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, 2019

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 of securities:	Trading Symbol(s):	Name of exchange on which registered:
Common Stock, par value $0.0001	PHIO	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 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 registrant's common stock, $0.0001 par value per share ("Common Stock"), held by non-affiliates of the registrant, based on the closing sale price of the registrant's Common Stock on June 28, 2019, was $9,357,037. Shares of Common Stock held by each officer and director and by each person who is known to own 10% or more of the outstanding Common Stock have been excluded in that such persons may be deemed to be affiliates of the registrant. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 20, 2020, the registrant had 2,867,851 shares of Common Stock, par value $0.0001, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

TABLE OF CONTENTS

PHIO PHARMACEUTICALS CORP.
ANNUAL REPORT ON FORM 10-K
For the Fiscal Year Ended December 31, 2019

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K 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,” “would,” “should,” “potential,” “designed to,” “will,” “ongoing,” “estimate,” “forecast,” “predict,” “could,” 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. Risks that could cause actual results to vary from expected results expressed in our forward-looking statements include, but are not limited to:

- our business and operations may be materially and adversely affected by the recent coronavirus outbreak;
- our product candidates are in an early stage of development and may fail or experience significant delays or may never advance to the clinic, which may materially and adversely impact our business;
- we are dependent on collaboration partners for the successful development of our adoptive cell therapy product candidates;
- the approach we are taking to discover and develop novel therapeutics using RNAi may never lead to marketable products;
- a number of different factors could prevent us from advancing into clinical development, obtaining regulatory approval, and ultimately commercializing our product candidates on a timely basis, or at all;
- the FDA could impose a unique regulatory regime for our therapeutics;
- 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;
- we are subject to significant competition and may not be able to compete successfully;
- 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;
- 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; and
- the price of our common stock has been and may continue to be volatile.

Our actual results and financial condition may differ materially from those indicated in the forward-looking statements as a result of the foregoing factors, including those identified in this Annual Report on Form 10-K under the heading Risk Factors,” for the reasons described elsewhere in this Annual Report on Form 10-K and in other filings Phio Pharmaceuticals Corp. periodically makes with the Securities and Exchange Commission. Therefore, you should not rely unduly 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

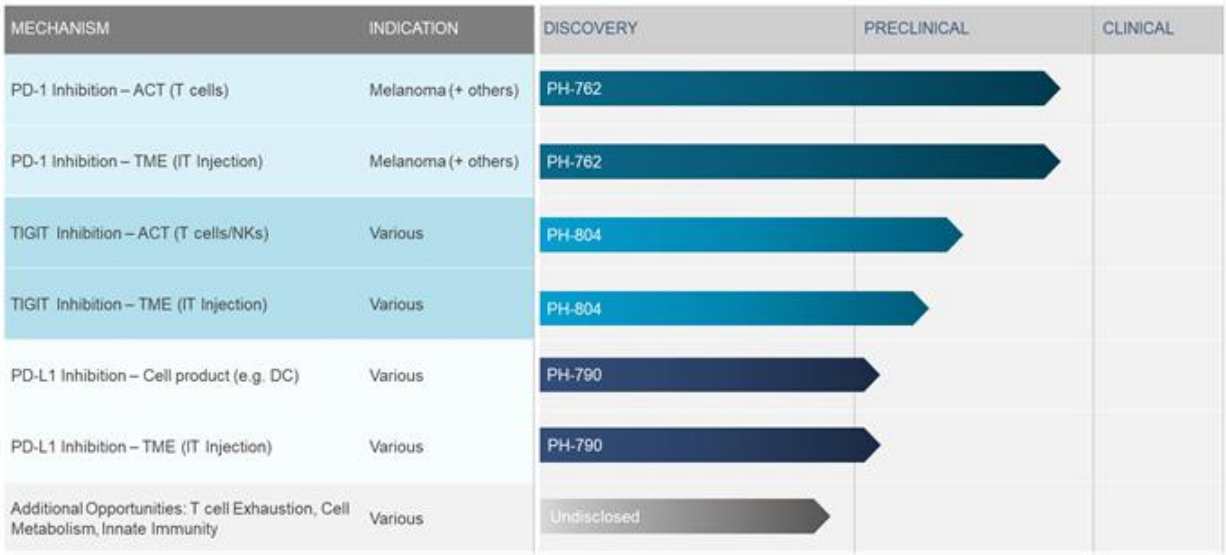
Phio Pharmaceuticals Corp. is a biotechnology company developing the next generation of immuno-oncology therapeutics based on our self-delivering RNAi ("**INTASYL™**") therapeutic platform. The Company's efforts are focused on silencing tumor-induced suppression of the immune system through our proprietary INTASYL™ platform with utility in immune cells and/or the tumor micro-environment. Our goal is to develop powerful INTASYL™ therapeutic compounds that can weaponize immune effector cells to overcome tumor immune escape, thereby providing patients a powerful new treatment option that goes beyond current treatment modalities.

Our development efforts are based on our broadly patented INTASYL™ technology platform. Our INTASYL™ 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 which is over-expressed in cancer. We believe that our INTASYL™ platform uniquely positions the Company in the field of immuno-oncology because of this and the following reasons:

- Efficient uptake of INTASYL™ to immune cells obviating the need for facilitated delivery (mechanical or formulation);
- Can target multiple genes (i.e. multiple immunosuppression pathways) in a single therapeutic entity;
- Gene silencing by INTASYL™ has been shown to have a sustained, or long-term, effect *in vivo*;
- Favorable clinical safety profile of INTASYL™ with local administration; and
- Can be readily manufactured under current good manufacturing practices.

Our Development Pipeline

The table below sets forth the Company's stage of development for its programs and product candidates:



The self-delivering nature of our compounds makes INTASYL™ ideally suited for use with adoptive cell transfer ("**ACT**") treatments and direct therapeutic use. ACT consists of the infusion of immune cells with antitumor properties. These cells can be derived from unmodified (i.e. naturally occurring) immune cells, immune cells isolated from resected tumors, or genetically engineered immune cells recognizing tumor neoantigen/neoepitope cells.

Currently, ACT therapies for the treatment of solid tumors face several hurdles. Multiple inhibitory mechanisms restrain immune cells used in ACT from effectively eradicating tumors, including immune checkpoints, reduced cell fitness and cell persistence. Furthermore, the immunosuppressive tumor micro-environment (the "**TME**") can pose a formidable barrier to immune cell infiltration and function.

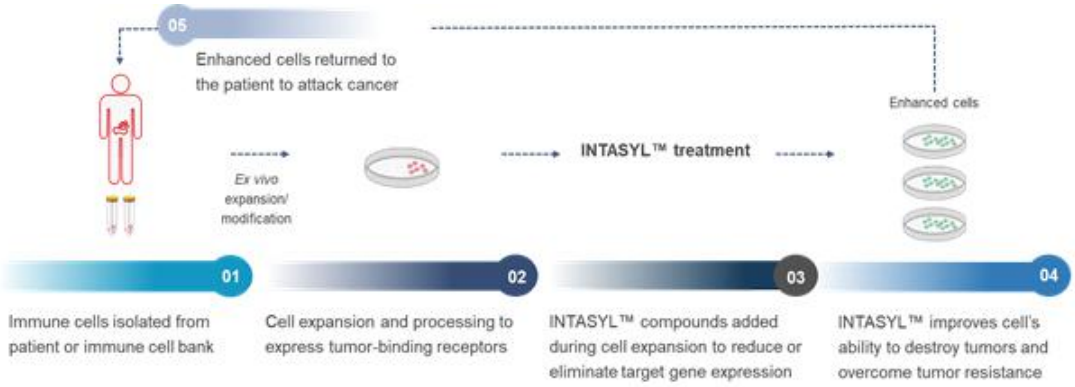
Phio has developed a product platform based on our INTASYL™ technology that allows easy, precise, rapid, and selective non-genetically modified programming of ACT cells (*ex vivo*, during manufacturing) and of the TME (*in vivo*, by local application), resulting in improved immunotherapy.

Adoptive Cell Transfer

ACT includes a number of different types of immunotherapy treatments. These treatments use immune 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 tumor infiltrating lymphocytes ("**TILs**"), or from donor blood or tissue such as natural killer ("**NK**") cells, dendritic cells ("**DC**") and macrophages, and b.) engineered immune cells that are genetically modified to recognize specific tumor proteins and to remain in an activated state (such as T cell receptor technology ("**TCRs**"), chimeric antigen receptor ("**CAR**") T cells, or CAR-NK cells).

In ACT, immune cells are isolated from patients, donors or retrieved from allogeneic immune cell banks. The immune cells are then expanded and modified before being returned and used to treat the patient. We believe our INTASYL™ compounds are ideally suited to be used in combination with ACT, in order to make these immune cells more effective.

Our approach to immunotherapy builds on well-established methodologies of ACT and involves the treatment of immune cells with our INTASYL™ compounds while they are grown in the lab and before administering them to the patient. Because our INTASYL™ compounds do not require a delivery vehicle to penetrate into the cells, we are able to enhance the function of these cells (for example, by inhibiting the expression of immune checkpoint genes) by merely adding our INTASYL™ 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 INTASYL™ technology to reduce or eliminate the expression of genes that make the immune cells less effective. For example, with our INTASYL™ 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, INTASYL™ treatment results in potent silencing while maintaining close to 100% transfection efficiency and nearly full cell viability.

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 used in ACT, such as with INTASYL™ technology, is of key interest now in the current immuno-oncology world. In comparison to other technologies available, reprogramming cells with INTASYL™ does not require genetic engineering, its use is not limited to specific cell types and can be easily integrated with cell manufacturing approaches.

We currently have two product candidates that are being developed for use in ACT, PH-762 and PH-804. PH-762, our most advanced program and lead pipeline compound, targets the checkpoint protein PD-1, a checkpoint protein on immune cells. PD-1 normally acts as a type of “off switch” that helps keep the T cells from attacking other cells in the body. T cells are immune cells that protect the body from cancer cells and are important for the activation of immune cells to fight infection. Our second pipeline compound, PH-804, targets the suppressive immune receptor TIGIT, which is a checkpoint protein present on T cells and NK cells.

Data developed in-house and with our collaborators, which include both leading academic centers and corporate institutions, has shown that PH-762 can elicit PD-1 checkpoint blockade by silencing PD-1 receptor expression resulting in enhanced T cell activation and tumor cytotoxicity. We have also shown with studies completed with our collaborators that PH-804 can silence the expression of TIGIT in NK cells and T cells, overcoming their exhaustion and thereby becoming “weaponized.”

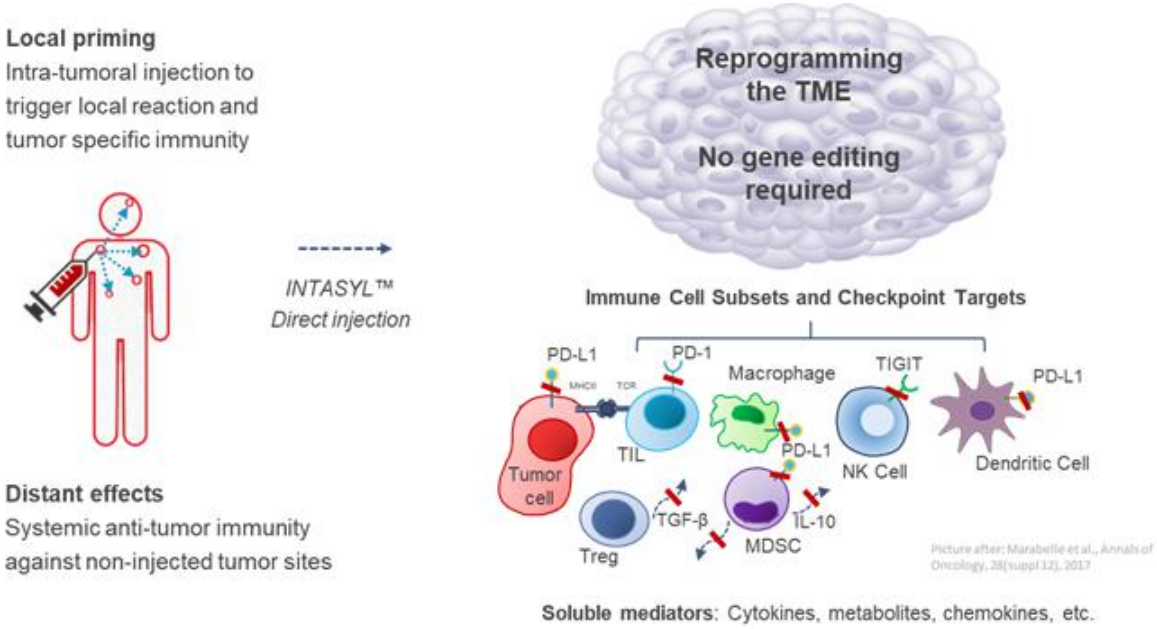
Recent data shown by the Company as well as with our collaborators, Iovance Biotherapeutics, Inc. and the Karolinska Institutet, at the 2019 Society for Immunotherapy of Cancer annual meeting further supports the application of INTASYL™ technology in immunotherapy of cancer. PH-762 has shown to silence the expression of checkpoint molecule PD-1 in target human T cells in a potent and durable manner suitable for both ACT and intra-tumoral injection, and increases function of patient derived TILs for ACT. The application of INTASYL™ compounds to novel immuno-oncology targets was shown by the silencing of BRD4, a regulator of gene expression impacting cell differentiation and function, by a BRD4 targeting INTASYL™ compound in human T cells during expansion for ACT, which has the potential to confer superior anti-tumor activity.

We expect that PH-762 can be ready to enter into the clinic with a partner in ACT therapy in the second half of 2020 and we are developing PH-804 with the aim to enter the clinic with a partner in ACT in 2021.

Tumor Micro-Environment

The TME is the environment that surrounds and feeds a tumor, including normal cells, blood vessels, immune cells and the extracellular matrix. A tumor can change the microenvironment and the microenvironment can affect how a tumor grows and spreads and can create an immunosuppressive microenvironment that inhibits the immune system’s natural ability to recognize and destroy tumor cells. This attracts immunosuppressive cells, induces and activates immune checkpoint expression and excludes and exhausts T cells. Reprogramming different components of the TME may overcome its resistance to immunotherapy.

Such reprogramming of the TME by INTASYL™ compounds through direct local administration into the tumor, could potentially become an important form of (neo)adjuvant therapy. We believe that this will also show that our contributions with our INTASYL™ compounds in immuno-oncology are not limited to use with a cell therapy platform. Additionally, the Company has shown in a clinical setting that its INTASYL™ compounds are safe and well-tolerated following local administration.



Our INTASYL™ compounds being developed for use in ACT, are also being developed for use directly towards the TME, including PH-762 and PH-804. We are also working on other relevant compounds for TME targets, such as PH-790, an INTASYL™ compound targeting PD-L1. PD-L1 is a protein that keeps immune cells from attacking nonharmful cells in the body. If cancer cells have large amounts of PD-L1, this “tricks” the immune system into not recognizing and attacking the tumor. Our approach with PH-790 is to block the PD-L1 protein, which may prevent cancer cells from inactivating T cells and attack the cancer.

Our collaborative research agreement with Gustave Roussy, a leading comprehensive cancer center in France, concentrates on determining the feasibility of our INTASYL™ platform to target the TME via intra-tumoral injection. An *in vivo* study completed with Gustave Roussy demonstrated that an INTASYL™ compound delivered via intra-tumoral injection showed silencing of gene expression with our INTASYL™ compounds with greater than 90% reduction of the target gene expression in a mouse model of melanoma.

Recent *in vivo* studies performed by the Company showed that intra-tumoral injections of a mouse version of PH-804 reduced the tumor growth in colorectal carcinoma tumor bearing mice, which was shown to be correlated with the silencing of TIGIT messenger RNA (“**mRNA**”) expression and an increase in cytotoxic effector T cells in the TME.

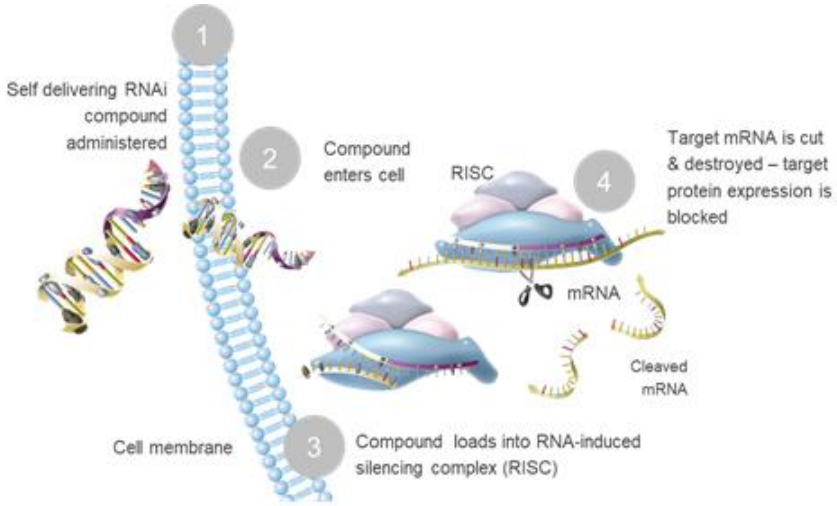
The Company expects to move PH-762 for intra-tumoral injection into the clinical development stage in 2021.

Our INTASYL™ 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 INTASYL™.

Our INTASYL™ compounds 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, INTASYL™ compounds 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 INTASYL™ compounds to achieve efficient spontaneous cellular uptake and potent, long-lasting intracellular activity.



We believe that our next generation INTASYL™ 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;
- Ability 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 INTASYL™ 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 INTASYL™ compounds are optimized for stability and efficacy and have unique properties that improve tissue and cell uptake.

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. A combined summary of these patents and patent applications is set forth below in the following table:

	Pending Applications	Issued Patents
United States	24	41
Canada	10	4
Europe	14	45
Japan	12	13
Other Markets	16	9

Our portfolio includes 112 issued patents, 45 of which cover our INTASYL™ 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 INTASYL™ compounds targeting immune checkpoint, cellular differentiation and metabolism targets for *ex vivo* cell-based cancer immunotherapies. These patents are scheduled to expire between 2029 and 2038. Furthermore, there are 71 patent applications, encompassing what we believe to be important new RNAi compounds and their use as therapeutics, chemical modifications of RNAi compounds that improve the compounds' suitability for therapeutic uses (including delivery) and compounds directed to specific targets (*i.e.*, that address specific disease states). The patents and any patents that may issue from these pending patent applications will, if issued, be set to expire between 2022 and 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).

Option and License Agreements

Medigene AG and the Helmholtz Zentrum München. On March 6, 2020, we entered into a Collaboration and Option Agreement (the "**Collaboration Agreement**") with Medigene AG and the Helmholtz Zentrum München ("**HMGU**"). The Collaboration Agreement expands upon the Company's outstanding research agreement with HMGU to design and develop novel candidates for the use of INTASYL™ compounds in ACT to enhance immune cell function. Under the Collaboration Agreement, Medigene will contribute expertise regarding clinical development, as well as proprietary research material, and has an option to an exclusive license for the clinical and/or commercial exploitation of the potential immune cell enhancers against certain fee payments.

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

Legacy Dermatology and Ophthalmology Programs

In January 2018, the Company announced that it was exploring strategic alternatives, including a potential sale or out-license, with respect to the Company's legacy dermatology and ophthalmology programs following the Company's change in strategic direction to focus solely on immuno-oncology. Due to resource constraints, the Company has significantly reduced its efforts to out-license or sell these programs and does not expect to provide further updates on these assets going forward.

Research and Development

Our research and development expense primarily consists of compensation and benefits for research and development personnel, facility-related expenses, supplies, external services, costs to acquire technology licenses, expenses associated with preclinical and clinical development activities and other operating costs.

Total research and development expense for the years ended December 31, 2019 and 2018 was $4,300,000 and $4,326,000, respectively.

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 cells, TCR-T cells, Gamma Delta T cells, CAR-NK cells, NK cells, NKT cells and cytotoxic T cells. We believe that competitors in this field include, but are not limited to: Adicet Bio, Inc., Allogene Therapeutics, Inc., Atara Biotherapeutics, Inc., Autolus Therapeutics plc, Baylor College of Medicine, Bellicum Pharmaceuticals, Inc., bluebird bio, Inc., Celyad S.A., Celgene Corporation, Cell Medica Ltd., Cellectis S.A., Celularity, Inc., CiMaas B.V., CRISPR Therapeutics AG, Fate Therapeutics, Inc., Formula Therapeutics, Inc., Fortress Biotech, Inc., GAIA Biomedicine Inc., Glycostem Therapeutics BV, Immatics Biotechnologies GmbH, Iovance Biotherapeutics, Inc., Intrexon Corporation, Janssen Biotech, Inc., Kite Pharma, Inc.(a Gilead company), Medigene AG, Mustang Bio, Inc., NantKwest, Inc., BioNTech NE, Novartis International AG, Precigen, Inc., Refuge Biotechnologies, Inc., Sorrento Therapeutics, Inc., Tactiva Therapeutics, Inc., TC BioPharm Limited and Ziopharm Oncology, Inc.

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, RNAi, zinc-finger nucleases, transcription activator-like effector nucleases, mRNA, and genetic engineering techniques such as clustered regularly interspaced short palindromic repeats, or CRISPR, and various others. We believe that competitors in this field include, but are not limited to: BioNTech NE, Cellectis S.A., CRISPR Therapeutics AG, Dicerna Pharmaceuticals, Inc., Editas Medicine, Inc., eTheRna immunotherapies NV, Horizon Discovery Group plc, Intellia Therapeutics, Inc., Kymera Therapeutics Inc., miRagen Therapeutics, Inc., Moderna, Inc., Noxxon Pharma N.V., Obsidian Therapeutics, Inc., OliPass Corporation, OncoSec Medical Incorporated, Mateon Therapeutics, Inc., PTC Therapeutics, Inc., Sangamo Therapeutics, Inc., Sirnaomics, Inc., Stemirna Therapeutics Co., Ltd. and Takara Bio Inc.

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 current good manufacturing practice regulations ("**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 20, 2020, we had eleven 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

On January 10, 2020, the Board of Directors of the Company approved a 1-for-55 reverse stock split of the Company's outstanding common stock, which was effected on January 15, 2020. All share and per share amounts have been adjusted to give effect to the reverse stock split.

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, (the "**Exchange Act**") 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

Our business and operations may be materially and adversely affected by the recent coronavirus outbreak.

In December 2019, a novel strain of coronavirus was reported to have surfaced in Wuhan, China and has since spread to other parts of the world, including the United States and Europe. In March 2020, the World Health Organization declared the outbreak a pandemic. The coronavirus pandemic is affecting the United States and global economies. If the outbreak continues to spread, it may affect the Company's operations and those of third parties on which the Company relies, including causing disruptions in the supply of the Company's product candidates and the conduct of current and planned preclinical and clinical studies. We may need to limit operations or implement limitations, and may experience limitations in employee resources. There are risks that it may be more difficult to contain if the outbreak reaches a larger population or broader geography, in which case the risks described herein could be elevated significantly. The extent to which the coronavirus impacts our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others.

Additionally, while the potential economic impact brought by, and the duration of, the coronavirus pandemic is difficult to assess or predict, the impact of the coronavirus on the global financial markets may reduce the Company's ability to access capital, which could negatively impact the Company's short-term and long-term liquidity and the Company's ability to complete its preclinical studies on a timely basis, or at all. For instance, our preclinical and clinical may be temporarily delayed or paused, and the operations of our contracted third parties may be significantly delayed as well. The ultimate impact of coronavirus is highly uncertain and subject to change. The Company does not yet know the full extent of potential delays or impacts on its business, financing or preclinical and clinical trial activities or the global economy as a whole. However, these effects could have a material impact on the Company's liquidity, capital resources, operations and business and those of the third parties on which we rely.

Our product candidates are in an early stage of development and may fail or experience significant delays or may never advance to the clinic, which may materially and adversely impact our business.

All of our pipeline programs are in preclinical development and our future success heavily depends on the successful development of our INTASYL™ product candidates, which may never occur. These product candidates could be delayed, not advance into the clinic or unexpectedly fail at any stage of development. Before we can commence clinical trials for a product candidate, we must conduct extensive preclinical and other non-clinical tests in order to support an IND application, including IND-enabling good laboratory practice ("**GLP**") toxicology studies, in the United States or their equivalents with regulatory authorities in other jurisdictions. Preclinical studies and clinical trials are expensive, difficult to design and can take many years. There is no assurance that we will be able to successfully develop our product candidates, and we may focus our efforts and resources on product candidates that may prove to be unsuccessful.

We cannot be certain of the outcome of preclinical testing and clinical studies and results from these studies may not predict the results that will be obtained in later phase trials of our product candidates. Even if we are able to complete our preclinical studies and planned clinical trials in line with our projected timelines, results from such studies and trials may be not replicated in subsequent preclinical studies or clinical trial results. Additionally, such studies may be delayed due to events beyond our control including as a result of natural disasters, epidemics or pandemic outbreaks such as the novel coronavirus. Further, the FDA, or equivalent regulatory authority, may not accept the results of our preclinical studies or proposed clinical study designs and may require the Company to complete additional preclinical studies or impose stricter approval conditions than we expect. As a result, we cannot guarantee that we will be able to submit INDs, or similar applications, within our projected timelines, if at all, or that the FDA, or similar regulatory authorities, will allow us to commence clinical trials.

We are dependent on collaboration partners for the successful development of our adoptive cell therapy product candidates.

We are not a cell company and expect to depend on third-party collaborators to support the clinical development of our ACT product candidates. We have entered into research agreements with our academic and industry collaborators, each of which is terminable by the relevant party at any time, subject to applicable notice periods. We may not be successful in negotiating agreements with these collaborators to continue the development and commercialization of our ACT product candidates through collaborations such as joint development or licensing agreements. 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 preclinical data that we have generated, the perceived risks specific to developing our product candidates and our partners' own strategic and corporate objectives. If we fail to negotiate these agreements, we may not be able commence clinical trials with our ACT product candidates or we may be required to obtain licenses from third-party cell companies and our business, financial condition, results of operations and prospects could be materially and adversely affected.

We rely upon third-party relationships to conduct preclinical studies, and any future clinical trials, for our product candidates and may not be able to establish or maintain the third-party relationships that are necessary to support their development.

We depend upon third-party contract research organizations ("**CROs**"), medical institutions, clinical investigators, consultants and other third parties to support our preclinical research efforts such as through managing and conducting research studies, formulating our product candidates and manufacturing our product candidates and expect to rely on the same for our future clinical trials. Because we rely on these third parties, we cannot necessarily control the timing, quality of work or amount of resources that our contract partners will devote to these activities and we cannot guarantee that these parties will fulfill their obligations to us under these arrangements. Furthermore, we compete with many other companies for the resources of these third parties, some of which may be our competitors, and may detract from our programs. Additionally, our contracted CROs and other third parties we rely upon may be impacted by the coronavirus outbreak, resulting in delays or interruptions, If these third parties do not successfully carry out their responsibilities, as well as within a timely fashion, our preclinical and clinical development may be delayed, unsuccessful or otherwise adversely affected.

We cannot guarantee that we will be able to successfully negotiate agreements with or maintain relationships with these third parties on favorable terms, if at all. If we are unable to obtain or maintain these agreements, we may not be able to develop, formulate, manufacture, obtain regulatory approval(s) or commercialize our product candidates. The third parties whom we rely on generally may terminate their agreements with us at any time, subject to applicable notice periods, and we may not be able to readily terminate any such agreements with contract partners even if such partners do not fulfill their obligations to us. If we have to enter into alternative arrangements it may delay or adversely affect the development of our product candidates and our business operations.

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

We rely on third party suppliers and manufacturers to provide us with the materials and services to manufacture our INTASYL™ compounds and product candidates for certain of our preclinical research and expect that we will rely on them for our future clinical trials. While we do have in-house expertise and capacity to manufacture our INTASYL™ compounds, we do not own or lease manufacturing facilities or have our own supply source for the required materials. Accordingly, we will be dependent upon third party suppliers and our 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 INTASYL™ compounds 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.

Although we have used multiple contract manufacturers, we currently contract with only one manufacturer for the supply of our clinical product candidates. There is no assurance that our supply of our clinical drug product will not be limited, interrupted, of satisfactory quality or be available at acceptable prices. If for any reason we are unable to obtain the clinical supply of our product candidates from our current manufacturer, we would have to seek to contract with another major manufacturer. While we believe that we currently have sufficient supply of our PH-762 product candidate for our planned preclinical and clinical studies, some of our other product candidates or the materials contained therein, may come from facilities in areas impacted by the coronavirus, which may result in delays or shortages due to ongoing efforts to address the outbreak. Our failure to secure these arrangements as needed could have a material adverse effect on our ability to complete the development of our clinical product candidates or, if we obtain regulatory approval, to commercialize them.

The FDA, or equivalent regulatory authority, governs the manufacturing process for product candidates and will inspect the facilities at which the product manufactured. Approval of the product will not occur unless the manufacturing facilities are in compliance with the FDA's cGMP regulations, or equivalent foreign authority. If our suppliers or manufacturers do not comply with the FDA or foreign regulations for our product candidates, we may experience delays in timing or supply, be forced to manufacture our product candidates ourselves or seek to enter contract with another supplier or manufacturer. If we are required to switch suppliers or manufacturers, we will be required to verify that the new supplier or manufacturer maintains facilities and processes in line with cGMP regulations, which may result in delays, additional expenses, and may have a material adverse effect on our ability to complete the development of our product candidates.

Natural disasters, epidemic or pandemic disease outbreaks, trade wars, political unrest or other events could disrupt our business or operations or those of our development partners, manufacturers, regulators or other third parties with whom we conduct business now or in the future.

A wide variety of events beyond our control, including natural disasters, epidemic or pandemic disease outbreaks (such as the recent novel coronavirus outbreak), trade wars, political unrest or other events could disrupt our business or operations or those of our manufacturers, regulatory authorities, or other third parties with whom we conduct business. These events may cause businesses and government agencies to be shut down, supply chains to be interrupted, slowed, or rendered inoperable, and individuals to become ill, quarantined, or otherwise unable to work and/or travel due to health reasons or governmental restrictions. For example, Massachusetts recently ordered most businesses closed, mandating work-from-home arrangements, where feasible, in response to the coronavirus pandemic. These limitations could negatively affect our business operations and continuity, and could negatively impact our development timelines and ability to timely perform basic business functions, including making SEC filings and preparing financial reports. If our operations or those of third parties with whom we have business are impaired or curtailed as a result of these events, the development and commercialization of our products and product candidates could be impaired or halted, which could have a material adverse impact on our business.

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 INTASYL™ technology platform. We plan to develop our INTASYL™ products for the treatment of cancer to be delivered via direct injection for use intratumorally and with ACT by isolating immune cells from patients, treating the cells *ex vivo* and then returning them to the patient for treatment. We believe that our INTASYL™ compounds may offer a new treatment option to current standards of care, such as antibodies, and potentially with a more cost-effective approach. Successful development of our INTASYL™ compounds by us, or by our collaborative partners, is highly uncertain and depends on a number of factors, many of which are beyond our control. The scientific research used to support our efforts and approach to developing RNAi therapeutics is limited. Decisions made by the Company to advance the development of our pipeline, including those related to our technology or manufacturing processes, may show to be incorrect based on further work by us or our collaborators.

The use of RNAi is a relatively new scientific discovery and the scientific evidence to support the feasibility of developing drugs based on these discoveries, or INTASYL™, is limited. Therefore, it is difficult to accurately predict challenges we may face with our product candidates as they move through the discovery, preclinical and clinical development stages. We may spend large amounts of money trying to develop our INTASYL™ technology and may never succeed in doing so. In addition, our research methodology by be unsuccessful in identifying product candidates and results from preclinical and clinical studies may not predict the results that will be obtained in later phase trials of our product candidates or our product candidates may interact with patients in unforeseen or harmful ways that may make it impractical to manufacture, market or receive regulatory approval. If we are not successful in bringing an INTASYL™ product candidate to market, it could negatively impact our business and financial condition and we may not be able to identify and successfully implement an alternative product development strategy.

A number of different factors could prevent us from advancing into clinical development, obtaining regulatory approval, and ultimately commercializing our product candidates on a timely basis, or at all.

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. Before human clinical trials may commence, we must submit to the FDA an IND application. An IND application involves the completion of preclinical studies and the submission of the results, together with proposed clinical protocols, manufacturing information, analytical data and other data in the IND submission. The FDA may require us to complete additional preclinical studies or disagree with our clinical trial study design. Also, animal models may not exist for some of the disease areas we choose to develop our INTASYL™ product candidates for. As a result, our clinical trials may be delayed or we may be required to incur more expense than we anticipated.

Clinical trials require the review and oversight of IRBs, which approve and continually review clinical investigations and protect the rights and welfare of human subjects. Before our clinical trials can begin, we must also submit to the FDA a clinical protocol accompanied by the approval of the IRB at the institution(s) participating in the clinical trial. An inability or delay in obtaining IRB approval could prevent or delay the initiation and completion of our 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.

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 testing is lengthy and expensive, and its outcome is highly uncertain. Historical failure rates are high due to number of factors, such as safety and efficacy of drug candidates. We, our collaborators, the FDA, 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.

An additional number of 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;
- The impact from the recent coronavirus outbreak;
- Reallocation of our limited financial and other resources to other clinical programs; and
- Adverse results obtained by other companies developing similar drugs.

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 and 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. Because of these factors, it is difficult to predict the time and cost of the development of our product candidates. Any delay or failure in obtaining required approvals may prevent us from completing our preclinical or clinical studies and could have a material adverse effect on our ability to initiate or commercialize any drug candidate on a timely basis, or at all.

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.

We are dependent on the success of our product candidates and even if we complete the necessary preclinical and clinical studies, we may not receive or be delayed in receiving regulatory approval and as a result, we will not be able to commercialize or will be delayed in commercializing our product candidates.

We have no commercial products and currently generate no revenue from product sales 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. We, and any of our collaborators, must demonstrate and establish our product candidate's safety, purity and effectiveness to patients through extensive clinical trials before we can submit an NDA or BLA to the FDA for approval. Even if we complete the necessary preclinical and clinical studies, it is possible that none of the product candidates that we may attempt to develop will obtain the appropriate regulatory approvals needed to begin selling them or they may be subject to limitations on the indicated uses for which we may market the product.

The process for obtaining FDA and other approval is both time consuming and costly, with no certainty of a successful outcome, and can often take years following the commencement of clinical trials, depending on 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. The FDA has substantial discretion in the approval process and may deny our application, may decide our data is insufficient or require additional information from us 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. Any changes in marketing approval policies or regulatory statutes and regulations during product development, trials and the review process, may cause delays in the approval of an application. 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.

We have no experience in filing the applications necessary to obtain marketing approval and expect that we and need to rely on CROs and regulatory consultants to assist us with this process. Regulatory approval also requires the submission about the product manufacturing process and inspection of the manufacturing facilities, to the relevant regulatory authority. Any product candidates we develop may not be effective, may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

If we experience delays or fail to obtain marketing approval for any of our product candidates that we may develop, we would be prevented from being able to commercialize our product candidates and our commercial prospects and ability to generate revenues may be materially impaired.

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.

Even if we receive regulatory approval for a product candidate, we may not generate or sustain revenues from sales of the product. The product candidates that we are developing are based on new technologies and therapeutic approaches, which are largely unproven. 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. 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. 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 INTASYL™ 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 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 at December 31, 2019, and the proceeds received from our capital raises completed in February 2020, will be sufficient to fund our currently planned operations for at least the next 12 months from the date this Annual Report on Form 10-K is filed. 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.

Moreover, the global coronavirus pandemic has led to significant uncertainty and increased volatility in the capital markets. If these conditions in the capital markets continue for an extended period of time it may impact our ability to raise capital. 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, particularly in response to the coronavirus outbreak, 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. 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.

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, and subsequent amendment on January 22, 2019, 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 expires on March 31, 2024, for a total of a ten year lease term. The base rent for the premises is $124,865 per annum, payable on a monthly basis. 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 20, 2020, there were approximately 18 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 upon, among other things, 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, 2019 or 2018.

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 ("**INTASYL™**") therapeutic platform. The Company's efforts are focused on silencing tumor-induced suppression of the immune system through our proprietary INTASYL™ platform with utility in immune cells and/or the tumor micro-environment. Our goal is to develop powerful INTASYL™ therapeutic compounds that can weaponize immune effector cells to overcome tumor immune escape, thereby providing patients a powerful new treatment option that goes beyond current treatment modalities.

Our development efforts are based on our broadly patented INTASYL™ technology platform. Our INTASYL™ 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 which is over-expressed in cancer. We believe that our INTASYL™ platform uniquely positions the Company in the field of immuno-oncology because of this and the following reasons:

- Efficient uptake of INTASYL™ to immune cells obviating the need for facilitated delivery (mechanical or formulation);
- Can target multiple genes (i.e. multiple immunosuppression pathways) in a single therapeutic entity;
- Gene silencing by INTASYL™ has been shown to have a sustained, or long-term, effect *in vivo*;
- Favorable clinical safety profile of INTASYL™ with local administration; and
- Can be readily manufactured under current good manufacturing practices.

The self-delivering nature of our compounds makes INTASYL™ ideally suited for use with adoptive cell transfer ("**ACT**") treatments and direct therapeutic use. ACT consists of the infusion of immune cells with antitumor properties. These cells can be derived from unmodified (i.e. naturally occurring) immune cells, immune cells isolated from resected tumors, or genetically engineered immune cells recognizing tumor neoantigen/neoepitope cells.

Currently, ACT therapies for the treatment of solid tumors face several hurdles. Multiple inhibitory mechanisms restrain immune cells used in ACT from effectively eradicating tumors, including immune checkpoints, reduced cell fitness and cell persistence. Furthermore, the immunosuppressive tumor micro-environment (the "**TME**") can pose a formidable barrier to immune cell infiltration and function.

Phio has developed a product platform based on our INTASYL™ technology that allows easy, precise, rapid, and selective non-genetically modified programming of ACT cells (*ex vivo*, during manufacturing) and of the TME (*in vivo*, by local application), resulting in improved immunotherapy.

Adoptive Cell Transfer

ACT includes a number of different types of immunotherapy treatments. These treatments use immune 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 tumor infiltrating lymphocytes ("**TILs**"), or from donor blood or tissue such as natural killer ("**NK**") cells, dendritic cells ("**DC**") and macrophages, and b.) engineered immune cells that are genetically modified to recognize specific tumor proteins and to remain in an activated state (such as T cell receptor technology ("**TCRs**"), chimeric antigen receptor ("**CAR**") T cells, or CAR-NK cells).

In ACT, immune cells are isolated from patients, donors or retrieved from allogeneic immune cell banks. The immune cells are then expanded and modified before being returned and used to treat the patient. We believe our INTASYL™ compounds are ideally suited to be used in combination with ACT, in order to make these immune cells more effective.

Our approach to immunotherapy builds on well-established methodologies of ACT and involves the treatment of immune cells with our INTASYL™ compounds while they are grown in the lab and before administering them to the patient. Because our INTASYL™ compounds do not require a delivery vehicle to penetrate into the cells, we are able to enhance the function of these cells (for example, by inhibiting the expression of immune checkpoint genes) by merely adding our INTASYL™ 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 INTASYL™ technology to reduce or eliminate the expression of genes that make the immune cells less effective. For example, with our INTASYL™ 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, INTASYL™ treatment results in potent silencing while maintaining close to 100% transfection efficiency and nearly full cell viability.

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 used in ACT, such as with INTASYL™ technology, is of key interest now in the current immuno-oncology world. In comparison to other technologies available, reprogramming cells with INTASYL™ does not require genetic engineering, its use is not limited to specific cell types and can be easily integrated with cell manufacturing approaches.

We currently have two product candidates that are being developed for use in ACT, PH-762 and PH-804. PH-762, our most advanced program and lead pipeline compound, targets the checkpoint protein PD-1, a checkpoint protein on immune cells. PD-1 normally acts as a type of “off switch” that helps keep the T cells from attacking other cells in the body. T cells are immune cells that protect the body from cancer cells and are important for the activation of immune cells to fight infection. Our second pipeline compound, PH-804, targets the suppressive immune receptor TIGIT, which is a checkpoint protein present on T cells and NK cells.

Data developed in-house and with our collaborators, which include both leading academic centers and corporate institutions, to date has shown that PH-762 can elicit PD-1 checkpoint blockade by silencing PD-1 receptor expression resulting in enhanced T cell activation and tumor cytotoxicity. We have also shown with studies completed with our collaborators that PH-804 can silence the expression of TIGIT in NK cells and T cells, overcoming their exhaustion and thereby becoming “weaponized.”

Recent data shown by the Company as well as with our collaborators, Iovance Biotherapeutics, Inc. and the Karolinska Institutet, at the 2019 Society for Immunotherapy of Cancer annual meeting further supports the application of INTASYL™ technology in immunotherapy of cancer. PH-762, our most advanced program, has shown to silence the expression of checkpoint molecule PD-1 in target human T cells in a potent and durable manner suitable for both ACT and intra-tumoral injection, and increases function of patient derived TILs for ACT. The application of INTASYL™ compounds to novel immuno-oncology targets was shown by the silencing of BRD4, a regulator of gene expression impacting cell differentiation and function, by a BRD4 targeting INTASYL™ compound in human T cells during expansion for ACT, which has the potential to confer superior anti-tumor activity.

Tumor Micro-Environment

The TME is the environment that surrounds and feeds a tumor, including normal cells, blood vessels, immune cells and the extracellular matrix. A tumor can change the microenvironment and the microenvironment can affect how a tumor grows and spreads and can create an immunosuppressive microenvironment that inhibits the immune system’s natural ability to recognize and destroy tumor cells. This attracts immunosuppressive cells, induces and activates immune checkpoint expression and excludes and exhausts T cells. Reprogramming different components of the TME may overcome its resistance to immunotherapy.

Such reprogramming of the TME by INTASYL™ compounds through direct local administration into the tumor, could potentially become an important form of (neo)adjuvant therapy. We believe that this will also show that our contributions with our INTASYL™ compounds in immuno-oncology are not limited to use with a cell therapy platform. Additionally, the Company has shown in a clinical setting that its INTASYL™ compounds are safe and well-tolerated following local administration.

Our INTASYL™ compounds being developed for use in ACT, are also being developed for use directly towards the TME, including PH-762 and PH-804. We are also working on other relevant compounds for TME targets, such as PH-790, an INTASYL™ compound targeting PD-L1. PD-L1 is a protein that keeps immune cells from attacking nonharmful cells in the body. If cancer cells have large amounts of PD-L1, this “tricks” the immune system into not recognizing and attacking the tumor. Our approach with PH-790 is to block the PD-L1 protein, which may prevent cancer cells from inactivating T cells and attack the cancer.

Our collaborative research agreement with Gustave Roussy, a leading comprehensive cancer center in France, concentrates on determining the feasibility of our INTASYL™ platform to target the TME via intra-tumoral injection. An *in-vivo* study completed with Gustave Roussy demonstrated that an INTASYL™ compound delivered via intra-tumoral injection showed silencing of gene expression with our INTASYL™ compounds with greater than 90% reduction of the target gene expression in a mouse model of melanoma.

Recent *in vivo* studies performed by the Company showed that intra-tumoral injections of a mouse version of PH-804 reduced the tumor growth in colorectal carcinoma tumor bearing mice, which was shown to be correlated with the silencing of TIGIT mRNA expression and an increase in cytotoxic effector T cells in the TME.

Corporate Information

On January 10, 2020, the Board of Directors of the Company approved a 1-for-55 reverse stock split of the Company’s outstanding common stock, which was effected on January 15, 2020. All share and per share amounts have been retroactively adjusted for all periods presented to give effect to the reverse stock split.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these consolidated 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.

Research and Development Expenses

We are required to estimate our accrued research and development expenses, of which a significant portion related to third party providers the Company has contracted with to perform various preclinical and clinical activities on our behalf for the continued development of our product candidates. This process includes reviewing open contracts and purchase orders, estimating the service performed and the associated cost incurred for research and development services not yet billed or otherwise notified of actual cost. Examples of estimated accrued expenses related to research and development expenses include 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.

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. The financial terms of these contracts are subject to negotiation, vary from provider to provider and may result in uneven payment flows. There may be instances in which payments made to our vendors exceed the level of services provided and result in a prepayment of the expense. In other instances, payment depends on factors such as the successful completion of the enrollment of subjects or milestones.

Accruals and expenses are recorded during the period incurred based on such estimates and assumptions as expected cost, passage of time over which services will be performed, the level of effort to be expended in each period, the achievement of milestones and adjustment accordingly. Estimates of our research and development accruals are assessed on a quarterly basis based on the facts and circumstances known to us at that time and other information available to us. We recognize costs for certain development activities based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors. We periodically confirm the accuracy of the estimates with our third party contractors and make adjustments, if necessary. Actual results may differ from these estimates and could have a material impact on our reported results. Our historical accrual estimates have not been materially different from our actual costs. Due to the nature of estimates, we cannot provide assurance that we will not make changes to our estimates in the future as we become aware of additional information about the conduct of our preclinical or clinical activities.

Stock-based Compensation

The Company follows the provisions of the Financial Accounting Standards Board (the "**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.

We determine the fair value of restricted stock and restricted stock units based on the fair value of our common stock on the date of grant. We estimate the fair value of our stock option using the Black-Scholes option pricing model, which requires us to develop subjective estimates to be used in calculating the grant date fair value of stock options. The use of the model requires us to make estimates of highly subjective assumptions, such as expected stock price volatility and the estimated expected term of each award.

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.

Leases

In connection with our adoption on January 1, 2019, the Company follows the provisions of the FASB ASC 842, "*Leases*" ("**ASC 842**"). At the inception of a contract, the Company determines whether the contract is or contains a lease based on all relevant facts and circumstances. For contracts that contain a lease, the Company identifies the lease and non-lease components, determines the consideration in the contract and recognizes the classification of the lease as operating or financing. At the commencement date of the lease, the Company recognizes a liability to make lease payments and an asset representing the right to use the underlying asset during the lease term. The Company has elected not to recognize leases with a term less than one year on the balance sheet.

Lease liabilities and the corresponding right of use assets are recorded based on the present value of lease payments to be made over the lease term. The discount rate used to calculate the present value is the rate implicit in the lease, or if not readily determinable, the Company's incremental borrowing rate. The Company's incremental borrowing rate is the rate of interest that we would have to pay to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. Certain adjustments to the right of use asset may be required for items such as initial direct costs or incentives received. Lease payments on operating leases are recognized on a straight-line basis over the expected term of the lease. Lease payments on financing leases are recognized using the effective interest method.

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 compensation and benefits for research and development personnel, facility-related expenses, supplies, external services, costs to acquire technology licenses, expenses associated with preclinical and clinical development activities and other operating costs. 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.

Our research and development programs are focused on the development of the next generation of immuno-oncology therapeutics based on INTASYL™ therapeutic platform. 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 programs 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.

General and Administrative Expenses

General and administrative expenses relate to compensation and benefits for general and administrative personnel, facility-related expenses, professional fees for legal, audit, tax and consulting services, as well as other general corporate expenses.

Other Income, net

Other income 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
	2019	2018	Change
Revenues	$ 21	$ 138	$ (117)
Operating expenses	9,008	7,502	1,506
Operating loss	(8,987)	(7,364)	(1,623)
Net loss	$ (8,908)	$ (7,360)	$ (1,548)

Comparison of the Years Ended December 31, 2019 and 2018

Revenues

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

	Years Ended December 31,		Dollar
	2019	2018	Change
Revenues	$ 21	$ 138	$ (117)

Revenues for the years ended December 31, 2019 and 2018 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 provided funding for the development of a novel INTASYL™ compound, BA-434, that targets PTEN for the treatment of spinal cord injury. Work performed by the Company as a sub-awardee under the grant was completed during the first quarter of 2019.

Operating Expenses

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

	Years Ended December 31,		Dollar
	2019	2018	Change
Research and development	$ 4,300	$ 4,326	$ (26)
General and administrative	4,708	3,176	1,532
Total operating expenses	$ 9,008	$ 7,502	$ 1,506

Research and Development Expenses

Research and development expenses for the year ended December 31, 2019 decreased less than 1% compared with the year ended December 31, 2018. Overall, research and development expenses were consistent year over year which was driven in part by the reduction in the Company's legacy clinical trial-related fees as these trials ended in 2018 offset by the increase in the use of third-party CROs to support the Company's preclinical immuno-oncology research during 2019.

General and Administrative Expenses

General and administrative expenses for the year ended December 31, 2019 increased 48% compared with the year ended December 31, 2018, primarily due to professional fees for legal related expenses, recruiting fees to support employee hiring activities and increased proxy-related fees as a result of the Company's annual and special stockholder meetings held in 2019 as compared to the prior year period.

Liquidity and Capital Resources

On August 8, 2017, the Company entered into a purchase agreement (the "**2017 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 up to $15,000,000 in shares of the Company's common stock, subject to certain limitations and conditions set forth in the 2017 Purchase Agreement. To date, the Company has sold 9,000 shares of common stock to LPC for net proceeds of $1,602,000. The Company has approximately $13,300,000 remaining under the 2017 Purchase Agreement, which expires on April 1, 2020.

On August 7, 2019, the Company entered into a purchase agreement (the "**2019 Purchase Agreement**") and a registration rights agreement with LPC, pursuant to which the Company has the right to sell to LPC up to $10,000,000 in shares of the Company's common stock over the 30-month term of the 2019 Purchase Agreement, subject to certain limitations and conditions. The 2019 Purchase Agreement initially limits the Company's issuance of shares of common stock to LPC to 19.99% of the Company's shares outstanding on the date of the 2019 Purchase Agreement unless stockholder approval is obtained to issue more than such amount or the average price of all sales under the 2019 Purchase Agreement exceed certain amounts as set forth in the 2019 Purchase Agreement. To date, no shares of common stock have been sold to LPC under the 2019 Purchase Agreement.

On February 6, 2020, the Company closed a registered direct offering of 197,056 shares of the Company's common stock at a purchase price of $8.705 and in a concurrent private placement, sold warrants to purchase an aggregate of 197,056 shares of the Company's common stock at a purchase price of $0.125 per underlying warrant share and with an exercise price of $8.71 per share (the "**February 2020 Registered Offering**"). Net proceeds to the Company from the February 2020 Registered Offering are estimated to be $1,400,000 after deducting placement agent fees and offering expenses.

On February 13, 2020, the Company closed an underwritten public offering of 993,633 shares of the Company's common stock and pre-funded warrants (the "**2020 Pre-Funded Warrants**") to purchase an aggregate of 1,006,367 shares of the Company's common stock (the "**February 2020 Underwritten Offering**"). The 2020 Pre-Funded Warrants were immediately exercisable at an exercise price per share of $0.001. Each share of common stock or 2020 Pre-Funded Warrant, as applicable, was sold as a unit with a warrant to purchase one share of common stock at an exercise price of $4.00 per share. The combined public offering price was $4.00 per common stock unit or $3.999 per 2020 Pre-Funded Warrant unit. Net proceeds from the February 2020 Underwritten Offering are estimated to be $7,000,000 after deducting underwriting discounts and commissions and offering expenses paid by the Company.

We had cash of $6,934,000 as of December 31, 2019, compared with $14,879,000 as of December 31, 2018. 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. Moreover, the global coronavirus pandemic has led to significant uncertainty and increased volatility in the capital markets. If these conditions in the capital markets continue for an extended period of time it may impact our ability to raise capital. 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 and the proceeds from the Company's February 2020 Registered Offering and February 2020 Underwritten Offering, should be sufficient to fund operations for at least the next 12 months from the date this Annual Report on Form 10-K is filed.

Cash Flow

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

	Years Ended December 31,	
	2019	**2018**
Net cash used in operating activities	$ (8,645)	$ (7,520)
Net cash used in investing activities	(72)	(5)
Net cash provided by financing activities	772	18,823
Net (decrease) increase in cash and restricted cash	$ (7,945)	$ 11,298

Net Cash Flow from Operating Activities

Net cash used in operating activities was $8,645,000 for the year ended December 31, 2019, compared with $7,520,000 for the year ended December 31, 2018. The increase of $1,125,000 was primarily attributable to an increase in net loss as result of the increase in the Company's operating expenses as compared with the prior year, as discussed above, partially offset by a reduction in cash used for working capital.

Net Cash Flow from Investing Activities

Net cash used in investing activities was $72,000 for the year ended December 31, 2019, compared with $5,000 for the year ended December 31, 2018. The increase was related to the purchase of office and lab equipment as compared with the prior year period.

Net Cash Flow from Financing Activities

Net cash provided by financing activities was $772,000 for the year ended December 31, 2019, compared with $18,823,000 for the year ended December 31, 2018. The decrease was primarily due to the timing and amount of capital raise activity completed by the Company during fiscal year 2019 as compared with fiscal year 2018.

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 7 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, 2019 and 2018, the related consolidated statements of operations, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2019, 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, 2019 and 2018, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2019**,** in conformity with accounting principles generally accepted in the United States of America.

Change in Accounting Principle

As discussed in Note 4 to the consolidated financial statements, on January 1, 2019, the Company changed its method of accounting for leases due to the adoption of Accounting Standards Update 2016-02, *Leases* (ASC 842).

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 26, 2020

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

	Years Ended December 31,	
	2019	**2018**
ASSETS		
Current assets:		
Cash	$ 6,934	$ 14,879
Restricted cash	50	50
Prepaid expenses and other current assets	316	221
Total current assets	7,300	15,150
Right of use asset	511	–
Property and equipment, net of accumulated depreciation of $1,048 and $981, in 2019 and 2018, respectively	210	172
Other assets	18	–
Total assets	$ 8,039	$ 15,322
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 809	$ 550
Accrued expenses and other current liabilities	964	1,194
Lease liability	107	–
Total current liabilities	1,880	1,744
Lease liability, net of current portion	411	–
Total liabilities	2,291	1,744
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, $0.0001 par value, 10,000,000 shares authorized	–	–
Common stock, $0.0001 par value, 100,000,000 shares authorized; 669,433 and 342,578 shares issued and outstanding at December 31, 2019 and December 31, 2018, respectively	1	–
Additional paid-in capital	100,566	99,489
Accumulated deficit	(94,819)	(85,911)
Total stockholders' equity	5,748	13,578
Total liabilities and stockholders' equity	$ 8,039	$ 15,322

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,	
	2019	**2018**
Revenues	$ 21	$ 138
Operating expenses:		
Research and development	4,300	4,326
General and administrative	4,708	3,176
Total operating expenses	9,008	7,502
Operating loss	(8,987)	(7,364)
Total other income, net	79	4
Loss before income taxes	(8,908)	(7,360)
Provision for income taxes	–	–
Net loss	$ (8,908)	$ (7,360)
Net loss per share:		
Basic and diluted	$ (19.33)	$ (57.46)
Weighted average shares: basic and diluted	460,809	128,085

See accompanying notes to consolidated financial statements.

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

	Common Stock		Additional Paid-in	Accumulated	
	Shares	Amount	Capital	Deficit	Total
Balance at December 31, 2017	44,181	$ –	$ 80,384	$ (78,551)	$ 1,833
Issuance of common stock under Lincoln Park Capital, LLC purchase agreement	7,910	–	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	27,465	–	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	67,740	–	13,193	–	13,193
Issuance of common stock upon the exercise of pre-funded warrants	191,532	–	105	–	105
Issuance of common stock under employee stock purchase plan	53	–	3	–	3
Issuance of restricted stock	3,697	–	–	–	–
Stock-based compensation expense	–	–	282	–	282
Net loss	–	–	–	(7,360)	(7,360)
Balance at December 31, 2018	342,578	–	99,489	(85,911)	13,578
Issuance of common stock upon the exercise of pre-funded warrants	130,338	–	72	–	72
Issuance of common stock under Lincoln Park Capital, LLC purchase agreement	9,090	–	(58)	–	(58)
Issuance of restricted stock	4,419	–	–	–	–
Issuance of common stock under employee stock purchase plan	36	–	1	–	1
Issuance of common stock in connection with registered direct public offering, net of offering costs of $234	181,818	1	765	–	766
Issuance of common stock upon vesting of restricted stock units	1,154	–	(3)	–	(3)
Stock-based compensation expense	–	–	300	–	300
Net loss	–	–	–	(8,908)	(8,908)
Balance at December 31, 2019	669,433	$ 1	$ 100,566	$ (94,819)	$ 5,748

See accompanying notes to consolidated financial statements.

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

	Years Ended December 31,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (8,908)	$ (7,360)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	67	81
Non-cash lease expense	109	–
Non-cash stock-based compensation expense	300	282
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(113)	(2)
Accounts payable	259	39
Accrued expenses and other liabilities	(257)	(560)
Lease liability	(102)	–
Net cash used in operating activities	(8,645)	(7,520)
Cash flows from investing activities:		
Cash paid for purchase of property and equipment	(72)	(5)
Net cash used in investing activities	(72)	(5)
Cash flows from financing activities:		
Net proceeds from the issuance of common stock and warrants	708	18,715
Payment of taxes for net share settled restricted stock unit issuances	(3)	–
Proceeds from the issuance of common stock upon exercise of pre-funded warrants	72	105
Proceeds from the issuance of common stock in connection with the employee stock purchase plan	1	3
Payments for capital lease obligations less than one year	(6)	–
Net cash provided by financing activities	772	18,823
Net (decrease) increase in cash and restricted cash	(7,945)	11,298
Cash and restricted cash at the beginning of period	14,929	3,631
Cash and restricted cash at the end of period	$ 6,984	$ 14,929
Supplemental disclosure of non-cash investing and financing activities:		
Right of use asset obtained in exchange for operating lease liability	$ 620	$ –
Purchase of equipment through short-term financing lease included in accrued expenses and other current liabilities	$ 33	$ –

See accompanying notes to consolidated financial statements.

1. Nature of Operations

Phio Pharmaceuticals Corp. ("**Phio**," "**we**," "**our**" or the "**Company**") is a biotechnology company developing the next generation of immuno-oncology therapeutics based on its self-delivering RNAi ("**INTASYL™**") therapeutic platform. The Company's efforts are focused on silencing tumor-induced suppression of the immune system through its proprietary INTASYL™ platform with utility in immune cells and/or the tumor micro-environment. The Company's goal is to develop powerful INTASYL™ therapeutic compounds that can weaponize immune effector cells to overcome tumor immune escape, thereby providing patients a powerful new treatment option that goes beyond current treatment modalities.

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**").

Reverse Stock Split

Effective January 15, 2020, the Company completed a 1-for-55 reverse stock split of the Company's outstanding common stock. 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. Unless otherwise noted, shares of common stock issued and outstanding, shares underlying warrants and stock awards, shares reserved, conversion price of convertible securities, exercise prices of warrants and stock awards and loss per share have been proportionately adjusted to reflect the reverse stock split. The reverse stock split did not reduce the number of authorized shares of the Company's common stock or preferred stock.

Principles of Consolidation

The consolidated financial statements include the accounts of Phio 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. On an ongoing basis we evaluate our estimates and base our estimates on historical experience and other relevant assumptions that we believe are reasonable under the circumstances. Actual results could differ materially from these estimates. The areas subject to significant estimates and judgement include, among others, those related to fair value of equity awards, research and development expenses, right of use lease assets, the fair value of financial instruments, useful lives of property and equipment, income taxes, and our valuation allowance on our deferred tax assets.

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 a financial institution that management believes is creditworthy, 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.

Leases

In connection with the adoption on January 1, 2019, the Company follows the provisions of the Financial Accounting Standards Board ("**FASB**") Accounting Standards Codification ("**ASC**") Topic 842, "*Leases*" ("**ASC 842**"). At the inception of a contract, the Company determines whether the contract is or contains a lease based on all relevant facts and circumstances. For contracts that contain a lease, the Company identifies the lease and non-lease components, determines the consideration in the contract and recognizes the classification of the lease as operating or financing. At the commencement date of the lease, the Company recognizes a liability to make lease payments and an asset representing the right to use the underlying asset during the lease term.

The Company has elected the package of practical expedients to not reassess its prior conclusions about lease identification, lease classification and indirect costs and to not separate lease and non-lease components. The Company has also elected not to recognize leases with a term less than one year on the balance sheet.

Lease liabilities and the corresponding right of use assets are recorded based on the present value of lease payments to be made over the lease term. The discount rate used to calculate the present value is the rate implicit in the lease, or if not readily determinable, the Company's incremental borrowing rate. The Company's incremental borrowing rate is the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. Certain adjustments to the right of use asset may be required for items such as initial direct costs or incentives received. Lease payments on operating leases are recognized on a straight-line basis over the expected term of the lease. Lease payments on financing leases are recognized using the effective interest method.

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, 2019 and 2018 was $67,000 and $81,000, respectively.

Derivative Financial Instruments

The Company follows the provisions of the FASB 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 whenever an event occurs or change in circumstances that the related carrying amounts may not be recoverable. 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, 2019 or 2018.

Research and Development Expenses

Research and development expenses relate to compensation and benefits for research and development personnel, facility-related expenses, supplies, external services, costs to acquire technology licenses, expenses associated with preclinical and clinical development activities and other operating costs. 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.

The Company contracts with third parties to perform various preclinical and clinical activities on its behalf for the continued development of its product candidates. Accruals and expenses are recorded during the period incurred based on such estimates and assumptions as expected cost, passage of time, the achievement of milestones and other information available to us and are assessed on a quarterly basis. 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.

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. Those temporary differences referred to as deferred tax assets and liabilities are determined at the end of each period using the tax rate expected to be in effect when taxes are actually paid or recovered.

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. The Company follows a more-likely-than not threshold for financial statement recognition and measurement of a tax position taken, or expected to be taken in a tax return. The guidance relates to, amongst other things, classification, accounting for interest and penalties associated with tax positions, and disclosure requirements. Any interest and penalties accrued related to uncertain tax positions are recorded as tax expense. 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 in accordance with the FASB ASC Topic 260, "*Earnings per Share.*" Basic and diluted net loss per share 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 loss by the weighted average number of common shares outstanding and the impact of all dilutive potential common shares.

3. Liquidity and Going Concern

The Company has reported recurring losses from operations since inception and expects that the Company will continue to have negative cash flows from operations for the foreseeable future. Historically, the Company's primary source of funding has been the sale of its securities. The Company's ability to continue to fund its operations are 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. This is dependent on a number of factors, including the market demand or liquidity of the Company's common stock. 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.

The Company believes that its existing cash and the proceeds from the Company's February 2020 Registered Offering and February 2020 Underwritten Offering (as discussed in the footnotes below), should be sufficient to fund operations for at least the next 12 months from the date this Annual Report on Form 10-K is filed.

4. Recent Accounting Pronouncements

In February 2016, the FASB issued Accounting Standards Update ("**ASU**") 2016-02, "*Leases (Topic 842)*" ("**Topic 842**"), which requires lessees to recognize a right of use asset and lease liability on the balance sheet for most leases that do not meet the definition of a short-term lease and to disclose key information about leasing arrangements. Leases will continue to be classified as either operating or financing. The Company adopted Topic 842 on January 1, 2019 using the modified retrospective approach and elected to apply the transition method that allows companies to continue applying guidance under the lease standard in effect at that time in the comparative period financial statements and recognize a cumulative-effect adjustment to the balance sheet on the date of adoption. The Company has also elected the package of practical expedients to not reassess its prior conclusions about lease identification, lease classification and indirect costs and to not separate lease and non-lease components.

Upon adoption of Topic 842 on January 1, 2019, the Company recorded a right of use asset of $28,000 and an operating lease liability of $28,000. Comparative periods have not been restated. For additional information regarding how the Company is accounting for leases under Topic 842, refer to Note 5.

In November 2018, the FASB issued ASU 2018-18, "*Collaborative Arrangements (Topic 808)*" ("**Topic 808**"), which clarifies the interaction between Topic 808 and ASC Topic 606, "*Revenue from Customers.*" The update provides guidance on whether certain transactions between collaborative arrangement participants should be accounted for with revenue under ASC Topic 606 and provide more comparability in the presentation of revenue for certain transactions between collaborative arrangement participants. This will be effective for annual reporting periods beginning after December 15, 2019, including interim periods within that reporting period. The Company does not expect the adoption of Topic 808 to have a material impact on its financial statements.

5. Leases

The Company adopted Topic 842 on January 1, 2019 using the modified retrospective approach and elected to apply the transition method that allows companies to continue applying guidance under the lease standard in effect at that time in the comparative period financial statements and recognize a cumulative-effect adjustment to the balance sheet on the date of adoption. The Company has also elected the package of practical expedients to not reassess its prior conclusions about lease identification, lease classification and indirect costs and to not separate lease and non-lease components. With the adoption of Topic 842, the Company's balance sheet now contains line items for right of use asset, current lease liability and noncurrent lease liability.

The Company determined that it held an operating lease for its office and laboratory space as of January 1, 2019. The Company held no other lease agreements. The Company leases 7,581 square feet of office and laboratory space for its corporate headquarters and primary research facility in Marlborough, Massachusetts. On January 1, 2019, the Company recorded a right of use asset and corresponding lease liability of $28,000.

On January 22, 2019, the Company amended the lease for its office and laboratory space to extend the term by five years, such that the lease will expire on March 31, 2024. With the amendment, the Company also has the option to terminate the lease after two or three years by providing advance written notice. As the Company cannot provide reasonable assurance at this time that the Company will choose to exercise the option to terminate the lease early, the lease term, as per ASC 842, currently only takes into consideration the additional five years as a result of the amendment. Due to the extension of the lease agreement, the Company increased the right of use asset and corresponding lease liability by $592,000.

Additionally, the lease agreements did not contain information to determine the rate implicit in the lease. As such, the Company calculated its incremental borrowing rate based on what the Company would have to pay to borrow on a collateralized basis over the lease term for an amount equal to the remaining lease payments taking into consideration such assumptions as, but not limited to, the U.S. treasury yield rate and borrowing rates from a creditworthy financial institution using the above lease factors.

Future lease payments for non-cancellable operating leases as of December 31, 2019 were as follows, in thousands:

2020	$	128
2021		132
2022		135
2023		139
2024		35
Total undiscounted lease payments		569
Less: Effects of discounting		(51)
Total operating lease liabilities	$	518

Amounts reported in the consolidated balance sheet for operating leases in which the Company is the lessee as of December 31, 2019 were as follows (amounts in thousands):

Right of use asset	$	511
Lease liability, current		107
Lease liability, non-current		411
Weighted average remaining lease term		4.43
Weighted average discount rate		4.64%

The components of the lease costs were as follows, in thousands:

	December 31,	
	2019	2018
Operating leases		
Operating lease cost	$ 121	$ 120

Total rent expense for the years ended December 31, 2019 and 2018 was $127,000 and $120,000, respectively.

Supplemental cash flow information relating to our lease was as follows, in thousands:

	December 31,	
	2019	2018
Cash paid for amounts included in the measurement of lease liabilities		
Operating cash flows used in operating leases	$ (102)	$ –
Right of use assets obtained in exchange for lease liabilities		
Right of use asset	620	–

6. Accrued Expenses and Other Current Liabilities

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

	December 31,	
	2019	2018
Compensation and benefits	$ 524	$ 437
Clinical development expenses	–	107
Professional fees	171	170
Research and development costs	242	480
Other	27	–
Total accrued expenses	$ 964	$ 1,194

7. 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 12).

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, 2019 are as follows, in thousands:

Year Ending December 31,	
2020	$ 165
2021	165
2022	100
2023	100
2024	100
Thereafter	500
Total	$ 1,130

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.

From time to time, the Company is party to legal proceedings. There are none deemed to be material at this time. Accordingly, the Company has not accrued any liabilities in its consolidated financial statements related to proceedings.

8. Stockholders' Equity

Lincoln Park Capital Fund, LLC – On August 8, 2017, the Company entered into a purchase agreement (the "**2017 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 up to $15,000,000 in shares of the Company's common stock, subject to certain limitations and conditions set forth in the 2017 Purchase Agreement. The 2017 Purchase Agreement will expire on April 1, 2020.

No shares of common stock were sold to LPC under the 2017 Purchase Agreement during the year ended December 31, 2019. During the year ended December 31, 2018, the Company sold 7,910 shares of common stock to LPC under the 2017 Purchase Agreement for net proceeds of $1,312,000.

On August 7, 2019, the Company entered into a purchase agreement (the "**2019 Purchase Agreement**") and a registration rights agreement with LPC, pursuant to which the Company has the right to sell to LPC up to $10,000,000 in shares of the Company's common stock, subject to certain limitations and conditions set forth in the 2019 Purchase Agreement. The 2019 Purchase Agreement will expire on May 1, 2022.

As a commitment fee for entering into the 2019 Purchase Agreement, the Company issued 9,090 shares of the Company's common stock to LPC at a value per share of $20.72, which was recorded as a cost of capital. No shares of common stock were sold to LPC under the 2019 Purchase Agreement during the year ended December 31, 2019.

April 2018 Registered Direct Offering and Private Placement — On April 11, 2018, the Company closed a registered direct offering of 27,465 shares of the Company's common stock at a purchase price of $173.25 per share and in a concurrent private placement, sold warrants to purchase a total of 20,599 shares of common stock at a purchase price of $6.875 per underlying warrant share and with an exercise price of $173.25 per share (the "**April 2018 Offering**"). Net proceeds to the Company from the April 2018 Offering were $4,210,000 after deducting placement agent fees and offering expenses paid by the Company. In connection with the April 2018 Offering, the Company issued warrants to purchase a total of 1,373 shares of common stock with an exercise price of $223.00 per share to the placement agent, H.C. Wainwright & Co., LLC ("**HCW**").

October 2018 Underwritten Public Offering — On October 3, 2018, the Company closed an underwritten public offering of 67,740 shares of the Company's common stock and pre-funded warrants (the "**2018 Pre-Funded Warrants**") to purchase an aggregate of 321,870 shares of the Company's common stock (the "**October 2018 Offering**"). The 2018 Pre-Funded Warrants were immediately exercisable at an exercise price per share of $0.55. Each share of common stock or 2018 Pre-Funded Warrant, as applicable, was sold as a unit with a warrant to purchase one share of common stock at an exercise price of $38.50 per share. The combined public offering price was $38.50 per common stock unit or $37.95 per 2018 Pre-Funded Warrant unit. 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 29,220 shares of common stock at an exercise price of $48.125 per share to the underwriter, HCW.

November 2019 Registered Public Offering— On November 19, 2019, the Company closed a registered public offering of 181,818 shares of the Company's common stock at an offering price of $5.50 per share (the "**November 2019 Offering**"). Net proceeds from the November 2019 Offering were $766,000, after deducting fees and expenses. In connection with the November 2019 Offering, the Company issued warrants to purchase a total of 13,636 shares of common stock with an exercise price of $6.875 per share to the placement agent, HCW.

Concurrent with the close of the November 2019 Offering, the Company unilaterally reduced the per share exercise price of all of the outstanding common stock warrants issued in the October 2018 Offering to an exercise of $10.45 per share, which was equal to the closing price of the Company's common stock on November 15, 2019, and to $13.06 per share for the warrants issued to HCW, which was equal to 125% of the closing price of the Company's common stock on November 15, 2019. The modification resulted in an increase in fair value of approximately $800,000. This amount was recorded as a cost of capital of the November 2019 Offering and recorded in additional paid-in capital as the modification was required to complete the capital raise.

Warrants

The Company first assesses the warrants it issues under the FASB ASC Topic 480, "*Distinguishing Liabilities from Equity*" ("**ASC 480**") to determine whether they are within the scope of ASC 480. As there are no instances outside of the Company's control that could require cash settlement of the warrants, the Company's outstanding warrants are outside the scope of ASC 480.

The Company then applies and follows the applicable accounting guidance in ASC 815. Financial instruments are accounted for as either derivative liabilities or as equity instruments depending on the specific terms of the agreement. The Company's outstanding warrants do not meet the definition of a derivative instrument as they are indexed to the Company's common stock and classified within stockholders' equity. Based on this determination, all of the Company's outstanding warrants issued are classified within stockholders' equity.

The following table summarizes warrant activity and the shares of common stock underlying the Company's outstanding equity-classified warrants for the year ended December 31, 2019:

Description	Exercise Price	Expiration Date	Balance December 31, 2018	Warrants Issued	Warrants Exercised	Warrants Expired	Balance December 31, 2019
June 2015 Warrants	$ 2,860.00	6/2/2020	2,364	–	–	–	2,364
December 2016 Warrants	$ 495.00	12/21/2021	23,233	–	–	–	23,233
April 2018 Warrants	$ 173.25	5/31/2023	20,599	–	–	–	20,599
April 2018 Placement Agent Warrants	$ 223.00	4/9/2023	1,373	–	–	–	1,373
October 2018 Pre-Funded Warrants	$ 0.55	No expiration	130,338	–	(130,338)	–	–
October 2018 Warrants	$ 10.45	10/3/2025	389,610	–	–	–	389,610
October 2018 Underwriter Warrants	$ 13.06	10/1/2023	29,220	–	–	–	29,220
November 2019 Placement Agent Warrants	$ 6.875	11/18/2024	–	13,636	–	–	13,636
			596,737	13,636	(130,338)	–	480,035

During the year ended December 31, 2019, the Company received proceeds of approximately $72,000 from the exercise of the Company's 2018 Pre-Funded Warrants for a total of 130,338 shares of common stock. During the year ended December 31, 2018, the Company received proceeds of $105,000 from the exercise of the 2018 Pre-Funded Warrants for a total of 191,532 shares of common stock. All of the 2018 Pre-Funded Warrants issued in October 2018 have been exercised.

9. 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,	
	2019	**2018**
Options to purchase common stock	2,649	2,576
Restricted stock units	14,945	2,500
Restricted stock	–	3,697
Warrants to purchase common stock	480,035	596,737
Total	497,629	605,510

10. 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 "**Plan**"). Under the Plan, the Company may grant incentive stock options, nonqualified stock options, cash awards, stock appreciation rights, restricted 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 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, 2019, an aggregate of 72,728 shares of common stock were reserved for issuance under the Company's Plan, including 2,649 shares subject to outstanding common stock options and 14,945 shares subject to unvested restricted stock units ("**RSUs**") granted under the Plan and 53,864 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, 2019 and 2018, the following assumptions were used:

	December 31,	
	2019	**2018**
Risk-free interest rate	1.85 – 2.58%	2.70 – 2.93%
Expected volatility	97.67 – 98.87%	91.28 – 161.45%
Expected lives (in years)	5.31	5.50 – 10.00
Expected dividend yield	0.00%	0.00%

The weighted-average fair value of options granted during the years ended December 31, 2019 and 2018 was $16.50 and $96.25 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, 2019:

	Total Number of Shares	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Balance at December 31, 2018	2,576	$ 3,645.95		
Granted	273	22.00		
Exercised	–	–		
Cancelled	(200)	3,296.15		
Balance at December 31, 2019	2,649	$ 3,298.90	7.39 years	$ –
Exercisable at December 31, 2019	1,344	$ 6,389.90	6.26 years	$ –

Stock-based compensation expense related to stock options for the year ended December 31, 2019 and 2018 was $69,000 and $112,000, 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, 2019, the compensation expense for all unvested stock options in the amount of approximately $116,000 will be recognized in the Company's results of operations over a weighted average period of 2.31 years.

Restricted Stock Units

RSUs are issued under the Plan or as inducement grants granted outside of the Plan to new employees. 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. Employee RSU recipients may elect to net share settle upon vesting, in which case the Company pays the employee's income taxes due upon vesting and withholds a number of shares of equal value. 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, 2019:

	Number of Shares	Weighted-Average Grant Date Fair Value Per Share
Unvested units at December 31, 2018	2,500	$ 98.45
Granted	18,467	17.05
Vested	(1,268)	98.45
Forfeited	(4,754)	27.30
Unvested units at December 31, 2019	14,945	$ 20.50

Stock-based compensation expense related to RSUs was $125,000 and $52,000 for the years ended December 31, 2019 and 2018, respectively.

As of December 31, 2019, the compensation expense for all unvested RSUs in the amount of approximately $254,000 will be recognized in the Company's results of operations over a weighted average period of 3.31 years.

Restricted Stock

On August 31, 2018, and through subsequent amendments on December 19, 2018 and February 14, 2019, 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 February 28, 2019, 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 were received in the form of a series of grants made on each Company payroll date in lieu of cash payment of the Compensation. All shares issued in lieu of Compensation vested in full on June 1, 2019.

The fair value of the restricted stock was based on the Company's closing stock price on the date of grant and was expensed over the related vesting period. During the year ended December 31, 2019, the Company granted 4,419 shares of restricted stock in lieu of Compensation to Dr. Cauwenbergh and recorded $106,000 in stock-based compensation expense related to the restricted stock. During the year ended December 31, 2018, the Company granted 3,697 shares of restricted stock in lieu of Compensation to Dr. Cauwenbergh and recorded $118,000 in stock-based compensation expense related to the restricted stock.

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, 2019 and 2018 as follows, in thousands:

	December 31,	
	2019	**2018**
Research and development	$ 21	$ 40
General and administrative	279	242
Total stock-based compensation	$ 300	$ 282

11. Income Taxes

For the years ended December 31, 2019 and 2018, 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,	
	2019	**2018**
Current		
Federal	$ –	$ –
State	–	–
Total current	–	–
Deferred		
Federal	(1,773)	(1,555)
State	(759)	(639)
Total deferred	(2,532)	(2,194)
Valuation allowance	2,532	2,194
Total income tax expense (benefit)	$ –	$ –

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

	Years Ended December 31,	
	2019	2018
Federal statutory rate	21.0%	21.0%
State income taxes, net of federal benefit	6.7	5.5
Non-deductible expenses	(0.2)	(1.2)
Income tax credits	1.5	4.3
Valuation allowance	(29.0)	(29.6)
Effective tax rate	–	–

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

	Years Ending December 31,	
	2019	2018
Net operating loss carryforwards	$ 19,647	$ 16,957
Tax credit carryforwards	1,710	1,556
Stock-based compensation	1,391	1,388
Licensing deduction deferral	2,717	3,059
Other timing differences	165	140
ASC 842	2	–
Gross deferred tax assets	25,632	23,100
Valuation allowance	(25,632)	(23,100)
Net deferred tax asset (liability)	$ –	$ –

The Company's deferred tax assets at December 31, 2019 and 2018 consisted primarily of its net operating loss carryforwards, tax credit carryforwards, deferred compensation and intangible assets capitalized for federal income tax purposes. The valuation allowance increased $2,532,000 and $2,194,000 for the years ended December 31, 2019 and 2018, respectively, and is primarily attributable to an increase in net operating losses and tax credits.

The Company has incurred net operating losses since inception. At December 31, 2019, the Company had federal and state net operating loss carryforwards of approximately $73,800,000 and $66,000,000, respectively. Approximately, $55,400,000 of the federal net operating loss carryforwards will begin to expire in 2032, unless previously utilized. The federal net operating loss carryforwards generated after December 31, 2017 of $18,400,000 will carryforward indefinitely. The Company's state tax loss carryforwards will begin to expire in 2032, unless previously utilized. In addition, the Company has federal and state research credits of $1,204,000 and $633,000, respectively, which begin to expire in 2032. 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.

In general, an ownership change, as defined by Section 382 of the Internal Revenue Code, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50% over a three-year period. The Company has not conducted a study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception due to their history of losses. If the Company has experienced a change of control, as defined by Section 382, at any time since inception, utilization of the net operating loss carryforwards or research and development tax credit carryforwards would be subject to an annual limitation under Section 382. Any limitation may result in expiration of a portion of the net operating loss carryforwards or research and development tax credit carryforwards before utilization. Further, until a study is completed and any limitation is known, no adjustments have been reflected in the deferred tax asset for net operating loss carryforwards.

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 2019. The Company has not recorded any uncertain tax positions as of December 31, 2019 or 2018. 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.

12. 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 INTASYL™ technology. In exchange, the Company is obligated to pay Advirna an annual maintenance fee and a milestone payment upon the issuance of the first patent with valid claims covering the assigned technology, which was paid 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.

13. Subsequent Events

February 2020 Registered Direct Offering and Private Placement — On February 6, 2020, the Company closed a registered direct offering of 197,056 shares of the Company's common stock at a purchase price of $8.705 and in a concurrent private placement, sold warrants to purchase an aggregate of 197,056 shares of the Company's common stock at a purchase price of $0.125 per underlying warrant share and with an exercise price of $8.71 per share (the "**February 2020 Registered Offering**"). Net proceeds to the Company from the February 2020 Registered Offering are estimated to be $1,400,000 after deducting placement agent fees and offering expenses. In connection with the February 2020 Registered Offering, the Company issued warrants to purchase a total of 14,779 shares of common stock with an exercise price of $11.0375 per share to the placement agent, HCW.

February 2020 Underwritten Public Offering — On February 13, 2020, the Company closed an underwritten public offering of 993,633 shares of the Company's common stock and pre-funded warrants (the "**2020 Pre-Funded Warrants**") to purchase an aggregate of 1,006,367 shares of the Company's common stock (the "**February 2020 Underwritten Offering**"). The 2020 Pre-Funded Warrants were immediately exercisable at an exercise price per share of $0.001. Each share of common stock or 2020 Pre-Funded Warrant, as applicable, was sold as a unit with a warrant to purchase one share of common stock at an exercise price of $4.00 per share. The combined public offering price was $4.00 per common stock unit or $3.999 per 2020 Pre-Funded Warrant unit. Net proceeds from the February 2020 Underwritten Offering are estimated to be $7,000,000 after deducting underwriting discounts and commissions and offering expenses paid by the Company. Additionally, pursuant to the February 2020 Underwritten Offering, the Company issued warrants to purchase up to 150,000 shares of common stock at an exercise price of $5.00 per share to the underwriter, HCW.

The Company is currently reviewing the accounting for the 2020 Pre-Funded Warrants and the warrants issued in the February 2020 Registered Offering and the February 2020 Underwritten Offering.

Subsequent to the balance sheet date, the Company received proceeds of approximately $1,000 from the exercise of the Company's 2020 Pre-Funded Warrants for a total of 1,006,367 shares of common stock.

Coronavirus — In December 2019, a novel strain of coronavirus was reported to have surfaced in Wuhan, China and has since spread to other parts of the world, including the United States and Europe. In March 2020, the World Health Organization declared the outbreak a pandemic. The coronavirus pandemic is affecting the United States and global economies. If the outbreak continues to spread, it may affect the Company's operations and those of third parties on which the Company relies, including causing disruptions in the supply of the Company's product candidates and the conduct of current and planned preclinical and clinical studies. We may need to limit operations or implement limitations, and may experience limitations in employee resources. There are risks that it may be more difficult to contain if the outbreak reaches a larger population or broader geography, in which case the risks described herein could be elevated significantly. The extent to which the coronavirus impacts our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others. Additionally, while the potential economic impact brought by, and the duration of, the coronavirus pandemic is difficult to assess or predict, the impact of the coronavirus on the global financial markets may reduce the Company's ability to access capital, which could negatively impact the Company's short-term and long-term liquidity and the Company's ability to complete its preclinical studies on a timely basis, or at all. The ultimate impact of coronavirus is highly uncertain and subject to change. The Company does not yet know the full extent of potential delays or impacts on its business, financing or preclinical and clinical trial activities or the global economy as a whole. However, these effects could have a material impact on the Company's liquidity, capital resources, operations and business and those of the third parties on which we rely.

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 (who is also acting as our principal financial officer) and our Principal Accounting 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 the 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, with the participation of our Chief Executive Officer (who is also acting as our principal financial officer) and our Principal Accounting Officer, concluded that our disclosure controls and procedures were effective as of such date.

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, 2019. 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, with the participation of our Chief Executive Officer (who is also acting as our principal financial officer) and our Principal Accounting Officer, concluded that, as of December 31, 2019, 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

There have been no changes in our internal control over financial reporting that occurred during the year ended December 31, 2019 that has materially affected, or is 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 current directors and executive officers, their ages and the positions currently held by each person:

Name	Age	Position
Gerrit Dispersyn, Dr. Med. Sc.	45	President and Chief Executive Officer
Robert J. Bitterman	68	Chairman of the Board of Directors
Geert Cauwenbergh, Dr. Med. Sc.	65	Director
H. Paul Dorman	83	Director
Robert L. Ferrara	68	Director
Jonathan E. Freeman, Ph.D.	51	Director
Curtis A. Lockshin, Ph.D.	59	Director

Gerrit Dispersyn, Dr. Med. Sc. joined the Company in April 2017 as our Chief Development Officer and became our President and CEO in March 2019. From 2014 to April 2017, Dr. Dispersyn was the Vice President, Global Head of Affairs at Integra LifeSciences Corporation, a world leader in medical technology. Prior to assuming this role, Dr. Dispersyn held the position of Vice President, Program Management & Clinical Affairs from 2008 to 2014. In these positions, Dr. Dispersyn was responsible for the global strategy and execution of clinical and product development, clinical operations and medical affairs projects. 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 served as the President and Chief Executive Officer of Cutanea Life Sciences, Inc., a private company he founded in 2005 that focused on developing innovative technologies to treat diseases and disorders of the skin and subcutaneous tissue, until its acquisition by Biofrontera, Inc., USA in March 2019. Prior to his role at Cutanea Life Sciences, Inc., Mr. Bitterman 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 Human Letters (Honoris Causa) from the New York College of Podiatric Medicine and is a member of the Philadelphia Business Leaders Network.

Geert Cauwenbergh, Dr. Med. Sc. has served as a member of our Board of Directors since April 2012. He served as our President and Chief Executive Officer from April 2012 to November 2018, and as our Chief Executive Officer from November 2018 until his retirement in March 2019. Dr. Cauwenbergh served as Chairman and Chief Executive Officer of RHEI Pharmaceuticals, Inc., a private company that develops and commercializes proprietary drug therapies, from 2008 to 2011. In 2001, Dr. Cauwenbergh founded Barrier Therapeutics, Inc., a biopharmaceutical company focused on dermatology drug development, until its acquisition by Stiefel Laboratories, Inc. in 2008. Prior to Barrier Therapeutics, Inc. Dr. Cauwenbergh was employed by Johnson & Johnson for 23 years where he held a number of ascending senior management positions. He currently serves as a director of Moberg Pharma AB and Cutanea Life Sciences, Inc. 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.

H. Paul Dorman has served as a member of our Board of Directors since April 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, Mr. Dorman was employed by Johnson & Johnson for 12 years, where he served in various positions, including Vice President and as a member of the board of directors of several Johnson & Johnson companies. 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.

Robert L. Ferrara has served as a member of our Board of Directors since October 2019. He most recently served as the Chief Financial Officer of Cutanea Life Sciences, Inc., a private company focused on developing innovative technologies to treat diseases and disorders of the skin and subcutaneous tissue, from January 2012 to June 2019. Prior to Cutanea, Mr. Ferrara served as the Chief Financial Officer of Storeroom Solutions Inc., a venture capital financed, technology enhanced, integrated supply chain solutions company, from 2004 to 2011, and NER Data Products, Inc., an IT service management company, from 2000 to 2003, as well as holding other senior level financial positions in national and international public companies in the greater Philadelphia area. Mr. Ferrara previously served on the board of directors of the Planned Lifetime Assistance Network of Pennsylvania, where he was on the executive committee and chairman of the governance and audit committees from July 2011 to September 2013. Mr. Ferrara received a B.S. in Accounting from Lehigh University and is a Certified Public Accountant.

Jonathan E. Freeman, Ph.D. has served has a member of our Board of Directors since June 2017. Dr. Freeman currently serves as the Chief Operating Officer of Anthos Therapeutics Inc., a clinical-stage biopharmaceutical company developing therapies for cardiovascular patients. Anthos Therapeutics Inc. was launched by Novartis and Blackstone Life Sciences, a private investment firm, where Dr. Freeman has also served as a Senior Advisor since July 2018. From 2017 to June 2018, Dr. Freeman held the position of Chief Business Officer of Vedanta Biosciences, a clinical-stage company developing therapies for immune-mediated diseases. Prior to his role with Vedanta Biosciences, Dr. Freeman was the Senior Vice President of Strategy and Portfolio Management and Head of Business Development and Licensing at Merck KGaA, a leading science and technology company, from 2008 to 2016. Dr. Freeman received a Ph.D. in Molecular Pharmacology and Drug Metabolism from the Imperial Cancer Research Fund (now CRUK), an M.A. and First Class Honours in Biochemistry from Cambridge University and a MBA with a finance major from Webster, St. Louis.

Curtis A. Lockshin, Ph.D. has served as a member of our Board of Directors since April 2013. Dr. Lockshin currently serves as the Chief Scientific Officer of Xenetic Biosciences, Inc., a biopharmaceutical company focused on the development of novel oncology therapeutics. Prior to this appointment, Dr. Lockshin served as Xenetic Biosciences, Inc.'s Vice President of Research and Operations from March 2014 to January 2017. From July 2016 to December 2016, Dr. Lockshin served as Chief Technical Officer of VBI Vaccines, Inc., a company developing vaccines in infectious disease and immuno-oncology. VBI Vaccines, Inc. merged with SciVac Therapeutics, Inc. and its subsidiary SciVac, Ltd., a commercial-stage biologics and vaccine company, in July 2016 where Dr. Lockshin had served as its Chief Executive Officer and director since September 2014. Since May 2013, Dr. Lockshin has also served as President and Chief Executive Officer of Guardum Pharmaceuticals, LLC, a private pharmaceutical company, and as Vice President of Corporate R&D Initiatives for OPKO Health, Inc., a multinational pharmaceutical and diagnostics company, from October 2011 to February 2013. Dr. Lockshin holds a S.B. degree in Life Sciences and a Ph.D. in Biological Chemistry from the Massachusetts Institute of Technology.

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 comprised of Messrs. Ferrara (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 Exchange Act and the current Nasdaq independence standards, and the Board has determined that Mr. Ferrara is an "audit committee financial expert," as the SEC has defined that term in Item 407 of Regulation S-K.

Compensation Committee. The Compensation Committee is comprised of Messrs. Bitterman (Chairman) and Ferrara 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 Governance Committee. The Nominating and 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.

Delinquent Section 16(a) Reports

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 2019, 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 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, 2019 are Gerrit Dispersyn, Dr. Med. Sc., our President and Chief Executive Officer, Geert Cauwenbergh, Dr. Med. Sc., our former Chief Executive Officer and John Barrett, Ph.D., our former Chief Development Officer.

Name and principal position	Year	Salary ($)	Option awards ($)[1]	Stock awards ($)[1]	Non-equity incentive plan compensation ($)[2]	All other compensation ($)[3]	Total ($)
Gerrit Dispersyn, Dr. Med. Sc. [4]	2019	372,251	–	117,662	168,935	534	659,382
President and Chief Executive Officer	2018	315,558	27,504	28,640	52,800	454	424,956
Geert Cauwenbergh, Dr. Med. Sc. [5]	2019	131,654[6]	–	–	–	152	131,806
Former Chief Executive Officer	2018	420,366[6]	36,099	37,590	115,775[6]	606	610,436
John Barrett, Ph.D. [7]	2019	156,742	–	103,691	–	161	260,594
Former Chief Development Officer							

(1) The amounts shown reflect the grant date fair value of stock options and restricted stock units computed in accordance with ASC 718 for the indicated year.

(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 2019 was paid in March 2020 and the annual cash bonus for fiscal year 2018 was paid in February 2019. In 2019, Dr. Dispersyn received a retention bonus.

(3) Represents amounts for the dollar value of life insurance premiums paid.

(4) 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.

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

(6) 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 vesting in full on June 1, 2019. In lieu of cash compensation, Dr. Cauwenbergh received: a.) 1,647 shares of common stock related to $32,385 in base salary for the year ended December 31, 2019 and b.) 2,484 shares of common stock related to $56,673 of base salary and 2,771 shares of common stock related to $57,887 of bonus compensation for the year ended December 31, 2018. The shares of restricted stock issued to the Company's former Chief Executive Officer are described more fully in the notes to the Company's consolidated financial statements.

(7) Dr. Barrett became our Chief Development Officer effective April 22, 2019. In October 2019, Dr. Barrett resigned from his position with the Company to pursue another opportunity.

Outstanding Equity Awards at Fiscal Year-End

The following table shows information regarding outstanding equity awards as of December 31, 2019 for our named executive officers:

		Option Awards				Stock Awards			
Name	Grant Date	Number of Securities Underlying Unexercised Options (# Exercisable)	Number of Securities Underlying Unexercised Options (# Unexercisable)	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)	Equity Incentive Plan Awards: Number of Unearned Shares or Units of Stock That Have Not Vested (#)	Equity Incentive Plan Awards: Market Value of Unearned Shares or Units of Stock That Have Not Vested ($)[1]
Gerrit Dispersyn,	4/24/2017	115	58	357.50	4/24/2027	–	–	–	–
Dr. Med. Sc.[2]	8/1/2018	73	218	98.45	8/1/2028	–	–	218	2,051
	2/13/2019	–	–	–	–	–	–	1,000	9,410
	10/24/2019	–	–	–	–	–	–	7,413	69,756
Geert Cauwenbergh,	6/8/2012	207	–	14,025.00	6/8/2022	–	–	–	–
Dr. Med. Sc.[3]	6/7/2013	24	–	33,000.00	6/7/2023	–	–	–	–
	6/2/2014	24	–	15,675.00	6/2/2024	–	–	–	–
	6/1/2015	24	–	2,090.00	6/1/2025	–	–	–	–
	2/10/2016	23	1	1,573.00	2/10/2026	–	–	–	–
	2/1/2017	17	7	345.95	2/1/2027	–	–	–	–
	8/1/2018	95	286	98.45	8/1/2028	–	–	286	2,691
John Barrett, Ph.D.	–	–	–	–	–	–	–	–	–

(1) Value is based on the closing price of $9.41 of the Company's common stock on December 31, 2019.

(2) The equity award granted to Dr. Dispersyn in 2017 vests in equal monthly installments over a four years. The equity awards granted to Dr. Dispersyn subsequent to 2017, vest in equal annual installments over four years.

(3) 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. So long as Dr. Cauwenbergh remains on the Company's Board of Directors, awards granted to him during his employment with the Company will continue to vest after his retirement.

Nonqualified Deferred Compensation Earnings

We do not have any nonqualified deferred compensation plans.

Employment and Change of Control Agreements

The following provides descriptions of the employment agreements currently in effect for our named executive officers:

Gerrit Dispersyn, Dr. Med. Sc.

We entered into an employment agreement with Dr. Dispersyn effective April 24, 2017 as our Chief Development Officer. As Chief Development Officer Dr. Dispersyn was entitled to receive an initial base salary of $285,000 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. In connection with Dr. Dispersyn's appointment to Chief Development Officer, he received a stock option entitling him to purchase 173 shares of the Company's Common Stock, which is subject to vesting in equal monthly installments over four years following the date of grant.

On March 1, 2019, Dr. Dispersyn was appointed as the Company's President and Chief Executive Officer. As President and Chief Executive Officer, Dr. Dispersyn is entitled to an initial base salary of $380,000 per annum, as well as a performance bonus of up to 50% of his base salary, subject to the achievement of performance goals to be established annually. As a one-time award in connection with his appointment on March 1, 2019, Dr. Dispersyn received a restricted stock unit award giving him the conditional right to receive 7,413 shares of Company Common Stock, which is subject to vesting in equal annual installments over four years. The award was subject to the Company's stockholders' approving an increase in the number of shares available for issuance under the Company's 2012 Incentive Plan, which occurred on October 24, 2019. Outside of the above-mentioned changes, Dr. Dispersyn's employment agreement dated April 24, 2017 continues to remain 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.

Dr. Cauwenbergh was appointed Chief Executive Officer pursuant to an employment agreement, dated April 27, 2012, pursuant to which he was entitled to receive an initial base salary of $360,000 per annum, as well as a performance bonus of up to 50% of his base salary, subject to the achievement of performance goals to be established annually.

Effective March 1, 2019, Dr. Cauwenbergh retired as our Chief Executive Officer. He did not receive any severance benefits in connection with his termination of employment.

John Barrett, Ph.D.

Dr. Barrett was appointed Chief Development Officer pursuant to an employment agreement, dated April 22, 2019, pursuant to which he was entitled to receive an initial base salary of $315,000 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.

Effective October 24, 2019, Dr. Barrett resigned from his position with the Company to pursue another opportunity. He did not receive any severance benefits in connection with his termination of employment.

Director Compensation

We compensate our non-employee directors for their service as a member of our Board. Each non-employee director is entitled to receive an annual cash retainer of $27,500. The chairs of our Board and Audit Committee are entitled to receive an additional annual cash retainer of $15,000, the chair of the Compensation Committee is entitled to receive an additional cash retainer of $5,000 and the chair of the Nominating and Corporate Governance Committee is entitled to receive an additional annual cash retainer of $7,500.

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.

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 following table shows the compensation paid in fiscal year 2019 to the Company's non-employee directors.

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)[1]	Total ($)
Robert J. Bitterman[2]	60,000	3,632	63,632
Keith L. Brownlie[3]	29,167	3,632	32,799
Geert Cauwenbergh, Dr. Med. Sc.[4]	123,726	–	123,726
H. Paul Dorman	25,000	3,632	28,632
Robert L. Ferrara [5]	18,333	–	18,333
Jonathan E. Freeman, Ph.D.	25,000	3,632	28,632
Curtis A. Lockshin, Ph.D.	30,000	3,632	33,632

(1) The amounts shown reflect the grant date fair value of restricted stock units issued in fiscal year 2019 as computed in accordance with ASC 718.
(2) Mr. Bitterman's fees include his annual compensation and compensation of $25,000 related to increased activity as Chairman of the Board during fiscal year 2019.
(3) Mr. Brownlie did not stand for re-election to the Board at the Company's Annual Meeting of Stockholders held on October 24, 2019 and served as a director until the end of his term.
(4) Dr. Cauwenbergh continued to serve as a member of the Board upon his retirement from the Company as Chief Executive Officer on March 1, 2019. The Company also entered into a consulting agreement with Dr. Cauwenbergh upon his retirement on March 1, 2019. Dr. Cauwenbergh's fees include his annual compensation, compensation of $12,500 for a special project to the Board to aid in the transition to the new Chief Executive Officer upon his retirement and $90,393 in consulting fees for fiscal year 2019.
(5) Mr. Ferrara was elected to the Board on October 24, 2019. Mr. Ferrara's fees include his annual compensation and a sign-on retainer of $12,500.

As of December 31, 2019, the aggregate number of shares underlying stock options and restricted stock units by our non-employee directors is as follows: Robert J. Bitterman — 22 option awards and 182 restricted stock units, Keith L. Brownlie — 22 option awards, H. Paul Dorman — 19 option awards and 182 restricted stock units, Jonathan E. Freeman, Ph.D. — 6 option awards and 182 restricted stock units and Curtis A. Lockshin, Ph.D. — 19 option awards and 182 restricted stock units. Refer to the "Executive Compensation" section for the aggregate number of shares underlying stock options and restricted stock units for Dr. Cauwenbergh as of December 31, 2019.

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, 2019, 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[(1)]	17,594	$ 3,298.90	53,864
Equity compensation plans not approved by security holders	–	–	–
Total	17,594	$ 3,298.90	53,864

(1) Includes options outstanding representing 2,649 shares of common stock under Plan. Also includes 14,945 restricted stock units subject to the Plan.

Beneficial Ownership

Based on information available to us and filings with the 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 executive officers, (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 January 14, 2020 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 through the exercise of any option, warrant or right within 60 days of January 14, 2020 are deemed outstanding for the purpose of computing the percentage ownership of the person holding the option, warrant or right, 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.

	Shares Beneficially Owned	
Name of Beneficial Owner	**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	36,341	5.42%
Directors and Executive Officers:		
Gerrit Dispersyn, Dr. Med. Sc. [4]	8,718	1.30%
Robert J. Bitterman[5]	5,851	*
Geert Cauwenbergh, Dr. Med. Sc.[6]	13,027	1.94%
H. Paul Dorman[7]	392	*
Robert Ferrara	2,318	*
Jonathan E. Freeman, Ph.D. [8]	369	*
Curtis A. Lockshin, Ph.D.[9]	386	*
All current directors and executive officers as a group (seven persons)	31,061	4.61%

* Indicates less than 1%.

(1) Represents shares of common stock held as of January 14, 2020 plus shares of common stock that may be acquired upon exercise of options, warrants or rights within 60 days of January 14, 2020.

(2) Based on 669,589 shares of common stock that were issued and outstanding as of January 14, 2020. The percentage ownership and voting power for each person (or all directors and executive officers as a group) is calculated by assuming the exercise of all options, warrants or rights within 60 days of January 14, 2020 held by such person and the non-exercise of all outstanding options, warrants or rights 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) Includes 6,420 shares of common stock and 2,298 shares of common stock underlying derivative securities exercisable within 60 days of January 14, 2020.

(5) Includes 5,644 shares of common stock and 207 shares of common stock underlying derivative securities exercisable within 60 days of January 14, 2020.

(6) Includes 12,542 shares of common stock and 485 shares of common stock underlying derivative securities exercisable within 60 days of January 14, 2020.

(7) Includes 188 shares of common stock and 204 shares of common stock underlying derivative securities exercisable within 60 days of January 14, 2020.

(8) Includes 181 shares of common stock and 188 shares of common stock underlying derivative securities exercisable within 60 days of January 14, 2020.

(9) Includes 184 shares of common stock and 202 shares of common stock underlying derivative securities exercisable within 60 days of January 14, 2020.

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

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. 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.

Outside of the Company's consulting agreement with Dr. Cauwenbergh (refer to the "Director Compensation" section for additional details), 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 "Executive Compensation" and "Director Compensation."

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.

Director Independence

We believe that the Company benefits from having a strong and independent Board of Directors. 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 of Directors 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 ACCOUNTING FEES AND SERVICES***

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 2019 and 2018 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.

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, 2019 and 2018. These fees are for work invoiced in the fiscal years indicated.

	2019	2018
Audit Fees	$ 204,545	$ 243,197
Audit-Related Fees	–	–
Tax Fees	–	–
All Other Fees	–	–
Total All Fees	$ 204,545	$ 243,197

Audit Fees consist of fees for the audit of the Company's financial statements included in our annual reports on Form 10-K, the review of the Company's financial statements included in our quarterly reports on Form 10-Q and other statutory and regulatory filings, including auditor consents.

Audit-Related Fees consist of fees billed for assurance and related services that are also performed by our independent registered public accounting firm.

Tax Fees consist of services rendered for tax compliance, tax advice and tax planning.

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
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	Certificate of Amendment to the Amendment and Restated Certificate of Incorporation of Phio Pharmaceuticals Corp.	Current Report on Form 8-K (File No. 001-36304)	January 14, 2020
3.3	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

4.7	Form of Underwriter Warrant.	Current Report on Form 8-K (File No. 001-36304)	October 5, 2018
4.8	Form of Placement Agent Warrant.	Current Report on Form 8-K (File No. 001-36304)	November 19, 2019
4.9	Form of Warrant	Current Report on Form 8-K (File No. 001-36304)	February 6, 2020
4.10	Form of Warrant.	Current Report on Form 8-K (File No. 001-36304)	February 13, 2020
4.11	Form of Pre-Funded Warrant.	Current Report on Form 8-K (File No. 001-36304)	February 13, 2020
4.12	Form of Underwriter Warrant.	Current Report on Form 8-K (File No. 001-36304)	February 13, 2020
4.13	Description of Securities Registered Pursuant to Section 12(b) of the Securities Exchange Act of 1934.**		
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	Phio Pharmaceuticals Corp. 2012 Long Term Incentive Plan.*	Quarterly Report on Form 10-Q (File No. 001-36304)	November 12, 2019
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 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

10.9	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
10.10	First Amendment to Lease dated January 22, 2019.	Current Report on Form 8-K (File No. 001-36304)	January 28, 2019
10.11	Purchase Agreement, dated as of August 8, 2017 by and between Phio Pharmaceuticals Corp. and Lincoln Park Capital Fund, LLC.	Registration Statement on Form S-1 (File No. 333-220062)	August 18, 2017
10.12	Registration Rights Agreement, dated as of August 8, 2017, by and between Phio Pharmaceuticals Corp. and Lincoln Park Capital Fund, LLC.	Current Report on Form 8-K (File No. 001-36304)	August 9, 2017
10.13	Purchase Agreement, dated as of August 7, 2019 by and between Phio Pharmaceuticals Corp. and Lincoln Park Capital Fund, LLC.	Current Report on Form 8-K (File No. 001-36304)	August 9, 2019
10.14	First Amendment to Purchase Agreement by and between Phio Pharmaceuticals Corp. and Lincoln Park Capital Fund, LLC.	Registration Statement on Form S-1 (File No. 333-233584)	August 30, 2019
10.15	Registration Rights Agreement, dated as of August 7, 2019, by and between Phio Pharmaceuticals Corp. and Lincoln Park Capital Fund, LLC.	Current Report on Form 8-K (File No. 001-36304)	August 9, 2019
10.16	Securities Purchase Agreement, dated February 4, 2020, by and between the Company and the Purchasers signatory therein.	Current Report on Form 8-K (File No. 001-36304)	February 6, 2020
23.1	Consent of BDO USA, LLP, an Independent Registered Public Accounting Firm.**		
31.1	Sarbanes-Oxley Act Section 302 Certification of Principal Executive Officer and Principal Financial Officer.**		
32.1	Sarbanes-Oxley Action Section 906 Certification of Principal Executive Officer and Principal Financial Officer.**		
101	The following financial information from the Annual Report on Form 10-K of Phio Pharmaceuticals Corp. for the year ended December 31, 2019, formatted in XBRL (eXtensible Business Reporting Language): (1) Consolidated Balance Sheets as of December 31, 2019 and 2018; (2) Consolidated Statements of Operations for the Years Ended December 31, 2019 and 2018; (3) Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2019 and 2018; (4) Consolidated Statements of Cash Flows for the Years Ended December 31, 2019 and 2018; 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 26, 2020

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 26, 2020
/s/ Caitlin Kontulis Caitlin Kontulis	Vice President of Finance and Administration and Secretary (Principal Accounting Officer)	March 26, 2020
/s/ Robert J. Bitterman Robert J. Bitterman	Director	March 26, 2020
/s/ Geert Cauwenbergh Geert Cauwenbergh, Dr. Med. Sc.	Director	March 26, 2020
/s/ H. Paul Dorman H. Paul Dorman	Director	March 26, 2020
/s/ Robert L. Ferrara Robert L. Ferrara	Director	March 26, 2020
/s/ Jonathan E. Freeman Jonathan E. Freeman, Ph.D.	Director	March 26, 2020
/s/ Curtis A. Lockshin Curtis A. Lockshin, Ph.D.	Director	March 26, 2020

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of the date of the Annual Report on Form 10-K of which this exhibit is a part, Phio Pharmaceuticals Corp. (the "Company" or "we" or "our") has one class of security registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"): our common stock, par value $0.0001 per share ("common stock").

Description of Common Stock

The following description of our common stock is a summary and does not purport to be complete. It is subject to and qualified in its entirety by reference to our Amended and Restated Certificate of Incorporation, as amended (the "certificate of incorporation") and our Amended and Restated Bylaws (the "bylaws"), each of which are incorporated by reference as an exhibit to the Annual Report on Form 10-K of which this exhibit is a part. We encourage you to read our certificate of incorporation, our bylaws and the applicable provisions of the Delaware General Corporation Law (the "DGCL") for additional information.

General

Authorized Shares. We are authorized to issue up to 100,000,000 shares of common stock.

Voting Rights. The holders of our common stock are entitled to one vote per share on all matters to be voted upon by the stockholders. When a quorum is present at any meeting of our stockholders, the affirmative vote of a majority of the votes properly cast on the matter (excluding any abstentions or broker non-votes) will be the act of the stockholders with respect to all matters other than the contested election of directors (which will be elected by a plurality of all votes properly cast), or as otherwise provided in the bylaws, the certificate of incorporation or a preferred stock designation, or as otherwise required by law.

Dividends. Subject to preferences that may be applicable to any outstanding preferred stock, the holders of our common stock are entitled to receive ratably all dividends, if any, as may be declared from time to time by our Board of Directors out of the funds legally available.

Other Rights. In the event of the liquidation, dissolution or winding up of the Company, the holders of our common stock are entitled to share ratably in all assets remaining after payment of liabilities, subject to prior distribution rights of preferred stock, if any, then outstanding. The common stock has no preemptive or conversion rights. There are no redemption or sinking fund provisions applicable to the common stock. All outstanding shares of common stock are fully paid and non-assessable.

Transfer Agent and Registrar. The transfer agent and registrar for our common stock is Computershare Trust Company N.A.

Listing. Our common stock is currently listed on The Nasdaq Capital Market under the symbol "PHIO".

Certain Provisions Affecting Control of the Company

Certificate of Incorporation and Bylaw Provisions. Some provisions of the DGCL and our certificate of incorporation and bylaws contain provisions that could make the following transactions more difficult:

- acquisition of us by means of a tender offer;
- acquisition of us by means of a proxy contest or otherwise; or
- removal of our incumbent officers and directors.

These provisions, summarized below, are intended to discourage coercive takeover practices and inadequate takeover bids and to promote stability in our management. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our Board of Directors.

Undesignated Preferred Stock. The ability to authorize undesignated preferred stock makes it possible for our Board of Directors to issue one or more series of preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of us. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management of our company.

Advance Notice Procedures. The advance notice procedures in our bylaws with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of our stockholders provide that notice of stockholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at our principal executive offices not less than 90 days nor more than 120 days prior to the first anniversary date of the annual meeting for the preceding year. Our bylaws specify the requirements as to form and content of all such stockholder notices. These requirements may have the effect of precluding stockholders from bringing proposals relating to the nomination of candidates for election as directors or new business before the stockholders at an annual or special meeting.

Delaware Anti-Takeover Statute. We are subject to Section 203 of the DGCL. This law prohibits a publicly held Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date that the stockholder became an interested stockholder unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding those shares owned by persons who are directors and also officers and by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or subsequent to the date of the transaction, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 of the DGCL defines “business combination” to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the corporation’s assets involving the interested stockholder;
- in general, any transaction that results in the issuance or transfer by the corporation of any of its stock to the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 of the DGCL defines an “interested stockholder” as an entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

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 Statements on Forms S-8 (Nos. 333-183633, 333-189521, 333-189522, 333-215870, 333-215871, 333-227013, 333-2350547 and 333-236784) and Form S-3 (No. 333-224031) of Phio Pharmaceuticals Corp. of our report dated March 26, 2020, relating to the consolidated financial statements, which appears in this Form 10-K.

/s/ BDO USA, LLP

Boston, Massachusetts
March 26, 2020

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL 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, 2019;

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 26, 2020

/s/ Gerrit Dispersyn

Gerrit Dispersyn, Dr. Med. Sec.
President and Chief Executive
(Principal Executive Officer and Principal Financial 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, 2019 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
(Principal Executive Officer and Principal Financial Officer)

Dated: March 26, 2020