2020

Phio Pharmaceuticals Corp.

Annual Report

Dear Shareholder,

When we wrote our letter to you last year, we were just at the beginning of the SARS-CoV-2 global pandemic, and no one could have predicted its duration and impact. As we continue to see progress toward a full recovery, we can all agree that the biopharmaceutical industry has been playing a crucial role in this path back to normalcy. We applaud the companies, and their employees, that have been delivering highly effective vaccines in record time.

At Phio, we are proud to be part of the biotech community and to be working on powerful RNA therapeutics. RNA is a component in all living cells and essential in various biological roles in coding, decoding, regulation and expression of genes. Thus it can be used as a platform for a new generation of drugs, including the most successful COVID-19 vaccines to date. Indeed, messenger RNA (mRNA) is a key component of the Pfizer/BioNTech and Moderna vaccines (and several others in development). With this version of RNA technology, the expression of a certain protein - encoded by the mRNA - can be induced or increased. Phio's approach to the use of RNA based therapeutics is RNA interference (RNAi), a biological process in which RNAi molecules inhibit gene expression or translation, by neutralizing targeted mRNA molecules. As a result, the target protein is no longer expressed, or expressed at lower levels. Since many diseases can be prevented or cured by either increasing or decreasing the levels of a certain protein, RNA technology has a long and bright future.

Phio focuses its product development efforts on the development of therapies that stimulate the immune system to fight cancer. We are using a proprietary RNAi technology platform, named INTASYL™, to develop novel, powerful, immune stimulating cancer treatments (immuno-oncology therapeutics) by silencing proteins that tumors use to evade the immune response. One of the key differentiating features of our INTASYL platform as compared to other RNA technologies, is that our INTASYL compounds are "self-delivering". This means that they do not need any complex formulations or tools to deliver the RNA molecules into the cell. Cell delivery is critical for RNA-based technologies for their function. Technologies that require lipid nanoparticles for the cell delivery of their RNA molecules are costly and complex. In contrast, Phio's INTASYL technology does not require such lipid-based formulations for fast and efficient uptake in cells. This is one of our key advantages. To put in context, issues with supply and manufacturing of lipid-based ingredients for the mRNA based coronavirus vaccines have been some of the key factors limiting the vaccine availability to date.

We believe the following vision, mission and strategy statements summarize well who we are, what we do, what we want to achieve, and how we go about it:

OUR VISION

To improve the lives of cancer patients around the world by expanding the immuno-oncology therapeutics armamentarium with better treatment options to treat and cure cancer.

OUR MISSION

To develop innovative cancer treatments that overcome tumor immunosuppression and weaponize the patient's immune system to attack the cancer without the need for genetic modification.

OUR STRATEGY

To maximize the value of our self-delivering RNAi technology in the immuno-oncology space by developing a product pipeline of self-delivering RNAi therapeutics in collaboration with leading companies and academic centers.

Our 2 strategic initiatives are:

1. To partner with leading companies to reprogram immune cells with increased anti-tumor effectiveness for use in next-generation adoptive cell therapy (ACT) products

2. To independently develop immuno-oncology therapeutics targeting the immunosuppressive tumor micro-environment (TME)

Our Immuno-Oncology Approach

The value proposition of Phio's technology in immuno-oncology lies in unlocking the full potential of immune cells by increasing their functionality. Our technology can be used in two ways: (1) we can directly increase the functionality of immune cells used in adoptive cell therapy (ACT), and (2) we can reduce the immunosuppressive nature of the TME by directly reprogramming immune cells within the tumor micro-environment (TME). In contrast to other available technologies, we believe we have many benefits, including high specificity and efficiency, lower cost and complexity, less safety concerns and lower regulatory hurdles.

We believe that our INTASYL platform uniquely positions our company in the field of immuno-oncology. Phio's proprietary INTASYL technology enables easy, precise, rapid, and selective reprograming of immune cells, thus providing a unique approach to immuno-oncology therapy. More specifically, INTASYL based therapeutics can "silence" (down-regulate) the expression of a specific gene which is over-expressed or otherwise implicated in cancer. As such, we develop therapeutics that can silence tumor-induced suppression of the immune system, which have utility both in immune cells and the TME of solid tumors. With our approach we can weaponize immune cells to overcome tumor immune escape, i.e. mechanisms by which tumor cells can avoid becoming killed by the immune system. In other words, INTASYL based therapeutics can result in improved tumor cell killing by immune cells. As such, we aim to provide patients with powerful new treatment options that go beyond current treatment modalities.

Our Pipeline Progress

PH-762

Our lead product candidate is PH-762, an INTASYL compound that targets the immune checkpoint protein PD-1. Checkpoint proteins, such as PD-1, normally act as a type of "off switch" that prevents immune cells, such as T cells, from attacking normal cells. Cancer cells can essentially hijack immune checkpoint signaling in order to suppress T cell activity and thereby prevent the immune system from attacking cancer cells. Such tumor induced suppression of T cells can be reversed by blocking or silencing PD-1 on immune cells, and this can be achieved with PH-762.

The development of direct therapeutic use of PH-762 (as a standalone drug) is one of our pipeline programs. A key challenge for many other immunotherapy platforms is to achieve an adequate therapeutic effect in solid tumors with an acceptable safety profile. Many of the available systemic immuno-therapeutics come with dose limiting immune-related adverse events, which we believe can be mitigated with local INTASYL treatment. With local administration of PH-762, we can reprogram the TME and achieve local activation of immune cells in the TME. Last year we presented animal studies highlighting the potential of such use of PH-762. Indeed, local administration of PH-762 through intra-tumoral injection resulted in potent anti-tumoral effects, whereby the treated animals showed a complete and statistically significant inhibition of tumor growth. In contrast, placebo treated animals displayed exponential tumor growth. Analysis of the tumor showed that PH-762 triggered an increase in tumor infiltrating lymphocytes (TILs), including $CD8^+$ T cells which are responsible for tumor cell killing. In addition, these T cells showed an increased expression of markers indicative of immune cell activation. These preclinical findings demonstrate that direct injection of INTASYL compounds can

successfully infiltrate solid tumors and impact the TME by activating the immune response in animal models of solid tumors resulting in reduced tumor growth. Based on our positive preclinical data, we are preparing for a clinical study with PH-762 using intra-tumoral administration for patients with advanced melanoma. The required preclinical studies and steps needed to initiate the clinical trial with PH-762 as a direct therapeutic are underway, and we expect to start the clinical trial in the fourth quarter of 2021.

Another development program with PH-762 is focused on improving the tumor cell killing activity of T cells used in adoptive cell therapy (ACT). ACT is a form of immune therapy based on the use of immune cells, isolated from patients, donors or retrieved from allogeneic immune cell banks. They are grown in a lab to large numbers, followed by administering them to the patient to fight cancer. With INTASYL compounds, we can unlock the full potential of ACT, by improving the immune cell function, differentiation and metabolism, in order to make these immune cells more effective. Using INTASYL is not only effective, but also very simple. INTASYL does not involve additional complicated manufacturing steps and/or genetic engineering. Since it does not require gene editing it does not come with any of the safety risks related to this technology. The use of INTASYL based compounds is as simple as adding them to the cell culture media used during the cell expansion phase. The compounds are then spontaneously taken up by all cells, and as such we can reduce or eliminate the expression of genes that make the immune cells less effective. For example, with PH-762, we can reduce the expression of the immunosuppressive protein PD-1 in T cells used for ACT, enabling them to overcome tumor resistance mechanisms and thus improving their ability to destroy the tumor cells. One form of ACT is to use the patient's own TILs. Data presented at SITC 2020 showed how PH-762 can activate TILs and increase their tumor cell killing ability. This research was performed in collaboration with AgonOx, Inc, a private company developing a proprietary TIL cell therapy referred to as "double positive" (DP) TILs. Together we have shown that by pretreating DP TILs with PH-762, we can increase their tumor cell killing rate by about two-fold. As a result, the use of PH-762 treated TILs is expected to enhance therapeutic responses in cancer. Based on these data, we recently announced that we will further collaborate with AgonOx on a clinical study with PH-762 treated DP TILs. This clinical trial in ACT with PH-762 and AgonOx's DP TIL technology is also expected to start later this year.

Other pipeline programs

While a significant amount of our focus and effort is related to the preparation of the two clinical studies mentioned above, we are continuing the development of other promising pipeline products. One of these product candidates is PH-894. This compound is in an earlier stage of development than PH-762, but exemplifies the potential of INTASYL. PH-894 is an INTASYL compound that targets BRD4 which is an intracellular regulator of gene expression that impacts cell differentiation, which is directly related to the function of a cell. Whereas this makes BRD4 an attractive target, it is a protein that has been shown to be hard to target with current technologies. Since it is an intracellular protein, antibody therapies cannot be used, and the small molecule inhibitors tested to date typically lack the required specificity. Considering INTASYL can target extracellular as well as intracellular proteins with a high level of specificity, PH-894 has significant potential. Data presented at the ASCO 2020 Virtual Scientific Meeting, showed that the use of PH-894 in a validated mouse model of hepatocellular carcinoma resulted in potent and statistically significant anti-tumoral effects. Based on this data we have started to work on the IND enabling studies for moving PH-894 into the clinical stage of development in 2022.

Other important findings from recent animal studies were presented at SITC 2020. The results demonstrated that INTASYL compounds can easily be combined in one therapeutic to achieve even higher antitumoral efficacy as seen with our individual pipeline products. We have shown that, in contrast to other technology platforms, we can efficiently target multiple proteins in a single drug treatment, and without negative consequences related to the potency of the individual components. The *in vivo* study results showed that a combination of our INTASYL compounds in a single formulation (at suboptimal doses of the individual agents)

inhibited tumor growth at a level higher than treatment with the individual components and without having a negative impact on the tolerability of the treatment.

Impact of the global pandemic and how we compensate

We took several proactive steps in response to challenges created by the coronavirus pandemic. For example, early on we engaged with third-party service providers in countries with limited or no impact. Unfortunately, with the global spread of the virus and ensuing restrictions, certain of our third-party suppliers and service providers have seen their operations becoming impacted. To date, the overall operational impact to us has been limited, but as the pandemic continues, the impact on our third-party suppliers and service providers continues to be a challenge. In response we have expanded our network of suppliers and service providers in order to reduce the risk, and to keep our preclinical and clinical activities on track as much as possible.

Moving to clinical development stage

Historically our operational spending has been about $2 million per quarter. As we are ramping up our activities in preparation for our clinical studies, we expect this to increase to about $3.5 million per quarter. In 2020, we created a development momentum that has resulted in positive investor response and share price appreciation. Based on this and the overall market conditions earlier this year, we were able to raise net proceeds of about $19.6 million. The appreciation of our share price also resulted in exercises of our outstanding warrants, providing us with an additional $2.1 million in cash inflows. The resulting improved cash position will allow us to fund our current programs for the next two years, including the execution of clinical studies on the safety and efficacy of PH-762 in adoptive cell therapy and of PH-762 as direct drug therapy. It will therefore allow us to execute towards important value inflection points related to clinical study start and clinical study data readouts.

Looking ahead

Even in a tumultuous year like 2020, we were able to stay focused and execute on our most important programs. We presented new and high-quality data at each of the large scientific conferences that are relevant to our business, including AACR, ASGCT, ASCO and SITC. In addition, behind the scenes we were working with clinicians and regulatory authorities to prepare for the clinical phase of development of our lead product candidate. We are committed to continue this level of execution in 2021, starting with a presentation of new data on the direct drug application of INTASYL at AACR in April. Thanks to our collaboration with AgonOx, more data will become available later this year on the use of INTASYL to improve adoptive cell therapy products.

The Phio team has shown that it is able to adapt, and to execute under difficult and changing circumstances imposed by the continuing pandemic. We owe it to our shareholders and to the patient community to overcome these additional challenges, and to remain dedicated to unlocking the value of our INTASYL platform.

On behalf of Phio Pharmaceuticals' employees, thank you for your investment to date, your continued support, your feedback and comments. Because of you we are moving closer to delivering on our corporate vision and to provide cancer patients with better treatment options to treat and cure their cancer.

Very truly yours,

Robert J. Bitterman
Chairman of the Board of Directors

Dr. Gerrit D. Dispersyn
President and Chief Executive Officer

2020 Form 10-K

2020

Phio Pharmaceuticals Corp.

Annual Report

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, 2020

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	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value, $0.0001 per share	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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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 30, 2020, was $12,583,469. 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 18, 2021, the registrant had 13,531,941 shares of Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Definitive Proxy Statement to be filed for Phio Pharmaceuticals Corp.'s 2021 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K.

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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 coronavirus pandemic;
- 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;
- 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 rely upon third parties for the manufacture of our 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;
- 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.

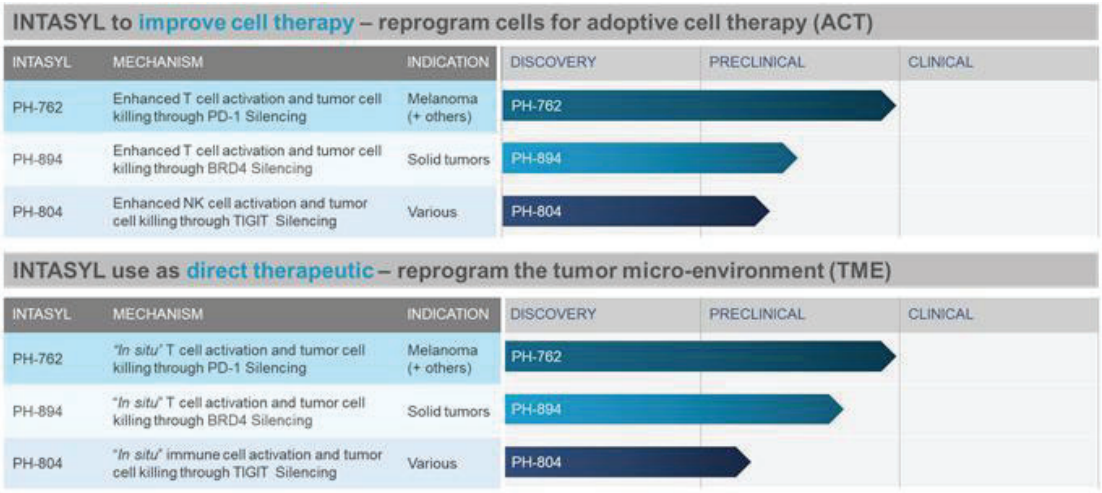
ITEM 1. *BUSINESS*

Overview

Phio Pharmaceuticals Corp. ("**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 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 potentially providing patients a powerful new treatment option that goes beyond current treatment modalities.

Our Development Pipeline

We have developed a product platform based on our INTASYL technology that allows easy, precise, rapid, and selective non-genetically modified programming of adoptive cell therapy ("**ACT**") cells (*ex vivo*, during manufacturing) and of the tumor micro-environment (the "**TME**") (*in vivo*, by local application), resulting in reduced immune inhibition and in improved immunotherapy. The table below sets forth the Company's stage of development for its programs and product candidates:



We believe our INTASYL platform uniquely positions the Company in the field of immuno-oncology for the following reasons:

- Efficient uptake of INTASYL by target cells obviating the need for facilitated delivery (mechanical or formulation);
- Does not require permanent genetic modification;
- 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.

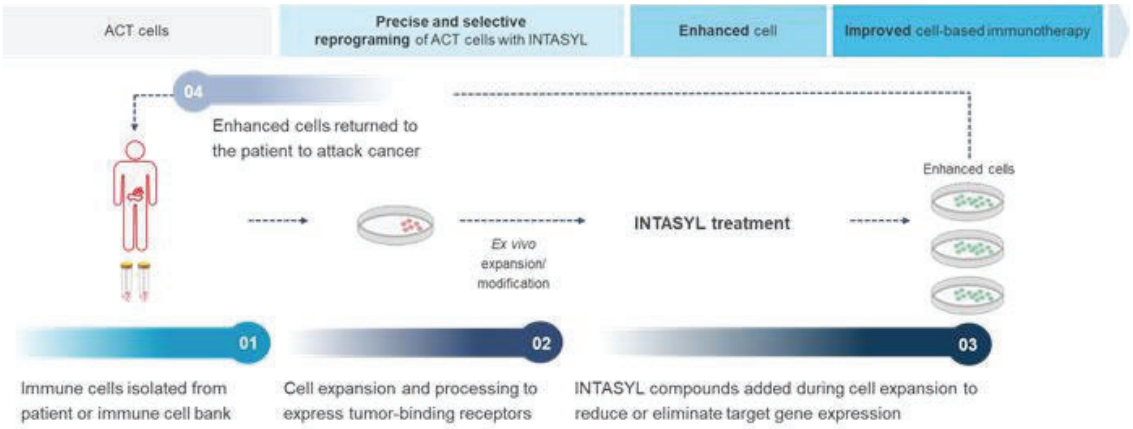
The self-delivering nature of our compounds makes INTASYL ideally suited for use with ACT treatments as well as for direct therapeutic use. ACT consists of the infusion of immune cells with antitumor properties, after growing them in a lab to large numbers. These cells can be derived from unmodified (i.e. naturally occurring) immune cells, immune cells isolated from resected tumors, or genetically engineered immune cells that recognize tumor cells. Regardless of the source of immune cells (ACT or naturally occurring immune cells), in patients with solid tumors, these cells have several shortcomings that inhibit their full therapeutic potential. By using INTASYL technology during the manufacturing of such ACT cell products we can improve the phenotype and function of these cells, potentially leading to better therapeutic outcomes. Multiple inhibitory mechanisms restrain immune cells from effectively eradicating tumors, including immune checkpoints, reduced cell fitness and cell persistence. Furthermore, the immunosuppressive TME can pose a formidable barrier to immune cell infiltration and function. By using INTASYL based drugs administered directly, we can reprogram cells in the TME to help overcome these immunosuppressive mechanisms.

INTASYL Use To Improve Adoptive Cell Therapy Products

ACT is a form of immune therapy based on the use of immune cells, isolated from patients, donors or retrieved from allogeneic immune cell banks. They are grown in a lab to large numbers, followed by administering them to the patient to fight cancer. Sometimes, immune cells that naturally recognize a tumor are used, while other times immune cells are modified or "genetically 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.) genetically 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).

Multiple inhibitory mechanisms restrain immune cells used in ACT from effectively eradicating tumors, including immune checkpoints, reduced cell fitness and cell persistence, and other barriers to immune cell infiltration and function mainly in solid tumors. We believe our INTASYL compounds are ideally suited to be used in ACT products. With INTASYL compounds, we can unlock the full potential of ACT, by improving the immune cell function, differentiation and metabolism, in order to make these immune cells more effective without the need for additional complicated manufacturing steps and/or genetic engineering.

Our approach builds on well-established methodologies of ACT and involves the treatment of immune cells with our INTASYL compounds *ex vivo* 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 by merely adding our INTASYL compounds during the expansion process and without the need for genetic engineering, without the need for complex delivery vehicles or formulations, and without additional needed complex manufacturing steps. By adding INTASYL to the cell culture media used during the cell expansion, we can 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 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 with close to 100% transfection efficiency and while maintaining nearly full cell viability. After expanding these cells and enhancing them with INTASYL *ex vivo*, they are returned to the patient for treatment.



Considering the significant growth of cell-based immunotherapy, a technology that can reprogram the immune cells used in ACT, such as INTASYL technology, is of key interest. 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 it can be easily integrated with cell manufacturing approaches.

Our lead product candidate and most advanced program being developed in ACT is PH-762, an INTASYL compound that targets the checkpoint protein PD-1. Checkpoint proteins, such as PD-1, normally act as a type of “off switch” that prevent T cells from attacking certain cells, such as cancer cells, in the body. Our T cells are immune cells that protect the body from cancer cells and infections.

Data developed by Phio and with collaborators has shown that PH-762 silences PD-1 checkpoint expression, thereby removing the “off switch” and resulting in enhanced T cell activation and tumor cytotoxicity. Experimental data shows that PH-762 can silence the expression of PD-1 in target human T cells in a potent and durable manner, and can increase the function of patient derived TILs for use in ACT, showing that PH-762 is applicable for use in both ACT and as a standalone direct therapeutic.

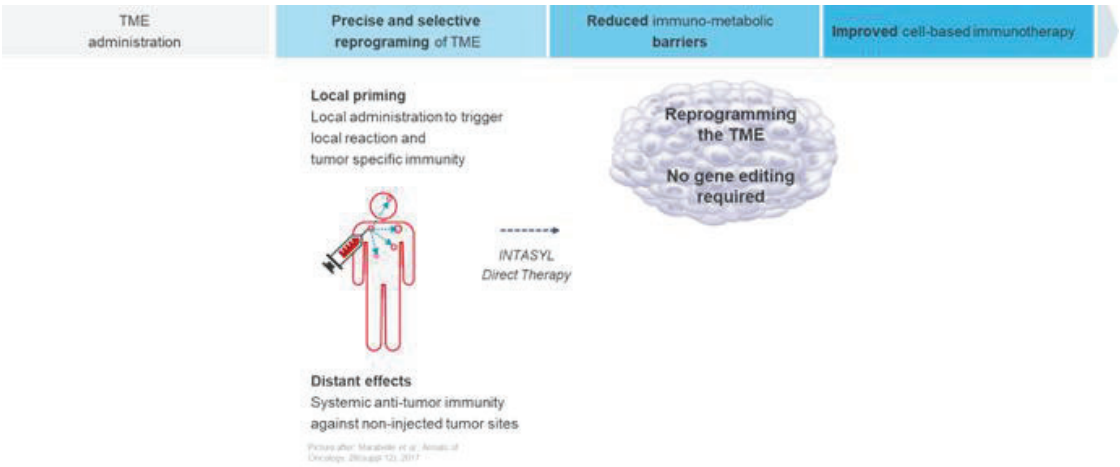
In March 2021, the Company announced that it entered into a clinical development collaboration with AgonOx, Inc. ("**AgonOx**"), a private company developing a pipeline of novel immunotherapy drugs targeting key regulators of the immune response to cancer. Under the agreement, the companies will collaborate on the development of novel T cell-based therapies using PH-762 and AgonOx's "double positive" (DP) TIL technology. AgonOx has demonstrated that their DP CD8+ T cells isolated from human solid tumors (DP TILs) have increased tumor killing activity when compared to TILs that were not enriched prior to expansion. Preclinical data from AgonOx in collaboration with Phio has shown that treating DP TIL with PH-762 increases the tumor killing activity of the DP TILs even further (a two-fold increase). As a result, the use of PH-762 treated DP TILs is expected to enhance therapeutic responses in cancer data. Based on these data showing that the combination of our technologies can result in TIL therapeutics, our collaboration will focus on conducting a clinical study for PH-762 treated DP TILs. Under the terms of the collaboration agreement, AgonOx will receive financial support for the clinical trial from Phio and Phio will be entitled to certain future development milestones and sales-related royalty payments from AgonOx's DP TIL technology. The clinical trial in ACT with PH-762 and AgonOx's DP TIL technology is expected to start in the third quarter of 2021.

Our second product candidate in ACT is PH-894, an INTASYL compound that targets BRD4 which is a regulator of gene expression impacting cell differentiation. In previous studies, PH-894 has been shown to improve T cell function and persistence by differentiating T cells into a more active state (stem-cell like memory phenotype). Data, completed in partnership with the Karolinska Institutet in Sweden, demonstrated that the application of PH-894, was shown to silence BRD4 in human T cells during expansion for ACT, which has the potential to confer superior anti-tumor activity, for example by improving T cell persistence. With this data, we expanded our collaboration with the Karolinska Institutet to build upon these findings and develop INTASYL compounds for additional targets and cell types toward clinical application in areas of the Karolinska Institutet's ongoing clinical research.

We are also developing our INTASYL compound PH-804 for use in ACT. PH-804 targets the suppressive immune receptor TIGIT, which is a checkpoint protein present on T cells and NK cells. We have shown that PH-804 can silence the expression of TIGIT in NK cells and T cells, overcoming their "off switch" and the cells becoming "weaponized" to kill cancer cells.

Direct Therapeutic Use of INTASYL Towards the 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. The TME is an immunosuppressive environment that inhibits the immune system's natural ability to recognize and destroy tumor cells by negatively impacting how immunosuppressive cells are being attracted and activated. Reprogramming different components of the TME may overcome 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 therapy. The Company has previously shown in a clinical setting that our INTASYL compounds are safe and well-tolerated following local administration, therefore we believe that our INTASYL technology can not only be used with ACT, but can also be used as an independent therapeutic platform.



We are developing our PH-762, PH-894 and PH-804 INTASYL compounds also for use as direct therapeutics to reprogram the TME through *in situ* transfection and activation of immune cells in the TME.

Animal studies conducted by the Company showed that local administration of PH-894 or the mouse version of PH-762 through intra-tumoral injection resulted in potent anti-tumoral effects. The treated animals showed a complete and statistically significant inhibition of tumor growth, whereas placebo treated animals displayed exponential tumor growth. *In vivo* studies performed by the Company with PH-804 showed that intra-tumoral injection of a mouse version of PH-804 reduced the tumor growth in colorectal carcinoma tumor bearing mice, which was shown to inhibit tumor growth and was correlated with the silencing of TIGIT mRNA expression and in increase in cytotoxic effector T cells in the TME.

The combined PH-804, PH-762, and PH-894 data further shows that INTASYL compounds can trigger associated changes in the TME such as an increase of TILs, including CD8+ T cells responsible for tumor cell killing, and an increase of activation markers on these cells. These preclinical findings demonstrate that direct injection of INTASYL compounds can successfully infiltrate solid tumors and impact the TME by activating the immune response in animal models of solid tumors resulting in reduced tumor growth. A key challenge for many other immunotherapy platforms is to be able to achieve an adequate therapeutic effect in solid tumors with an acceptable safety profile. Many of the available systemic immuno-therapeutics indeed come with dose limiting immune-related adverse events, which we believe can be mitigated with local INTASYL treatment.

Based on our positive preclinical data, the Company is preparing for a clinical study with PH-762 using intra-tumoral administration for patients with advanced melanoma. The required preclinical studies and steps needed to initiate the clinical trial with PH-762 as a direct therapeutic are continuing and ongoing. The clinical trial will be conducted at the Gustave Roussy Institute, which is France's largest cancer center and Dr. Caroline Robert will be our lead principal investigator. The Company expects to start the clinical trial evaluating the use of PH-762 as a direct therapeutic in the fourth quarter of 2021.

We are also investigating other relevant compounds for TME targets, such as PH-790, an INTASYL compound targeting PD-L1. PD-L1 is a protein formed by cancer cells that activate the PD-1 "off switch" on immune cells. Our approach with PH-790 is to block the formation of the PD-L1 protein, which may prevent cancer cells from inactivating T cells and attack the cancer. Recent data presented demonstrated that the antitumoral efficacy of our individual pipeline products, PH-762, PH-790 and PH-804, can be further improved by combining them in a single drug treatment. We have shown that, in contrast to other technology platforms, we can efficiently target multiple proteins, in a single drug treatment without negative consequences related to the potency of the individual components. Animal data showed that the combination of our INTASYL compounds in a single formulation (at suboptimal doses of the individual agents) inhibited tumor growth without having a negative impact on the tolerability of the treatment.

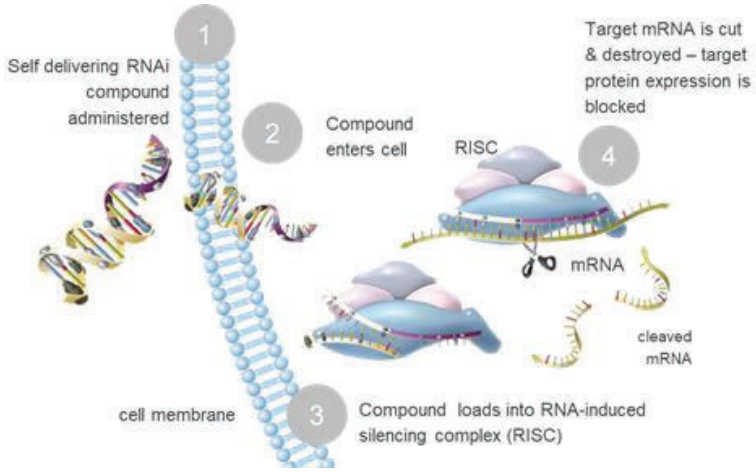
Our INTASYL Platform

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.

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 expression of proteins. RNA interference ("**RNAi**") is a biological process in which specific RNA molecules inhibit gene expression or translation into proteins. RNAi offers a novel approach to drug development because RNAi compounds can be designed to silence any one of the thousands of human genes, many of which are "undruggable" by other modalities. The potential of RNAi as a powerful drug development platform has been shown by several RNAi based drugs becoming approved over the last few years.

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 solution to the delivery problem involves encapsulation of siRNA into a lipid-based formulations, such as liposomes, to improve cellular uptake. Another approach is to use chemical conjugations of a ligand, such as GalNAC, for cell specific delivery limited to hepatocytes. We have developed an alternative approach where delivery and drug-like properties are built directly into the RNAi compound itself, whereby the RNAi uptake is neither dependent on complex formulation nor limited to addressing a specific cell type. 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. 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.



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.

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	19	46
Canada	7	5
Europe	9	47
Japan	13	12
Other Markets	19	9

Our portfolio includes 119 issued patents, 66 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 67 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).

Intellectual Property License Agreements

As we develop our own proprietary compounds, we continue to evaluate 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 intellectual property position.

Advirna LLC. On September 24, 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 and we granted back to Advirna a license for use of the assigned patent and technology rights outside of human therapeutics and diagnostics. Under the terms of the agreement, in April 2012, the Company issued to Advirna shares of common stock equal to 5% of the Company's fully-diluted shares outstanding at the time of issuance and paid a one-time milestone payment of $350,000 in 2014 upon the issuance of the first patent under the agreement. The Company also pays to Advirna an annual maintenance fee of $100,000 and is required to pay a low single-digit royalties on any license revenue received by the Company with respect to future licensing of the assigned Advirna patent and technology rights. To date, royalties owed to Advirna have been minimal.

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.

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, 2020 and 2019 was $4,431,000 and $4,300,000, 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: Achilles Therapeutics UK Ltd., Adicet Bio, Inc., AgonOx, 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., Fortress Biotech, Inc., GAIA Biomedicine Inc., Glycostem Therapeutics BV, Green Cross LabCell Corp., Immatics Biotechnologies GmbH, Iovance Biotherapeutics, Inc., 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, Turnstone Biologics Corp. 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: Avidity Biosciences, BioNTech NE, Cellectis S.A., CRISPR Therapeutics AG, Dicerna Pharmaceuticals, Inc., Editas Medicine, Inc., eTheRna immunotherapies NV, Exicure Inc., 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.

Human Capital Management

As of December 31, 2020, we had ten full-time employees at our facility in Marlborough, Massachusetts. None of our employees are represented by a labor union or covered by a collective bargaining agreement nor have we experienced any work stoppages.

We expect to add additional employees in fiscal year 2021 to increase our expertise and resources available in our preclinical and clinical research and development. We continually evaluate our business needs and weigh the use of in-house expertise and capacity with outsourced expertise and capacity. The Company currently outsources substantial preclinical and clinical trial work to third party contract research organizations and drug manufacturing contractors.

Our ability to identify, attract, retain and integrate additional qualified key personnel is also critical to our success and the competition for skilled research, product development, regulatory and technical personnel is intense. To attract qualified applicants to the Company, we offer a total rewards package consisting of base salary and cash target bonus based on geography and size of company, a comprehensive benefit package and equity compensation for every employee. Bonus opportunity and equity compensation increase as a percentage of total compensation based on level of responsibility. Actual bonus payout is based on performance.

A large majority of Phio's employees have obtained advanced degrees in their professions and we support our employees' further development with individualized development plans, mentoring, coaching, group training, conference attendance and financial support including tuition reimbursement.

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 coronavirus pandemic.

In December 2019, a novel strain of coronavirus that causes COVID-19 was reported to have surfaced in Wuhan, China and has since spread to other parts of the world, including the United States. In March 2020, the World Health Organization declared the outbreak a pandemic. The coronavirus pandemic is affecting the United States and global economies and as a result, government authorities have implemented restrictions and limited certain operations, such as limits on the number of people at a gathering, travel restrictions and stay-at-home orders, to try to slow the spread of coronavirus. The Company's facilities remain operational and are operating in accordance with federal and state governmental authority guidelines and with the implementation of safety measures such as social distancing protocols, suspending travel, the wearing of masks and frequently disinfecting our workspaces. Employee personnel who do not need to be physically present on our premises are continuing to work remotely, but have the ability to be on site as required. While the majority of these mandates have specific end dates, they may be modified or extended and as a result there is uncertainty regarding the length of time that such measures will be place. We believe the impact to our internal operations has not been material thus far, however, current and future restrictions may further impact our operations and may slow or diminish our research and development activities.

As a result of the coronavirus pandemic, certain of our third-party suppliers and service providers on which we rely have seen impacts to their operations. If the impact to their operations continue or extend, it may in turn affect our operations. The Company does not expect a material impact to its program's anticipated timelines as a result of potential delays from our third-party service providers and believes that we have a sufficient supply of our INTASYL compounds to conduct our ongoing preclinical studies and initial clinical activities. However, the ultimate impact to the third parties on which we rely is highly uncertain and subject to change. If the measures to contain the outbreak are extended or further expanded, it could reduce or delay the availability of supplies and services that we purchase and outsource, which may in turn slow or delay our preclinical and clinical activities, and/or result in higher costs. The extent to which the coronavirus pandemic 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 pandemic on the global financial markets may reduce the Company's ability to access capital and negatively affect our future liquidity.

The coronavirus pandemic continues to evolve and change rapidly. The ultimate impact of the coronavirus pandemic, or a similar public health emergency, 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 activities, preclinical studies, clinical trial activities or the global economy as a whole. However, these effects could have a material impact on the Company's liquidity, results of operations and financial condition.

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 currently in the preclinical development stage 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 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 pandemic. While the steps for us to initiate our clinical trials with PH-762 in the second half of 2021 are continuing and ongoing, 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 therapy company and expect to depend on third-party collaborators to support the clinical development of our ACT product candidates. We have entered into a clinical collaboration development agreement with AgonOx, Inc. for the clinical development of our PH-762 product candidate in ACT and 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. The success of our collaborations depends upon the efforts of our collaboration partners, and their performance in achieving the development activities to the extent they are responsible under our collaboration agreements. Each of our partners may not be successful in performing these activities, including completing the required preclinical studies and other information to be included in an IND application (or foreign equivalent), obtaining approval to initiate clinical trials, conducting the necessary clinical trials and arranging for the manufacturing or contract research organization ("**CRO**") relationships and obtaining marketing authorization. Our partners work with other companies, potentially including some of our competitors, and their corporate objectives may not align with ours, they may change their strategic focus or pursue alternative technologies. If our collaborations are not successful or a partner terminates our collaboration agreement, our business, financial condition, results of operations could be materially and adversely affected.

Further, we may not be successful in negotiating agreements with these collaborators or with future collaborators for 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 cell therapy 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 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, as a result of the coronavirus pandemic, certain of our contracted CROs and other third parties are now facing impacts to their operations, resulting in delays or interruptions. We previously had been able to engage with third-party service providers in areas with limited or no impact (e.g. countries with limited or no restrictions), but with the global spread of the virus and associated restrictions, this has been no longer possible. The Company has also undertaken efforts to mitigate potential future impact by identifying and engaging alternative third-party service providers and suppliers. However, the ultimate impact to the third parties on which we rely is highly uncertain and subject to change. If the measures to contain the coronavirus outbreak are extended or further expanded, it could reduce or delay the availability of supplies and services that we purchase and outsource, which may in turn slow or delay our preclinical and clinical activities, and/or result in higher costs. 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 activities and expect that we will rely on them for the supply of our product candidates 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.

We currently contract with multiple manufacturers for the supply of our clinical product candidates to reduce the risk of supply interruption or availability. However, 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 manufacturers, we would have to seek to contract with another major manufacturer. While we believe that we currently have sufficient supply of our INTASYL compounds to conduct our ongoing preclinical studies and initial clinical activities, we have begun to see some of our third-party supplies on which we rely becoming impacted from the coronavirus pandemic, which may result in delays or shortages due to ongoing efforts to address the pandemic. The Company has also undertaken efforts to mitigate potential future impact by identifying and engaging alternative third-party suppliers and manufacturers. However, the ultimate impact to these third parties on which we rely is highly uncertain and subject to change. If the measures to contain the outbreak are extended or further expanded, it could reduce or delay the availability of supplies and services that we

purchase and outsource, which may in turn slow or delay our preclinical and clinical activities, and/or result in higher costs. 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 coronavirus pandemic), 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. 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 may 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. With the global spread of the coronavirus and the associated safety measures to contain the spread by governmental authorities, a delay in the commencement of new clinical trials and in the enrollment and participation of patients in clinical trials may occur. The steps required for us to initiate our clinical trials with PH-762 in the second half of 2021 are continuing and ongoing, however, the Company does not yet know the full extent of potential delays or impacts related to its planned clinical activities from the coronavirus pandemic.

Preclinical studies and clinical trials are lengthy and expensive, and their 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 product candidates or other necessary materials necessary to conduct our clinical trials;
- Effects of our product candidates not having the desired effects or including undesirable side effects or the product 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 product 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 pandemic;
- 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. Additionally, preclinical studies and clinical trials are lengthy and expensive and if our cash resources become limited we may not be able to commence, continue or complete our clinical trials.

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 will 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 have a history of net losses, and we expect to continue to incur net losses for the foreseeable future and may not achieve or maintain profitability.

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. Our ability to achieve profitability, if ever, will depend on, among other things, us or our collaborators, obtaining regulatory approvals and successfully commercializing our drug candidates. Even if we are able to successfully commercialize our drug candidates, we may not be able to achieve or sustain profitability, which could have a material adverse effect on our business, financial condition and results of operations.

We will require substantial additional funds to complete our research and development activities.

We have used substantial funds to develop our product candidates and will need to raise additional substantial funds to continue our drug development efforts and support our operations. Based on our current operating plans and liquidity, we believe that our existing cash at December 31, 2020 and the proceeds received from our capital raise activities subsequent to the balance sheet date, will be sufficient to fund our currently planned operations for at least the next 12 months from the date of release of the associated financial statements. However, our future capital requirements and the period for which our existing resources are able to support our operations may vary significantly from what we expect. 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.

In the future, we will need to obtain funding from third parties, such as proceeds from the issuance of debt, sale of equity or strategic opportunities in order to fund our planned expenditures, as well as to make acquisitions and other investments. Historically, the Company's primary source of funding has been through the sale of its securities. 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. 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.

Our ability to utilize net operating loss carryforwards and other tax benefits may be limited.

We have historically incurred net losses. Under the Internal Revenue Code of 1986, as amended (the "**Code**"), a corporation is generally allowed a deduction for net operating losses carried forward from a prior taxable year. Under that provision, we can carryforward our net operating losses to offset our future taxable income, if any, until such net operating losses are used or expire. These net operating loss carryforwards could expire unused before offsetting potential future income tax liabilities.

Additionally, an ownership change, as defined by Section 382 of the Code, results from transactions increasing the ownership of certain stockholders or public groups in the stock of a corporation by more than 50% over a three-year period. If the Company has experienced a change of control, as defined by Section 382 of the Code, at any time since inception, utilization of the Company's net operating loss carryforwards would be subject to an annual limitation. Any limitation may result in expiration of a portion of the net operating loss carryforwards before utilization. The Company has not conducted a study to assess whether a change of control, as defined by Section 382 of the Code, has occurred and it is possible that we have experienced an ownership change limitation. We may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our net operating loss carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

Risks Relating to Our Securities

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

Our stock price has historically fluctuated widely and is likely to continue to be volatile. Because we are at an early stage of development and in the absence of product revenue as a measure of operating performance, we anticipate that the market price for our common stock may be influenced by, but not limited to, such factors as:

- Announcements regarding the initiation or completion, and the results of preclinical studies and clinical trials of our product candidates;
- Announcements regarding clinical trial results or development announcements concerning our competitors product candidates;
- Regulatory or legal developments in the United States and other countries;
- The recruitment or departure of key personnel;
- The issuance of competitive patents or disallowance or loss of our patent rights;
- Our ability to raise additional capital and the terms on which additional capital is raised;
- To acquire new technologies, licenses or products;
- Natural disasters and calamities, including the coronavirus pandemic; and
- General economic, industry and market conditions.

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

We may incur significant costs from class action litigation due to our historical or expected stock volatility.

Our stock price has historically fluctuated significantly and may continue to do so in the future. This risk is relevant to us as 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 that issued the stock. If litigation of this type is brought against us by any of our stockholders, even if the lawsuit is without merit, it could be extremely expensive and divert management's attention and the Company's resources.

Our Board of Directors has the authority to issue shares of "blank check" preferred stock 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 18, 2021, there were approximately 19 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, 2020 or 2019.

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. Our efforts are focused on silencing tumor-induced suppression of the immune system through our proprietary INTASYL platform with utility in immune cells and 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 potentially 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 for the following reasons:

- Efficient uptake of INTASYL to immune cells obviating the need for facilitated delivery (mechanical or formulation);
- Does not require permanent genetic modification;
- 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 therapy ("**ACT**") treatments as well as for direct therapeutic use. ACT consists of the infusion of immune cells with antitumor properties, after growing them in a lab to large numbers. These cells can be derived from unmodified (i.e. naturally occurring) immune cells, immune cells isolated from resected tumors, or genetically engineered immune cells that recognize tumor cells. Regardless of the source of immune cells (ACT or naturally occurring immune cells), in patients with solid tumors, these cells have several shortcomings that inhibit their full therapeutic potential. By using INTASYL technology during the manufacturing of such ACT cell products we can improve the phenotype and function of these cells, potentially leading to better therapeutic outcomes. Multiple inhibitory mechanisms restrain immune cells 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. By using INTASYL based drugs administered directly, we can reprogram cells in the TME to help overcome these immunosuppressive mechanisms.

We have 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 reduced immune inhibition and in improved immunotherapy.

INTASYL Use To Improve Adoptive Cell Therapy Products

ACT is a form of immune therapy based on the use of immune cells, isolated from patients, donors or retrieved from allogeneic immune cell banks. They are grown in a lab to large numbers, followed by administering them to the patient to fight cancer. Sometimes, immune cells that naturally recognize a tumor are used, while other times immune cells are modified or "genetically 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.) genetically 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).

Multiple inhibitory mechanisms restrain immune cells used in ACT from effectively eradicating tumors, including immune checkpoints, reduced cell fitness and cell persistence, and other barriers to immune cell infiltration and function mainly in solid tumors. We believe our INTASYL compounds are ideally suited to be used in ACT products. With INTASYL compounds, we can unlock the full potential of ACT, by improving the immune cell function, differentiation and metabolism, in order to make these immune cells more effective without the need for additional complicated manufacturing steps and/or genetic engineering.

Our approach builds on well-established methodologies of ACT and involves the treatment of immune cells with our INTASYL compounds *ex vivo* 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 by merely adding our INTASYL compounds during the expansion process and without the need for genetic engineering, without the need for complex delivery vehicles or formulations, and without additional needed complex manufacturing steps. By adding INTASYL to the cell culture media used during the cell expansion, we can 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 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 with close to 100% transfection efficiency and while maintaining nearly full cell viability. After expanding these cells and enhancing them with INTASYL *ex vivo*, they are returned to the patient for treatment.

Our lead product candidate and most advanced program being developed in ACT is PH-762, an INTASYL compound that targets the checkpoint protein PD-1. Checkpoint proteins, such as PD-1, normally act as a type of "off switch" that prevent T cells from attacking certain cells, such as cancer cells, in the body. Our T cells are immune cells that protect the body from cancer cells and infections.

Data developed by Phio and with collaborators has shown that PH-762 silences PD-1 checkpoint expression, thereby removing the "off switch" and resulting in enhanced T cell activation and tumor cytotoxicity. Experimental data shows that PH-762 can silence the expression of PD-1 in target human T cells in a potent and durable manner, and can increase the function of patient derived TILs for use in ACT, showing that PH-762 is applicable for use in both ACT and as a standalone direct therapeutic.

In March 2021, the Company announced that it entered into a clinical development collaboration with AgonOx, Inc. ("**AgonOx**"), a private company developing a pipeline of novel immunotherapy drugs targeting key regulators of the immune response to cancer. Under the agreement, the companies will collaborate on the development of novel T cell-based therapies using PH-762 and AgonOx's "double positive" (DP) TIL technology. AgonOx has demonstrated that their DP CD8+ T cells isolated from human solid tumors (DP TILs) have increased tumor killing activity when compared to TILs that were not enriched prior to expansion. Preclinical data from AgonOx in collaboration with Phio has shown that treating DP TIL with PH-762 increases the tumor killing activity of the DP TILs even further (a two-fold increase). As a result, the use of PH-762 treated DP TILs is expected to enhance therapeutic responses in cancer data. Based on these data showing that the combination of our technologies can result in TIL therapeutics, our collaboration will focus on conducting a clinical study for PH-762 treated DP TILs. Under the terms of the collaboration agreement, AgonOx will receive financial support for the clinical trial from Phio and Phio will be entitled to certain future development milestones and sales-related royalty payments from AgonOx's DP TIL technology. The clinical trial in ACT with PH-762 and AgonOx's DP TIL technology is expected to start in the third quarter of 2021.

Our second product candidate in ACT is PH-894, an INTASYL compound that targets BRD4 which is a regulator of gene expression impacting cell differentiation. In previous studies, PH-894 has been shown to improve T cell function and persistence by differentiating T cells into a more active state (stem-cell like memory phenotype). Data, completed in partnership with the Karolinska Institutet in Sweden, demonstrated that the application of PH-894, was shown to silence BRD4 in human T cells during expansion for ACT, which has the potential to confer superior anti-tumor activity, for example by improving T cell persistence. With this data, we expanded our collaboration with the Karolinska Institutet to build upon these findings and develop INTASYL compounds for additional targets and cell types toward clinical application in areas of the Karolinska Institutet's ongoing clinical research.

We are also developing our INTASYL compound PH-804 for use in ACT. PH-804 targets the suppressive immune receptor TIGIT, which is a checkpoint protein present on T cells and NK cells. We have shown that PH-804 can silence the expression of TIGIT in NK cells and T cells, overcoming their "off switch" and the cells becoming "weaponized" to kill cancer cells.

Direct Therapeutic Use of INTASYL Towards the 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. The TME is an immunosuppressive environment that inhibits the immune system's natural ability to recognize and destroy tumor cells by negatively impacting how immunosuppressive cells are being attracted and activated. Reprogramming different components of the TME may overcome 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 therapy. The Company has previously shown in a clinical setting that our INTASYL compounds are safe and well-tolerated following local administration, therefore we believe that our INTASYL technology can not only be used with ACT, but can also be used as an independent therapeutic platform.

We are developing our PH-762, PH-894 and PH-804 INTASYL compounds also for use as direct therapeutics to reprogram the TME *in situ* transfection and activation of immune cells in the TME.

Animal studies conducted by the Company showed that local administration of PH-894 or the mouse version of PH-762 through intra-tumoral injection resulted in potent anti-tumoral effects. The treated animals showed a complete and statistically significant inhibition of tumor growth, whereas placebo treated animals displayed exponential tumor growth. *In vivo* studies performed by the Company with PH-804showed that intra-tumoral injection of a mouse version of PH-804 reduced the tumor growth in colorectal carcinoma tumor bearing mice, which was shown to inhibit tumor growth and was correlated with the silencing of TIGIT mRNA expression and in increase in cytotoxic effector T cells in the TME.

The combined PH-804, PH-762, and PH-894 data further shows that INTASYL compounds can trigger associated changes in the TME such as an increase of TILs, including CD8+ T cells responsible for tumor cell killing, and an increase of activation markers on these cells. These preclinical findings demonstrate that direct injection of INTASYL compounds can successfully infiltrate solid tumors and impact the TME by activating the immune response in animal models of solid tumors resulting in reduced tumor growth. A key challenge for many other immunotherapy platforms is to be able to achieve an adequate therapeutic effect in solid tumors with an acceptable safety profile. Many of the available systemic immuno-therapeutics indeed come with dose limiting immune-related adverse events, which we believe can be mitigated with local INTASYL treatment.

Based on our positive preclinical data, the Company is preparing for a clinical study with PH-762 using intra-tumoral administration for patients with advanced melanoma. The required preclinical studies and steps needed to initiate the clinical trial with PH-762 as a direct therapeutic are continuing and ongoing. The clinical trial will be conducted at the Gustave Roussy Institute, which is France's largest cancer center and Dr. Caroline Robert will be our lead principal investigator. The Company expects to start the clinical trial evaluating the use of PH-762 as a direct therapeutic in the fourth quarter of 2021.

We are also investigating other relevant compounds for TME targets, such as PH-790, an INTASYL compound targeting PD-L1. PD-L1 is a protein formed by cancer cells that activate the PD-1 "off switch" on immune cells. Our approach with PH-790 is to block the formation of the PD-L1 protein, which may prevent cancer cells from inactivating T cells and attack the cancer. Recent data presented demonstrated that the antitumoral efficacy of our individual pipeline products, PH-762, PH-790 and PH-804, can be further improved by combining them in a single drug treatment. We have shown that, in contrast to other technology platforms, we can efficiently target multiple proteins, in a single drug treatment without negative consequences related to the potency of the individual components. Animal data showed that the combination of our INTASYL compounds in a single formulation (at suboptimal doses of the individual agents) inhibited tumor growth without having a negative impact on the tolerability of the treatment.

Impact of COVID-19 on our Business

In December 2019, a novel strain of coronavirus that causes COVID-19 was reported to have surfaced in Wuhan, China and has since spread to other parts of the world, including the United States. In March 2020, the World Health Organization (the "**WHO**") declared the outbreak a pandemic.

Health and Safety

From the first signs of the outbreak, we have taken proactive measures intended to protect the health and safety of our employees. We have implemented safety measures following the guidance provided by the WHO, the Centers for Disease Control (the "**CDC**") and governmental authorities, which include formal policies related to working remotely for employee personnel who do not need to be physically present in our offices, the wearing of face masks while in the office, physically distancing workspaces, cleaning protocols, staggered scheduling and social distancing protocols, and suspending travel. The Company has also implemented protocols to address actual and suspected cases of COVID-19 and encourages sick employees to remain home. We expect to continue following these safety measures and may take further actions as we require, as government authorities require or recommend, or as we determine to be in the best interests of our employees.

Operations

Our operations have continued to operate with limited impact and are operating in accordance with federal and state government, WHO and CDC guidelines. We have implemented enhanced safety measures, as discussed above, and have experienced limited absenteeism from our employees due to the coronavirus pandemic and we do not currently expect that our operations will be significantly impacted by employee absenteeism. While the measures to contain and prevent the spread of coronavirus may be modified or extended, we expect that our activities, including our internal research and development functions, will continue to remain largely operational. We believe the impact to our operations has been minimal thus far, however current and future restrictions may further impact our operations and may slow or diminish our research and development activities.

Supply and Services

As a result of the coronavirus pandemic, certain of our third-party suppliers and service providers on which we rely have seen impacts to their operations. If the impact to their operations continue or extend, it may in turn affect our operations. We previously had been able to engage with third-party service providers in areas with limited or no impact (e.g. countries with limited or no restrictions), but with the global spread of the virus and associated restrictions, this has been no longer possible. The Company does not expect a material impact to its program's anticipated timelines as a result of potential delays from our third-party service providers and believes that we have a sufficient supply of our INTASYL compounds to conduct our ongoing preclinical studies and initial clinical activities. The Company has also undertaken efforts to mitigate potential future impact by identifying and engaging alternative third-party service providers and suppliers. However, the ultimate impact to the third parties on which we rely is highly uncertain and subject to change. If the measures to contain the outbreak are extended or further expanded, it could reduce or delay the availability of supplies and services that we purchase and outsource, which may in turn slow or delay our preclinical and clinical activities, and/or result in higher costs.

With the global spread of the coronavirus and the associated safety measures to contain the spread by governmental authorities, a delay in the commencement of new clinical trials and in the enrollment and participation of patients in clinical trials may occur. The steps required for us to initiate our clinical trials with PH-762 in the second half of 2021 are continuing and ongoing, however, the Company does not yet know the full extent of potential delays or impacts related to its planned clinical activities.

Liquidity and Capital Resources

While we believe that the coronavirus pandemic has not had a significant impact on our financial condition at this time, the extent to which the coronavirus pandemic 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 pandemic and the actions to contain the coronavirus or treat its impact, among others.

Due to our uncertainty around our ability to access the capital markets to provide the necessary working capital to fund our long-term operations as a result of the coronavirus pandemic, the Company applied for and received a loan of $231,252 in May 2020 under the Paycheck Protection Program (the "**PPP**") as part of the Coronavirus Aid, Relief and Economic Security (the "**CARES Act**"). The Company carefully assessed the requirements at the time of applying for the PPP loan and believed it was necessary to support our operations. The PPP loan matures in May 2022, bears an interest rate of 1% per year and monthly principal and interest payments are deferred to that date that the amount of loan forgiveness is remitted to the lender. The Company believes it has used the loan proceeds for the eligible purposes allowed and applied for full loan forgiveness. On February 18, 2021, the Small Business Administration determined that the Company's application for full loan forgiveness was fully approved and the full amount of the PPP loan was remitted to the lender for forgiveness. In connection with and addition to the PPP, the Company took other proactive steps to control costs in response to the coronavirus pandemic, which included the reduction of senior management salaries by 10% from May to December 2020. We believe these savings helped to mitigate the financial impact of the coronavirus pandemic on our financial condition.

Overall, we do not yet know the full extent of potential delays or the impact on our business, financial condition, or our preclinical and clinical trial activities and there may be developments outside of our control that require us to adjust our operating plans and, therefore, given the nature of the situation, cannot reasonably estimate the impact of the coronavirus on our financial condition, results of operations or cash flows in the future.

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 ("**GAAP**"). 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

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 with respect to services provided and/or materials received for which vendors have not yet billed the Company. 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 milestones.

We are required to estimate our accrued research and development expenses, of which a significant portion relate to third party providers the Company has contracted with to perform various research 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. Accrued liabilities for the services provided by contract research organizations 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 other information available to us. Estimates of our research and development accruals are assessed on a quarterly basis based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and facts and circumstances known to us at that time, and adjusted accordingly.

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. 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 research 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. We determine the fair value of 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 options 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. Stock-based 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.

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

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. For leases with a term greater than one year, the Company recognizes a liability to make lease payments and an asset representing the right to use the underlying asset during the lease term at the commencement date of the lease.

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.

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, research activities under our research collaborations, expenses associated with preclinical and clinical development activities and other operating costs. Our research and development programs are focused on the development of immuno-oncology therapeutics based on our 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.

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
	2020	2019	Change
Revenues	$ –	$ 21	$ (21)
Operating expenses	8,793	9,008	(215)
Operating loss	(8,793)	(8,987)	194
Net loss	$ (8,794)	$ (8,908)	$ 114

Comparison of the Years Ended December 31, 2020 and 2019

Operating Expenses

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

	Years Ended December 31,		Dollar
	2020	2019	Change
Research and development	$ 4,431	$ 4,300	$ 131
General and administrative	4,362	4,708	(346)
Total operating expenses	$ 8,793	$ 9,008	$ (215)

Research and Development Expenses

Research and development expenses for the year ended December 31, 2020 increased 3% compared with the year ended December 31, 2019 primarily due to an increase in the use of sponsored research organizations to support the development of the Company's pipeline programs as compared to the prior year period.

General and Administrative Expenses

General and administrative expenses for the year ended December 31, 2020 decreased 7% compared with the year ended December 31, 2019, primarily due to decreases in legal-related expenses and recruiting fees to support employee hiring activities as compared to the prior year period.

Liquidity and Capital Resources

Historically, the Company's primary source of funding has been through 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. 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. At December 31, 2020, we had cash of $14,244,000 as compared with $6,934,000 at December 31, 2019.

In August 2017, the Company entered into a purchase agreement (the "**2017 Purchase Agreement**") with Lincoln Park Capital, LLC ("**LPC**"), pursuant to which the Company had the right to sell to LPC up to $15,000,000 in shares of the Company's common stock. The 2017 Purchase Agreement expired on April 1, 2020 and a total of $1,602,000 in shares of common stock were sold to LPC under the agreement. In August 2019, the Company entered into a purchase agreement (the "**2019 Purchase 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 agreement. The Company is initially limited to the issuance of 19.99% of the Company's shares outstanding on the date of the 2019 Purchase Agreement to LPC 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 agreement. To date, no shares of common stock have been sold to LPC under the 2019 Purchase Agreement.

On January 25, 2021, the Company sold 4,420,863 shares of Company common stock at a purchase price per share of $3.07, pre-funded warrants to purchase an aggregate of 140,065 shares of Company common stock at a purchase price per pre-funded warrant share of $3.069, and warrants to purchase an aggregate of 3,420,696 shares of the Company's common stock with an exercise price of $3.00 per warrant share in a private placement transaction. Net proceeds to the Company are estimated to be $12,700,000 after deducting placement agent fees and offering expenses.

On February 12, 2021, the Company sold 2,246,784 shares of Company common stock at a purchase price of $3.42 per share in a registered direct offering under the Company's Form S-3 "shelf" registration statement. Net proceeds to the Company are estimated to be $6,900,000 after deducting placement agent fees and offering expenses.

We believe that our existing cash at December 31, 2020 and the net proceeds received from the Company's financing activities subsequent to December 31, 2020, as discussed above, should be sufficient to fund operations for at least the next 12 months from the date of the release of the associated financial statements.

Cash Flow

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

	Years Ended December 31,	
	2020	**2019**
Net cash used in operating activities	$ (8,802)	$ (8,645)
Net cash used in investing activities	(19)	(72)
Net cash provided by financing activities	16,131	772
Net increase (decrease) in cash and restricted cash	$ 7,310	$ (7,945)

Net Cash Flow from Operating Activities

Net cash used in operating activities was $8,802,000 for the year ended December 31, 2020, as compared with $8,645,000 for the year ended December 31, 2019. The increase in cash used in operating activities was primarily due to an increase in the changes in operating assets and liabilities as compared to the same period in the prior year.

Net Cash Flow from Investing Activities

Net cash used in investing activities was $19,000 for the year ended December 31, 2020, as compared with $72,000 for the year ended December 31, 2019. The decrease in net cash flows from investing activities was primarily related to the amount of laboratory and computer equipment purchases year over year.

Net Cash Flow from Financing Activities

Net cash provided by financing activities was $16,131,000 for the year ended December 31, 2020, as compared with $772,000 for the year ended December 31, 2019. The increase in net cash flows from financing activities was primarily due to net proceeds received by the Company from the issuance of securities and warrant exercises during year ended December 31, 2020 as compared to the same period in the prior year.

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 8 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***

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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, 2020 and 2019, the related consolidated statements of operations, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2020, 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 at December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020**,** in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

Accounting for warrants issued as part of equity offerings

As described in Note 9 to the consolidated financial statements, the Company entered into two registered direct offerings and an underwritten public offering during 2020 that included the issuance of common stock and warrants to purchase common stock. The warrants were evaluated for proper classification on the balance sheet and it was determined that the warrants issued in these equity offerings should be classified within stockholders' equity.

We identified the accounting for warrants issued as part of equity offerings as a critical audit matter. Our principal considerations included the existence of accounting complexities related to certain provisions of the warrant agreements, including provisions of cash settlement and derivative elements. Auditing these elements required especially challenging auditor judgement and significant audit effort as well as the need for specialized knowledge and skill assessing these elements of the agreement.

The primary procedures we performed to address this critical audit matter included:

- Reading the agreements related to the warrants issued along with management's technical accounting memos to understand the facts and circumstances within the warrant agreements and other assumptions impacting the determination of warrant classification.

- Utilizing personnel with specialized knowledge and skill in debt and equity accounting to evaluate the appropriateness of management's interpretation on how to apply the relevant accounting guidance for the classification of the warrants issued, including the evaluation of derivative characteristics and the terms associated with the Company's control that could require cash settlement of the warrants.

/s/ BDO USA, LLP

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

Boston, Massachusetts

March 25, 2021

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

	Years Ended December 31,	
	2020	**2019**
ASSETS		
Current assets:		
Cash	$ 14,244	$ 6,934
Restricted cash	50	50
Prepaid expenses and other current assets	870	316
Total current assets	15,164	7,300
Right of use asset, net	400	511
Property and equipment, net of accumulated depreciation of $1,122 and $1,048 in 2020 and 2019, respectively	157	210
Other assets	18	18
Total assets	$ 15,739	$ 8,039
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 728	$ 809
Accrued expenses and other current liabilities	1,352	964
Lease liability	116	107
Total current liabilities	2,196	1,880
Lease liability, net of current portion	295	411
Long-term debt	231	–
Total liabilities	2,722	2,291
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, $0.0001 par value, 10,000,000 shares authorized	–	–
Common stock, $0.0001 par value, 100,000,000 shares authorized; 5,780,973 and 669,433 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively	1	1
Additional paid-in capital	116,629	100,566
Accumulated deficit	(103,613)	(94,819)
Total stockholders' equity	13,017	5,748
Total liabilities and stockholders' equity	$ 15,739	$ 8,039

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,	
	2020	**2019**
Revenues	$ –	$ 21
Operating expenses:		
Research and development	4,431	4,300
General and administrative	4,362	4,708
Total operating expenses	8,793	9,008
Operating loss	(8,793)	(8,987)
Total other (expense) income, net	(1)	79
Loss before income taxes	(8,794)	(8,908)
Provision for income taxes	–	–
Net loss	$ (8,794)	$ (8,908)
Net loss per common share:		
Basic and diluted	$ (1.92)	$ (19.33)
Weighted average number of common shares outstanding:		
Basic and diluted	4,587,346	460,809

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, 2018	342,578	$ –	$ 99,489	$ (85,911)	$ 13,578
Issuance of common stock upon the exercise of 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
Cash in lieu of fractional shares for 1:55 reverse stock split	(1,364)	–	(15)	–	(15)
Issuance of common stock under employee stock purchase plan	153	–	1	–	1
Issuance of common stock and warrants in connection with registered direct and private placement offerings, net of offering costs of $746	1,910,120	–	4,994	–	4,994
Issuance of common stock, pre-funded warrants and warrants in connection with underwritten public offering, net of offering costs of $906	993,633	–	7,093	–	7,093
Issuance of common stock upon the exercise of warrants	2,205,663	–	3,856	–	3,856
Issuance of common stock upon vesting of restricted stock units	3,335	–	(2)	–	(2)
Stock-based compensation expense	–	–	136	–	136
Net loss	–	–	–	(8,794)	(8,794)
Balance at December 31, 2020	5,780,973	$ 1	$ 116,629	$ (103,613)	$ 13,017

See accompanying notes to consolidated financial statements.

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

	Years Ended December 31,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (8,794)	$ (8,908)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	72	67
Non-cash lease expense	111	109
Non-cash stock-based compensation expense	136	300
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(554)	(113)
Accounts payable	(81)	259
Accrued expenses and other liabilities	415	(257)
Lease liability	(107)	(102)
Net cash used in operating activities	(8,802)	(8,645)
Cash flows from investing activities:		
Cash paid for purchase of property and equipment	(19)	(72)
Net cash used in investing activities	(19)	(72)
Cash flows from financing activities:		
Net proceeds from the issuance of common stock and warrants	12,087	708
Net proceeds from the exercise of warrants	3,856	72
Cash paid in lieu of fractional shares for 1:55 reverse stock split	(15)	–
Payment of taxes for net share settled restricted stock unit issuances	(2)	(3)
Proceeds from debt	231	–
Proceeds from the issuance of common stock in connection with the employee stock purchase plan	1	1
Payments for capital lease obligations less than one year	(27)	(6)
Net cash provided by financing activities	16,131	772
Net increase (decrease) in cash and restricted cash	7,310	(7,945)
Cash and restricted cash at the beginning of period	6,984	14,929
Cash and restricted cash at the end of period	$ 14,294	$ 6,984
Supplemental disclosure of cash flow information:		
Interest paid	$ 6	$ 5
Supplemental disclosure of non-cash investing and financing activities:		
Right of use asset obtained in exchange for operating lease liability	$ –	$ 620
Acquisition of property and equipment included in accrued expenses and other current liabilities	$ –	$ 33

See accompanying notes to consolidated financial statements.

PHIO PHARMACEUTICALS CORP.
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 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 potentially providing patients with a powerful new treatment option that goes beyond current treatment modalities.

In December 2019, a novel strain of coronavirus that causes COVID-19 was reported to have surfaced in Wuhan, China and has since spread to other parts of the world, including the United States. In March 2020, the World Health Organization (the "**WHO**") declared the outbreak a pandemic. Our operations have continued with limited impact and are operating in accordance with federal, state, WHO and the Center for Disease Control's guidelines, including the implementation of safety measures such as working remotely, staggered scheduling and cleaning protocols. While the measures to contain and prevent the spread of coronavirus may be modified or extended, we expect that our activities, including our internal research and development functions, will continue to remain largely operational.

As a result of the coronavirus pandemic, certain of our third-party suppliers and service providers on which we rely have seen impacts to their operations. If the impact to their operations continue or extend, it may in turn affect our operations. We previously had been able to engage with third-party service providers in areas with limited or no impact (e.g. countries with limited or no restrictions), but with the global spread of the virus and associated restrictions, this has been no longer possible. The Company does not expect a material impact to its program's anticipated timelines as a result of potential delays from our third-party service providers and believes that it has a sufficient supply of our INTASYL compounds to conduct its ongoing preclinical studies and initial clinical activities. The Company has also undertaken efforts to mitigate potential future impact by identifying and engaging alternative third-party service providers and suppliers. However, the ultimate impact to these third parties on which we rely is highly uncertain and subject to change. If the measures to contain the outbreak are extended or further expanded, it could reduce or delay the availability of supplies and services that we purchase and outsource, which may in turn slow or delay our preclinical and clinical activities, and/or result in higher costs.

We believe that the coronavirus pandemic has not had a significant impact on our operations and financial condition thus far, however a variety of factors, including current and future restrictions and the length of the pandemic, may further impact our operations and may slow or diminish our research and development activities. The extent to which the coronavirus pandemic impacts our results will depend on future developments, which are highly uncertain and cannot be predicted.

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**"). Additionally, certain reclassifications have been made to prior period financial statements to conform to the current period presentation.

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. The areas subject to significant estimates and judgement include, among others, those related to the fair value of equity awards, research and development expenses, useful lives of property and equipment, income taxes, and our valuation allowance on our deferred tax assets. 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, including as a result of new information that may emerge concerning the coronavirus pandemic. We have made estimates of the impact of the coronavirus pandemic within our financial statements and there may be changes to those estimates in future periods. Actual results could differ materially from these estimates.

Restricted Cash

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

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash. The Company maintains cash balances in several accounts with a financial institution that management believes is creditworthy, which at times are in excess of federally insured limits. These accounts are insured by the Federal Deposit Insurance Corporation (FDIC) for up to $250,000 per institution.

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, 2020 and 2019 was $72,000 and $67,000, respectively.

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, 2020 or 2019.

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.

Leases

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. For leases with a term greater than one year, the Company recognizes a liability to make lease payments and an asset representing the right to use the underlying asset during the lease term at the commencement date of the lease.

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.

Debt

On March 27, 2020, the United States enacted the Coronavirus Aid, Relief, and Economic Security Act (the "**CARES Act**") in response to the coronavirus pandemic. The CARES Act is an emergency economic stimulus package passed in response to the coronavirus outbreak that includes, but is not limited to, provisions providing aid to small businesses in the form of loans and grants and numerous tax provisions such as certain payroll tax benefits, changes to the net operating loss rules, and the business interest expense deduction rules. Outside of the Paycheck Protection Program (the "**PPP**") offered under the CARES Act, the Company has not utilized the other loan programs and tax provisions, such as certain payroll tax benefits. On May 11, 2020, the Company received loan proceeds pursuant to the PPP. The Company followed the guidance under the FASB ASC Topic 470, "*Debt*" ("**ASC 470**") in assessing the accounting for the PPP loan proceeds. Per ASC 470, the Company recorded a liability on the balance sheet for the full amount of PPP loan proceeds received and is accruing interest over the term of the loan. For additional information regarding the Company's accounting for the PPP loan proceeds, refer to Note 7. As there continues to be updates to the provisions under the CARES Act, the Company will continue to assess the potential impacts on its business, results of operations and financial statements.

Derivative Financial Instruments

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.

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. Accrued liabilities for the services provided by contract research organizations 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.

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. The Company uses the Black-Scholes option-pricing model to estimate the fair value of stock options at the grant date. The Black-Scholes valuation model requires the input of valuation assumptions to calculate the value of stock options, including expected volatility, expected term, risk-free interest rate and expected dividends. The fair value of restricted stock units is based upon the Company's closing stock price at the grant date. Stock-based compensation expense is recognized over the requisite service period, which generally represents the vesting period, and commences at the date of grant based on the fair value of the award.

Stock-based compensation expense recognized in the financial statements is based on awards that are ultimately expected to vest. Accordingly, we are also required to estimate forfeitures at the time of grant, and to revise those estimates in subsequent periods if actual forfeitures differ from estimates. We use historical data to estimate pre-vesting option forfeitures and record stock-based compensation expense only for those awards that are expected to vest. Our forfeiture rate estimates are based on an analysis of our actual forfeiture experience, employee turnover behavior, and other factors. The impact of any adjustments to our forfeiture rates would be recorded as a cumulative adjustment in the period of adjustment. To the extent that actual forfeitures differ from our estimates, the difference is recorded as a cumulative adjustment in the period the estimates were revised.

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

Basic net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding. Diluted net loss per share is computed by dividing the Company's net less by the weighted average number of common shares outstanding and the impact of all dilutive potential common shares outstanding, except where such dilutive potential common shares would be anti-dilutive. Dilutive potential common shares primarily consist of warrants, restricted stock units and stock options.

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 is 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 its 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 seek to merge with or to be acquired by another company.

While we believe that the coronavirus pandemic has not had a significant impact on our financial condition and results of operations at this time, the potential economic impact brought by, and the duration of, the coronavirus pandemic is difficult to assess or predict. There may be developments outside of our control that require us to adjust our operating plans and given the nature of the situation, we cannot reasonably estimate the impact of the coronavirus pandemic on our financial conditions, results of operations or cash flows in the future.

The Company believes that its existing cash and the net proceeds received from the Company's financing activities subsequent to the balance sheet date, discussed further in Note 14, should be sufficient to fund operations for at least the next 12 months from the date of the release of these financial statements.

4. Recent Accounting Pronouncements

In November 2018, the FASB issued Accounting Standards Update ("**ASU**") 2018-18, "*Collaborative Arrangements (Topic 808)*" ("**Topic 808**"), which clarifies the interaction between Topic 808 and ASC Topic 606, "*Revenue from Customers*" ("**Topic 606**"). The update provides guidance on whether certain transactions between collaborative arrangement participants should be accounted for with revenue under Topic 606 and provides more comparability in the presentation of revenue for certain transactions between collaborative arrangement participants. This ASU is effective for annual reporting periods beginning after December 15, 2019, including interim periods within that reporting period. This guidance is required to be applied retrospectively to the date of adoption of Topic 606. The Company adopted Topic 606 in the first quarter of 2018 and adopted ASU 2018-18 in the first quarter of 2020. The Company also elected to apply ASU 2018-18 only to contracts that were not completed at the date of initial application of Topic 606. Since the Company has no significant revenue, this ASU has no immediate impact on the Company's consolidated financial statements.

In December 2019, the FASB issued ASU 2019-12, "*Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*." The amendments in the update simplify the accounting for income taxes by eliminating the exceptions related to the incremental approach for intraperiod tax allocation, the recognition of a deferred tax liability for equity method investments, not recognizing a deferred tax liability for a foreign subsidiary and the general methodology for calculating income taxes in an interim period. The amendments also clarify and simplify other aspects of the accounting for income taxes. The amendments in ASU 2019-12 are effective for public entities for fiscal years, and the interim periods within those fiscal years, beginning after December 20, 2020. Early adoption is permitted. The Company does not expect the adoption of ASU 2019-12 to have a material impact on its consolidated financial statements.

In August 2020, the FASB issued ASU 2020-06, "*Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815 – 40)"* ("**ASU 2020-06**"), which simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts in an entity's own equity. The ASU is part of the FASB's simplification initiative, which aims to reduce unnecessary complexity in U.S. GAAP. For convertible instruments, the accounting models for instruments issued with beneficial conversion features or cash conversion features are removed. For contracts in an entity's own equity, ASU 2020-06 simplifies the settlement assessment by removing the requirements to (1) to consider whether the contract would be settled in registered shares, (2) to consider whether collateral is required to be posted, and (3) to assess shareholder rights. ASU 2020-06 is effective for fiscal years beginning after December 15, 2023, and interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, and interim periods within those fiscal years. The Company does not expect the adoption of ASU 2020-06 to have a material impact on its consolidated financial statements.

5. Accrued Expenses and Other Current Liabilities

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

	December 31,	
	2020	2019
Compensation and benefits	$ 618	$ 524
Professional fees	81	171
Research and development costs	549	242
Other	104	27
Total accrued expenses and other current liabilities	$ 1,352	$ 964

6. Leases

On January 22, 2019, the Company amended the lease for its corporate headquarters and primary research facility in Marlborough, Massachusetts. The Company leases 7,581 square feet of office and laboratory space, which will expire on March 31, 2024. The lease contains an option to terminate the lease after two years or three years by providing advance written notice of termination pursuant to the terms of the agreement. The exercise of this option was not determined to be reasonably certain and thus is not included in the lease liability on the Company's balance sheet. Additionally, the lease agreement 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.

The lease for our corporate headquarters represents substantially all of our significant lease obligations. The amounts reported in the consolidated balance sheets for operating leases in which the Company is the lessee and other supplemental balance sheet information is set forth as follows, in thousands, except lease term and discount rate:

	December 31, 2020	December 31, 2019
Assets		
Right of use asset	$ 400	$ 511
Liabilities		
Lease liability, current	116	107
Lease liability, non-current	295	411
Total lease liability	$ 411	$ 518
Lease Term and Discount Rate		
Weighted average remaining lease term	3.71	4.43
Weighted average discount rate	4.70%	4.64%

Operating lease cost included in operating expense was $132,000 and $127,000 for the years ended December 31, 2020 and 2019, respectively. Short-term lease costs were not material for the years ended December 31, 2020 and 2019.

Cash paid for the amounts included in the measurement of the operating lease liability on the Company's consolidated balance sheets and included within changes in the lease liability in the operating activities of our consolidated statement of cash flows was $127,800 and $121,000 for the years ended December 31, 2020 and 2019, respectively.

Future lease payments for our non-cancellable operating leases and a reconciliation to the carrying amount of the operating lease liability presented in the consolidated balance sheet as of December 31, 2020 is as follows, in thousands:

2021	$	132
2022		135
2023		140
2024		35
Total lease payments		442
Less: Imputed interest		(31)
Total operating lease liabilities (includes current portion)	$	411

7. Debt

On May 11, 2020, the Company received loan proceeds in the amount of $231,252 from Bank of America, N.A., as lender, pursuant to the PPP under the CARES Act. The PPP loan matures on May 11, 2022, bears interest at a rate of 1% per year and monthly principal and interest payments are deferred to the date that the Small Business Administration remits the borrower's loan forgiveness amount to the lender. The loan may be forgiven if used for eligible purposes, including payroll, benefits, rent and utilities. The Company believes it has used the loan proceeds for the eligible purposes allowed and applied for full loan forgiveness. On February 18, 2021, the Small Business Administration determined that the Company's application for full loan forgiveness was fully approved and the full amount of the PPP loan was remitted to the lender for forgiveness.

When applying for the PPP loan, the Company carefully assessed the requirements for application under the program and believed that the loan was necessary to support its operations. As loan forgiveness had not yet been determined at December 31, 2020, the Company followed the guidance under ASC 470 in assessing the accounting for the PPP loan proceeds. Per ASC 470, the Company recorded a liability on the balance sheet for the full amount of PPP loan proceeds received and is accruing interest over the term of the loan. As of December 31, 2020, the PPP loan proceeds have been classified as long-term debt on the balance sheet.

8. 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. During the years ended December 31, 2020 and 2019, the Company did not trigger any milestone payments.

The Company's contractual license obligations that will require future cash payments as of December 31, 2020 are as follows, in thousands:

Year Ending December 31,	
2021	165
2022	100
2023	100
2024	100
2025	100
Thereafter	400
Total	$ 965

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.

Litigation

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.

9. Stockholders' Equity

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 (the "**November 2019 Placement Agent Warrants**") to the placement agent, H.C. Wainwright & Co., LLC ("**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 October 2018 to an exercise price 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.

February 2020 Registered Direct Offering and Private Placement — On February 6, 2020, the Company completed a registered direct offering (the "**February 2020 Registered Offering**") of 197,056 shares of the Company's common stock at a purchase price of $8.705 per share 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 Direct Warrants**"). Net proceeds to the Company from the February 2020 Registered Offering were $1,467,000 after deducting placement agent fees and offering expenses paid by the Company. In connection with the February 2020 Registered Offering, the Company also issued warrants to purchase a total of 14,779 shares of the Company's common stock with an exercise price of $11.0375 per share (the "**February 2020 Placement Agent Warrants**") to the placement agent, HCW.

February 2020 Underwritten Public Offering — On February 13, 2020, the Company completed an underwritten public offering of 993,633 shares of the Company's common stock at a purchase price per share of $4.00, pre-funded warrants (the "**2020 Pre-Funded Warrants**") to purchase an aggregate of 1,006,367 shares of the Company's common stock at a purchase price per pre-funded warrant share of $3.999, and warrants (the "**February 2020 Warrants**") to purchase an aggregate of 2,000,000 shares of the Company's common stock with an exercise price of $4.00 per warrant shares (the "**February 2020 Underwritten Offering**"). The 2020 Pre-Funded Warrants were immediately exercisable at an exercise price per share of $0.001 and each share of Company common stock or 2020 Pre-Funded Warrant, as applicable, was sold with a February 2020 Warrant.

In connection with the February 2020 Underwritten Offering, the Company also granted to the underwriter, HCW, a 30-day option to purchase up to an additional 300,000 shares of the Company's common stock at a purchase price of $3.999 per such share and/or warrants to purchase up to 300,000 shares of the Company's common stock at a purchase price of $0.001 per such warrant. Such warrants have the same terms as the February 2020 Warrants. On February 12, 2020, HCW exercised its option to purchase warrants to purchase an aggregate of 300,000 shares of the Company's common stock. Additionally, pursuant to the February 2020 Underwritten Offering, the Company issued warrants to purchase up to 150,000 shares of Company common stock, immediately exercisable at an exercise price of $5.00 per share (the "**February 2020 Underwriter Warrants**") to HCW, as underwriter.

Net proceeds from the February 2020 Underwritten Offering were $7,093,000 after deducting underwriting discounts and commissions and offering expenses paid by the Company.

April 2020 Registered Direct Offering and Private Placement — On April 2, 2020, the Company completed a registered direct offering (the "**April 2020 Offering**") of 1,713,064 shares of the Company's common stock at a purchase price of $2.21 per share and in a concurrent private placement, sold warrants to purchase an aggregate of 1,713,064 shares of the Company's common stock at a purchase price of $0.125 per underlying warrant share and with an exercise price of $2.21 per share (the "**April 2020 Warrants**"). Net proceeds to the Company from the April 2020 Offering were $3,527,000 after deducting placement agent fees and offering expenses paid by the Company. In connection with the April 2020 Offering, the Company also issued warrants to purchase a total of 128,480 shares of the Company's common stock with an exercise price of $2.9188 per share (the "**April 2020 Placement Agent Warrants**") to the placement agent, HCW.

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, 2020:

Description	Exercise Price	Expiration Date	Balance December 31, 2019	Warrants Issued	Warrants Exercised	Warrants Expired	Balance December 31, 2020
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 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
February 2020 Registered Direct Warrants	$ 8.71	8/6/2025	–	197,056	–	–	197,056
February 2020 Placement Agent Warrants	$ 11.0375	2/4/2025	–	14,779	–	–	14,779
February 2020 Underwritten Offering Warrants	$ 4.00	2/13/2025	–	2,300,000	(973,500)	–	1,326,500
February 2020 Pre-funded Warrants	$ 0.001	No expiration	–	1,006,367	(1,006,367)	–	–
February 2020 Underwriter Warrants	$ 5.00	2/11/2025	–	150,000	–	–	150,000
April 2020 Warrants	$ 2.21	10/2/2025	–	1,713,064	(428,266)	–	1,284,798
April 2020 Placement Agent Warrants	$ 2.9188	3/31/2025	–	128,480	–	–	128,480
			480,035	5,509,746	(2,408,133)	(2,364)	3,579,284

During the year ended December 31, 2020, the Company received net proceeds of $3,856,000 from the exercise of warrants. During the year ended December 31, 2019, the Company received net proceeds of $72,000 from the exercise warrants.

Of the warrants exercised during the year ended December 31, 2020, 428,266 of the Company's April 2020 Warrants were exercised via a cashless exercise transaction and as a result a total of 225,796 shares of common stock were issued. There were no cashless exercises of warrants during the year ended December 31, 2019.

10. 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,	
	2020	2019
Options to purchase common stock	2,570	2,659
Nonvested restricted stock units	9,699	14,945
Warrants to purchase common stock	3,579,284	480,035
Total	3,591,553	497,639

11. Stock-based Compensation

Stock Plans

The Company's approved equity plans include the Phio Pharmaceuticals Corp. 2020 Long Term Incentive Plan (the "**2020 Plan**") and the Phio Pharmaceuticals Corp. 2012 Long Term Incentive Plan (the "**2012 Plan**"). These plans are administered by our board of directors and provide for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance stock awards, and performance cash awards. Upon adoption of the 2020 Plan, shares that remained available for grant under the 2012 Plan and shares that were subject to outstanding awards under the 2012 Plan were included in the authorized shares available for grant under the 2020 Plan. Further, upon adoption of the 2020 Plan, the Company no longer grants new equity awards under the 2012 Plan.

As of December 31, 2020, there were an aggregate of 1,267,675 shares of common stock reserved under the 2020 Plan, including 2,570 shares subject to outstanding stock options and 9,699 shares subject to unvested restricted stock units ("**RSUs**") and 1,254,906 shares available for future grants. Stock options and RSUs granted by the Company to employees generally vest annually over 4 years after the grant date and, in the instance of stock options, expire within ten years of issuance.

Restricted Stock Units

RSUs are issued under the 2020 Plan or as inducement grants issued outside of the plan to new employees. RSUs are generally subject to graded vesting and the satisfaction of service requirements. 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 upon 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, 2020:

	Number of Shares	Weighted-Average Grant Date Fair Value Per Share
Unvested units at December 31, 2019	14,945	$ 20.50
Granted	–	–
Vested	(4,282)	22.18
Forfeited	(964)	18.33
Unvested units at December 31, 2020	9,699	$ 19.97

Stock-based compensation expense related to RSUs was $85,000 and $125,000 for the years ended December 31, 2020 and 2019, respectively.

As of December 31, 2020, the compensation expense for all unvested RSUs in the amount of approximately $151,000 will be recognized in the Company's results of operations over a weighted average period of 2.35 years.

Stock Options

Stock options are issued under the 2020 Plan or as inducement grants issued outside of the plan to new employees. Stock options are generally subject to graded vesting and the satisfaction of service requirements. Upon the exercise of a stock option, the Company issues new shares and delivers them to the recipient. The Company does not expect to repurchase shares to satisfy stock option exercises. The Company uses the Black-Scholes option-pricing model to determine the fair value of all its option grants. The Company did not grant stock options during the year ended December 31, 2020. For valuing options granted during the year ended December 31, 2019, the following assumptions were used:

	December 31, 2019
Risk-free interest rate	1.85 – 2.58%
Expected volatility	97.67 – 98.87%
Expected lives (in years)	5.31
Expected dividend yield	0.00%

The weighted-average fair value of options granted during the year ended December 31, 2019 was $16.50 per share.

The Company uses the Black-Scholes option-pricing model to determine the fair value of all its option grants. 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. As the Company has limited stock option exercise information, the expected life assumption used 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, 2020:

	Total Number of Shares	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Balance at December 31, 2019	2,659	$ 3,298.90		
Granted	–	–		
Exercised	–	–		
Cancelled	(89)	2,671.45		
Balance at December 31, 2020	2,570	$ 3,334.06	6.22 years	$ –
Exercisable at December 31, 2020	1,855	$ 4,578.01	5.70 years	$ –

Stock-based compensation expense related to stock options for the years ended December 31, 2020 and 2019 was $51,000 and $69,000, respectively.

As of December 31, 2020, the compensation expense for all unvested stock options in the amount of approximately $58,000 will be recognized in the Company's results of operations over a weighted average period of 1.47 years.

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.

Restricted Stock

During the period of from September 15, 2018 to February 28, 2019, the Company's former Chief Executive Officer elected the right to receive, in lieu cash, 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 vesting period. During the year ended December 31, 2019, the Company granted 4,419 shares of restricted stock in lieu of Compensation and recorded $106,000 in stock-based compensation expense.

Compensation Expense Related to Equity Awards

The following table sets forth total stock-based compensation expense for the years ended December 31, 2020 and 2019, in thousands:

	December 31,	
	2020	2019
Research and development	$ 22	$ 21
General and administrative	114	279
Total stock-based compensation	$ 136	$ 300

12. Income Taxes

For the years ended December 31, 2020 and 2019, 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,	
	2020	2019
Current		
Federal	$ –	$ –
State	–	–
Total current	–	–
Deferred		
Federal	(1,873)	(1,773)
State	(768)	(759)
Total deferred	(2,641)	(2,532)
Valuation allowance	2,641	2,532
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,	
	2020	2019
Federal statutory rate	21.0%	21.0%
State income taxes, net of federal benefit	6.7	6.7
Non-deductible expenses	(0.5)	(0.2)
Income tax credits	2.1	1.5
Valuation allowance	(29.3)	(29.0)
Effective tax rate	–	–

The components of the Company's deferred tax assets are as follows, in thousands:

	Years Ending December 31,	
	2020	2019
Deferred tax assets:		
Net operating loss carryforwards	$ 22,307	$ 19,647
Tax credit carryforwards	2,017	1,710
Stock-based compensation	1,374	1,391
Licensing deduction deferral	2,376	2,717
Other timing differences	196	165
Lease liability	111	140
Deferred tax assets	28,381	25,770
Deferred tax liabilities:		
Right of use asset	(108)	(138)
Deferred tax liability	(108)	(138)
Valuation allowance	(28,273)	(25,632)
Net deferred tax asset	$ –	$ –

The Company's deferred tax assets at December 31, 2020 and 2019 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 $2,641,000 and $2,532,000 for the years ended December 31, 2020 and 2019, 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, 2020, the Company had federal and state net operating loss carryforwards of approximately $83,600,000 and $75,300,000, respectively, which will begin to expire in 2031. Approximately, $55,300,000 of the federal net operating loss carryforwards will begin to expire in 2031, unless previously utilized, and approximately $28,300,000 of the federal net operating loss carryforwards will carryforward indefinitely. The Company's state tax loss carryforwards will begin to expire in 2031, unless previously utilized. In addition, the Company has federal and state research credits of $1,430,000 and $742,000, respectively, which begin to expire in 2031. 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 and 383. 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 2020. The Company has not recorded any uncertain tax positions as of December 31, 2020 or 2019. 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.

13. 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. Under the terms of the agreement, in April 2012, the Company issued to Advirna shares of common stock equal to 5% of the Company's fully-diluted shares outstanding at the time of issuance. In exchange, the Company is also 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 low single-digit royalties 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.

14. Subsequent Events

January 2021 Private Placement — On January 25, 2021, the Company closed on its private placement of 4,420,863 shares of the Company's common stock at a purchase price per share of $3.07, pre-funded warrants to purchase an aggregate of 140,065 shares of the Company's common stock at a purchase price per pre-funded warrant share of $3.069, and warrants to purchase an aggregate of 3,420,696 shares of the Company's common stock with an exercise price of $3.00 per warrant share. In connection with the private placement, the Company issued warrants to the placement agent, HCW, to purchase a total of 342,070 shares of the Company's common stock at an exercise price of $3.8375. Net proceeds to the Company are estimated to be $12.7 million after deducting placement agent fees and offering expenses.

The Company is currently reviewing the accounting for the pre-funded warrants and warrants issued in the January 2021 private placement.

February 2021 Registered Direct Offering — On February 12, 2021, the Company closed on a registered direct offering of 2,246,784 shares of the Company's common stock at a purchase price of $3.42 per share. In connection with the registered direct offering, the Company issued warrants to the placement agent, HCW, to purchase a total of 168,509 shares of the Company's common stock at an exercise price of $4.275. Net proceeds to the Company are estimated to be $6.9 million after deducting placement agent fees and offering expenses.

Warrant Exercises — Subsequent to the balance sheet date, the Company received net proceeds of $2,146,000 from the exercise of warrants for a total of 1,083,321 shares of common stock.

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, 2020. 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, 2020, 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, 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings: any derivative action or proceeding brought on behalf of the Company, any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of the Company to the Company or the Company's stockholders, any action asserting a claim against the Company arising pursuant to any provision of the Delaware General Corporation Law or the Company's certificate of incorporation or bylaws, or any action asserting a claim against the Company governed by the internal affairs doctrine. Despite the fact that our certificate of incorporation provides for this exclusive forum provision to be applicable to the fullest extent permitted by applicable law, Section 27 of the Securities Act and Exchange Act, creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder and Section 22 of the Securities Act, creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. As a result, this provision of our certificate of incorporation would not apply to claims brought to enforce a duty or liability created by the Securities Act, Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction.

PART III

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

The information required by this Item will be incorporated by reference to the information contained in our Definitive Proxy Statement to be filed no later than 120 days after the fiscal year end of December 31, 2020.

ITEM 11. ***EXECUTIVE COMPENSATION***

The information required by this Item will be incorporated by reference to the information contained in our Definitive Proxy Statement to be filed no later than 120 days after the fiscal year end of December 31, 2020.

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

The information required by this Item will be incorporated by reference to the information contained in our Definitive Proxy Statement to be filed no later than 120 days after the fiscal year end of December 31, 2020.

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

The information required by this Item will be incorporated by reference to the information contained in our Definitive Proxy Statement to be filed no later than 120 days after the fiscal year end of December 31, 2020.

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

The information required by this Item will be incorporated by reference to the information contained in our Definitive Proxy Statement to be filed no later than 120 days after the fiscal year end of December 31, 2020.

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)	October 13, 2020
4.1	Form of Warrant.	Amendment No. 3 to the Registration Statement on Form S-1 (File No. 333-214199)	December 14, 2016
4.2	Form of Warrant.	Current Report on Form 8-K (File No. 001-36304)	April 11, 2018
4.3	Form of Placement Agent Warrant.	Current Report on Form 8-K (File No. 001-36304)	April 11, 2018
4.4	Form of Warrant.	Amendment No. 1 to the Registration Statement on Form S-1 (File No. 333-221173)	September 28, 2018

4.5	Form of Underwriter Warrant.	Current Report on Form 8-K (File No. 001-36304)	October 5, 2018
4.6	Form of Placement Agent Warrant.	Current Report on Form 8-K (File No. 001-36304)	November 19, 2019
4.7	Form of Warrant	Current Report on Form 8-K (File No. 001-36304)	February 6, 2020
4.8	Form of Warrant.	Current Report on Form 8-K (File No. 001-36304)	February 13, 2020
4.9	Form of Underwriter Warrant.	Current Report on Form 8-K (File No. 001-36304)	February 13, 2020
4.10	Form of Warrant.	Current Report on Form 8-K (File No. 001-36304)	April 2, 2020
4.11	Form of Warrant.	Current Report on Form 8-K (File No. 001-36304)	January 25, 2021
4.12	Form of Placement Agent Warrant.	Current Report on Form 8-K (File No. 001-36304)	February 17, 2021
4.13	Description of Securities Registered Pursuant to Section 12(b) of the Securities Exchange Act of 1934.**	Annual Report on Form 10-K (File. 001-36304)	March 26, 2020
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. 2020 Long Term Incentive Plan.*	Registration Statement on Form S-8 (File No. 333-251670)	December 23, 2020
10.3	Form of Restricted Stock Unit Award under the Company's 2020 Long Term Incentive Plan.*		
10.4	Phio Pharmaceuticals Corp. 2012 Long Term Incentive Plan.*	Quarterly Report on Form 10-Q (File No. 001-36304)	November 12, 2019
10.5	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
10.6	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
10.7	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
10.8	RXi Pharmaceuticals Corporation Employee Stock Purchase Plan.*	Registration Statement on Form S-8 (File No. 333-277013)	August 24, 2018
10.9	Form of Indemnification Agreement.*	Amendment No. 3 to the Registration Statement on Form S-1 (File No. 333-177498)	January 23, 2012
10.10	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

10.11	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
10.12	First Amendment to Lease dated January 22, 2019.	Current Report on Form 8-K (File No. 001-36304)	January 28, 2019
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
10.17	Securities Purchase Agreement, dated March 31, 2020, by and between the Company and the Purchasers signatory therein.	Current Report on Form 8-K (File No. 001-36304)	April 2, 2020
10.18	Securities Purchase Agreement, dated January 21, 2021, by and between the Company and the Purchasers signatory therein.	Current Report on Form 8-K (File No. 001-36304)	January 25, 2021
10.19	Registration Rights Agreement, dated January 21, 2021, by and between the Company and the Purchasers signatory therein.	Current Report on Form 8-K (File No. 001-36304)	January 25, 2021
10.20	Securities Purchase Agreement, dated February 12, 2021, by and between the Company and the Purchasers signatory therein.	Current Report on Form 8-K (File No. 001-36304)	February 17, 2021
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, 2020, formatted in XBRL (eXtensible Business Reporting Language): (1) Consolidated Balance Sheets as of December 31, 2020 and 2019; (2) Consolidated Statements of Operations for the Years Ended December 31, 2020 and 2019; (3) Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2020 and 2019; (4) Consolidated Statements of Cash Flows for the Years Ended December 31, 2020 and 2019; 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 25, 2021

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, Chief Executive Officer and Director (Principal Executive Officer and Principal Financial Officer)	March 25, 2021
/s/ Caitlin Kontulis Caitlin Kontulis	Vice President of Finance and Administration and Secretary (Principal Accounting Officer)	March 25, 2021
/s/ Robert J. Bitterman Robert J. Bitterman	Director	March 25, 2021
/s/ Geert Cauwenbergh Geert Cauwenbergh, Dr. Med. Sc.	Director	March 25, 2021
/s/ H. Paul Dorman H. Paul Dorman	Director	March 25, 2021
/s/ Robert L. Ferrara Robert L. Ferrara	Director	March 25, 2021
/s/ Jonathan E. Freeman Jonathan E. Freeman, Ph.D.	Director	March 25, 2021
/s/ Curtis A. Lockshin Curtis A. Lockshin, Ph.D.	Director	March 25, 2021

Board of Directors

Robert J. Bitterman, Chairman
Former President & CEO, Cutanea Life Sciences, Inc.

Geert Cauwenbergh, Dr.Med.Sc.
Former President & CEO, Phio Pharmaceuticals Corp.

Gerrit Dispersyn, Dr.Med.Sc.
President & CEO, Phio Pharmaceuticals Corp.

H. Paul Dorman
Chairman & CEO, DFB Pharmaceuticals

Robert L. Ferrara
Former CFO, Cutanea Life Sciences, Inc.

Jonathan E. Freeman, Ph.D.
Co-founder and COO, Anthos Therapeutics Inc.

Curtis A. Lockshin, Ph.D.
CSO, Xenetic Biosciences, Inc.

Management Team

Gerrit Dispersyn, Dr.Med.Sc.
President & CEO

James Cardia, Ph.D.
Vice President of Business Operations

Simon Fricker, Ph.D.
Vice President of Research

Caitlin Kontulis
Vice President of Finance & Administration

Transfer Agent

Computershare Trust Company, N.A.

By Regular Mail:

P.O. Box 505000
Louisville, KY 40233-5000

By Overnight Delivery:

462 South 4th Street, Suite 1600
Louisville, KY 40202

Securities Listing

The Nasdaq Capital Market

Ticker: PHIO

Corporate Counsel

Gibson, Dunn & Crutcher LLP

San Francisco, CA

Auditors

BDO USA, LLP

Boston, MA

Corporate Headquarters

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