27, 2019
/s/ Keith L. Brownlie Keith L. Brownlie	Director	March 27, 2019
/s/ Geert Cauwenbergh Geert Cauwenbergh, Dr. Med. Sc.	Director	March 27, 2019
/s/ H. Paul Dorman H. Paul Dorman	Director	March 27, 2019
/s/ Jonathan E. Freeman Jonathan E. Freeman, Ph.D.	Director	March 27, 2019
/s/ Curtis A. Lockshin Curtis A. Lockshin, Ph.D.	Director	March 27, 2019

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

Phio Pharmaceuticals Corp.
Marlborough, Massachusetts

We hereby consent to the incorporation by reference in the Registration Statement on Forms S-8 (Nos. 333-183633, 333-189521, 333-189522, 333-215870 and 333-215871) of Phio Pharmaceuticals Corp. of our report dated March 27, 2019, relating to the consolidated financial statements, which appears in this Form 10-K.

/s/ BDO USA, LLP

Boston, Massachusetts
March 27, 2019

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Gerrit Dispersyn, certify that:

1. I have reviewed this Annual Report on Form 10-K of Phio Pharmaceuticals Corp. for the year ended December 31, 2018;

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

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

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

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

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

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

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

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

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

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

Dated: March 27, 2019

/s/ Gerrit Dispersyn

Gerrit Dispersyn, Dr. Med. Sec.
President and Chief Executive Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Phio Pharmaceuticals Corp. (the "Company") on Form 10-K for the period ended December 31, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

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

2. The information contained in the Report fairly presents, in all material respects, the Company's financial condition and result of operations.

/s/ Gerrit Dispersyn

Gerrit Dispersyn, Dr. Med. Sec.
President and Chief Executive Officer

Dated: March 27, 2019