



2022

Phio Pharmaceuticals Corp.

Annual Report

Dear Shareholders and Friends of Phio:

This past year has been a decisive time in Phio's evolution transitioning from drug discovery to a clinical development company. We recently achieved a significant milestone with FDA approval to commence our first self-directed U.S. human clinical trial targeting various types of skin cancers with our INTASYL™ compound PH-762.

Last year under the guidance of Phio's Board of Directors and senior management, we undertook intense strategic planning, assessing every facet of our Company in the context of the current and projected immuno-oncology market. We specifically assessed where we should focus our technology, capital and human resources to meaningfully impact human health and, in turn, create shareholder value. After five months of rigorous Company introspection, medical market analysis and financial modeling, management developed a detailed three-year strategic plan, endorsed by our Board of Directors. This plan was driven by four immediate critical imperatives which management and the Board regarded as essential to driving shareholder value:

- To immediately commence the process of compiling, submitting and securing FDA clearance of an IND (Investigational New Drug) application to begin a phase 1b trial under Phio's direction to establish our patented INTASYL™ technology as safe and efficacious in man.
- To clearly articulate and align all aspects of our corporate messaging to be consistent and understandable among our stakeholders and target audiences.
- To determine and implement the appropriate business architecture to successfully execute the bridge from a drug discovery company to a clinical development company.
- To preserve the integrity of our NASDAQ Exchange listing.

We have already met each of these imperatives.

Today, we are primed to execute a dose-escalating clinical trial with our INTASYL compound (PH-762), in the 2nd half of 2023, to treat Stages I and II for cutaneous squamous cell carcinoma (cSCC) and late stages metastatic melanoma, Merkel and cSCC. Cutaneous squamous cell carcinoma represents over 50% of all solid tumors in the U.S. (excluding basal cell carcinoma) reaching 1.8 million incidents annually, a significant unsatisfied market. We believe our INTASYL drug may offer the optimal combination of relative efficacy, safety, tolerability, convenience and cost to many of those afflicted.

Concurrently, in concert with our development partner AgonOx, Inc., in conjunction with the Providence Cancer Institute, we have received FDA clearance to commence a combination trial of our PH-762 with the AgonOx 'double positive' (DP) CD8 tumor infiltrating lymphocytes (TIL) as adoptive cell therapy. This trial will treat metastatic melanoma, head and neck and other solid tumors.

In preparation for these clinical trials, we have implemented the redesign of our organization. We have secured human resource experience with a track record. Individuals who can drive these clinical imperatives without over-extending our infrastructure.

To more effectively convey the versatility of our RNA interference platform and compounds based on Nobel Prize winning technology, we completely revamped our website, facilitating access to information we believe you will find current and relevant. We invite you to access our website at www.phioharma.com in order to learn more about who we are and what our technology can do.

In summary, we see extraordinary potential to improve human health and in turn enhance shareholder value by continuing to focus and hone our unique technology to address the unmet needs of selected cancer targets. We appreciate your continued support.

Sincerely,
Robert J. Bitterman
President and CEO

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, 2022

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
(State or other jurisdiction of
incorporation or organization)

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

257 Simarano Drive, Suite 101, Marlborough, Massachusetts 01752
(Address of principal executive offices and Zip Code)

(508) 767-3861
(Registrant's telephone number, including area code)

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

Title of each class	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 Section 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 ☐
Non-accelerated filer ☒

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. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant’s executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the 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, 2022, was approximately \$9.5 million. 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 9, 2023, the registrant had 1,150,582 shares of Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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For the Fiscal Year Ended December 31, 2022

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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,” “target,” “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. Our actual results may differ materially from those indicated in the forward-looking statements as a result of a number of important factors, including, but not limited to:

- we are dependent on the success of our INTASYL™ technology platform, and our product candidates based on this platform, which is unproven and may never lead to approved and marketable products;
- our product candidates are in an early stage of development and we may fail, experience significant delays, never advance in clinical development or not be successful in our efforts to identify or discover additional product candidates, 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;
- if we experience delays or difficulties in identifying and enrolling subjects in clinical trials, it may lead to delays in generating clinical data and the receipt of necessary regulatory approvals;
- topline data may not accurately reflect or may materially differ from the complete results of a clinical trial;
- we rely upon third parties for the manufacture of the clinical supply for our product candidates;
- we are dependent on the patents we own and the technologies we license, and if we fail to maintain our patents or lose the right to license such technologies, our ability to develop new products would be harmed;
- we will require substantial additional funds to complete our research and development activities;
- 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.

The risks set forth above are not exhaustive and additional factors, including those identified in this Annual Report on Form 10-K under the heading “Risk Factors,” for 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, could adversely affect our business and financial performance. 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, except as required by law.

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 clinical stage biotechnology company whose proprietary INTASYL™ self-delivering RNAi technology platform is designed to make immune cells more effective in killing tumor cells. We are developing therapeutics that are designed to leverage INTASYL to precisely target specific proteins that reduce the body’s ability to fight cancer, without the need for specialized formulations or drug delivery systems. We are committed to discovering and developing innovative cancer treatments for patients by creating new pathways toward a cancer-free future.

INTASYL Platform

Overall, RNA is involved in the synthesis, regulation and expression of proteins. RNA takes the instructions from DNA and turns those instructions into proteins within the body’s cells. RNA interference, or RNAi, is a biological process that inhibits the expression of genes or the production of proteins. Diseases are often related to the incorrect protein being made, excessive amounts of a specific protein being made, or the correct protein being made, but at the wrong location or time. 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 considered “undruggable” by traditional therapeutics.

Our development efforts are based on our proprietary INTASYL self-delivering RNAi technology platform. It is a patented platform from which specific patented compounds are developed. INTASYL compounds are comprised of a unique sequence of chemically modified nucleotides (modified small interfering RNA, or siRNAs) that target a broad range of cell types and tissues. The compounds are designed to effectively silence genes that tumors use to evade the immune system.

Since the initial discovery of RNAi, drug delivery has been the primary challenge in developing RNAi-based therapeutics. Other siRNA technologies require cell targeting chemical conjugates which limit delivery to specific cell types. INTASYL is based on proprietary chemistry that is designed to maximize the activity and adaptability of the compound and is unique in that it can be delivered to any cell type or tissue without the need to modify the chemistry. This is designed to eliminate the need for formulations or delivery systems (for example, nanoparticles or electroporation). This provides efficient, spontaneous, cellular uptake with potent, long-lasting intracellular activity.

We believe that our INTASYL platform provides the following benefits including, but not limited to:

- Ability to target a broad range of cell types and tissues;
- Ability to target both intracellular and extracellular protein targets;
- Efficient uptake by target cells, avoiding the need for assisted delivery;
- Sustained, or long-term, effect *in vivo*;
- Ability to target multiple genes in one drug product;
- Favorable clinical safety profile with local administration; and
- Readily manufactured under current good manufacturing practices.

Our Pipeline

INTASYL compounds are designed to precisely target specific proteins that reduce the body's ability to fight cancer, without the need for specialized formulations or drug delivery systems, and are designed to make immune cells more effective in killing tumor cells. Our efforts are focused on developing immuno-oncology therapeutics using our INTASYL platform. We have demonstrated preclinical activity against multiple gene targets including PD-1, BRD4, CTLA-4, TIGIT and CTGF and have demonstrated preclinical efficacy in both direct-to-tumor injection and adoptive cell therapy ("ACT") applications with our INTASYL compounds.

The following table summarizes our product pipeline. Below we provide important information and context regarding each compound.

Program	Target(s) & Indication	Discovery	Preclinical Proof of Concept	Product Development	IND-enabling Studies	IND Filing or equivalent	Phase 1 Clinical Studies
PH-762 (EU)	PD-1 Metastatic Melanoma						
PH-762 (US)	PD-1 Metastatic Melanoma, HNSCC, cSCC, Merkel cell						
PH-762 (US) Enhanced TIL Study (Partnered w/ AgonOx, Inc.)	PD-1 Metastatic Melanoma, HNSCC						
PH-894 (US)	BRD-4 Metastatic Melanoma, HNSCC, HCC, TNBC						

PH-762

PH-762 is an INTASYL compound designed to reduce the expression of cell death protein 1 ("PD-1"). PD-1 is a protein that inhibits T cells' ability to kill cancer cells and is a clinically validated target in immunotherapy. Decreasing the expression of PD-1 can thereby increase the capacity of T cells, which protect the body from cancer cells and infections, to kill cancer cells.

Preclinical studies conducted by the Company have demonstrated that direct-to-tumor application of PH-762 resulted in potent anti-tumoral effects and have shown that direct-to-tumor treatment with PH-762 inhibits tumor growth in a dose dependent fashion in PD-1 responsive and refractory models. Importantly, direct-to-tumor administration of PH-762 resulted in activity against distant untreated tumors, indicative of a systemic anti-tumor response. We believe these data further support the potential for PH-762 to provide a strong local immune response without the dose immune-related adverse effects seen with systemic antibody therapy.

PH-762 is currently being evaluated in a Phase 1b dose escalation clinical trial in France that is expected to enroll up to 21 subjects with advanced melanoma. PH-762 will be administered as a neoadjuvant monotherapy intratumorally once a week, for a total of four injections, across five escalating dose levels. Dosing will be followed by tumoral excision after an additional two weeks. The primary study objectives are to evaluate the safety and tolerability, and pharmacokinetics of PH-762; to determine the potential immunologic and pathologic tumor responses; and to determine the recommended dose for later clinical trials. Safety data from the initial cohort of three subjects in the clinical trial was evaluated by a Data Monitoring Committee in the first quarter of 2023. The safety data review disclosed no dose-limiting toxicity, and no drug-related severe or serious adverse events, and the Data Monitoring Committee recommended proceeding to the enrollment of the subsequent dose cohort. The next cohort is now open for enrollment of subjects.

In addition to the French clinical trial, we expect to commence a U.S. Phase 1b clinical trial with PH-762 in the second half of 2023. The U.S. trial is expected to focus on the application of PH-762 to treat cutaneous squamous cell carcinoma (“cSCC”) and other selected cutaneous malignancies.

Due to INTASYL’s ease of administration, we have shown that our compounds can easily be incorporated into current ACT manufacturing processes. In ACT, T cells are usually taken from a patient’s own blood or tumor tissue, grown in large numbers in a laboratory, and then given back to the patient to help the immune system fight cancer. By treating T cells with our INTASYL compounds while they are being grown in the laboratory, we believe our INTASYL compounds can improve these immune cells to make them more effective in killing cancer. Preclinical data generated in collaboration with AgonOx, Inc. (“AgonOx”), a private company developing a pipeline of novel immunotherapy drugs targeting key regulators of the immune response to cancer, demonstrated that treating AgonOx’s “double positive” tumor infiltrating lymphocyte (“DP TIL”) with PH-762 increased by two-fold their tumor killing activity.

In March 2021, we entered into a clinical co-development collaboration agreement (the “**Clinical Co-Development Agreement**”) with AgonOx to conduct a Phase 1 clinical trial using DP TIL and PH-762. Under the Clinical Co-Development Agreement, we paid AgonOx \$0.3 million as an upfront payment in December 2022 and have agreed to provide up to \$4 million in total financial support to AgonOx to conduct a Phase 1 clinical trial of PH-762 treated DP TIL. Phio is also eligible to receive certain future development milestones and low single-digit sales-based royalty payments from AgonOx’s licensing of its DP TIL technology.

PH-762 treated DP TILs are expected to be evaluated in a Phase 1 clinical trial in the United States with up to 18 subjects with advanced melanoma and other advanced solid tumors. The primary study objectives are to evaluate the safety and to study the potential for enhanced therapeutic benefit from the administration of PH-762 treated DP TILs. Enrollment of subjects is expected to commence in the second quarter of 2023.

PH-762’s use in ACT is not limited to TILs. We have presented preclinical data showing that PH-762 significantly enhanced the antitumor efficacy of HER2-targeted chimeric antigen receptor (“CAR”) T cells (“HER2CART”) in solid tumors. Analysis of the PH-762 treated HER2CART cells isolated from the tumors suggest that PH-762 enhances CAR-T cell function through multiple mechanisms including enhanced efficiency, degranulation and promotion of memory/stem populations.

PH-894

PH-894 is an INTASYL compound that is designed to silence BRD4, a protein that controls gene expression in both T cells and tumor cells, thereby effecting the immune system as well as the tumor. Intracellular and/or commonly considered “undruggable” targets, such as BRD4, represent a challenge for small molecule and antibody therapies. Therefore, what sets this compound apart is its dual mechanism: PH-894 suppression of BRD4 in T cells results in T cell activation, and suppression of BRD4 in tumor cells results in tumors becoming more sensitive to being killed by T cells.

Preclinical studies conducted have demonstrated that PH-894 resulted in a strong, concentration dependent and durable silencing of BRD4 in T cells and in various cancer cells. Similar to PH-762, preclinical studies have also shown that direct-to-tumor application of PH-894 resulted in potent and statistically significant anti-tumoral effects and demonstrated a systemic anti-tumor response. These preclinical data indicate that PH-894 can reprogram T cells and other cells in the tumor microenvironment to provide enhanced immunotherapeutic activity. The Company has completed the investigational new drug (“IND”)-enabling studies and is in the process of finalizing the study reports required for an IND submission with PH-894. As a result of the reprioritization to advance the Company’s clinical trial with PH-762 in the U.S., the Company has elected to defer the IND submission for PH-894.

Phio has also demonstrated in preclinical studies that 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). Preclinical data indicates that silencing BRD4 with PH-894 may be used to improve the characteristics of CAR-T cell products during the cell manufacturing process. These data demonstrate that PH-894 could enhance the activity of CAR-T cells by improving the quality of the final CAR-T cell product by overcoming immunosuppression, reversing exhaustion, and preserving the characteristics associated with cell persistence.

Other Compounds in Discovery

PH-804 is an INTASYL compound that is designed to target TIGIT, a protein that inhibits the activity of Natural Killer (“NK”) cells. Preclinical studies conducted have demonstrated that NK cells treated with PH-804 displayed increased activation and enhanced the ability of NK cells to kill cancer cells.

PH-109 is an INTASYL compound that is designed to suppress the connective tissue growth factor (“CTGF”) protein, a protein that regulates a number of cellular functions and is associated with poor prognosis in breast cancer. In a preclinical study, mice were treated with either the drug doxorubicin, a chemotherapeutic which has a high toxicity profile, or with PH-109. In this study, PH-109 reduced tumor growth and reduced metastatic lung lesions, with no evidence of toxicity as compared to the toxicity profile of doxorubicin.

Phio has developed an INTASYL compound that is designed to target CTLA-4, a protein that inhibits the ability of T cells to kill tumor cells. The CTLA-4 targeting INTASYL compound demonstrated dose-associated anti-tumor efficacy in two preclinical tumor models. Delivering CTLA-4 by intratumoral injection may avoid or minimize the severe systemic adverse events associated with current CTLA-4 therapeutics.

We are also investigating the use of INTASYL to target multiple genes in a single formulation. Unlike other combination approaches, we believe the INTASYL platform can target multiple protein drug targets in a specific therapeutic dose, enhancing potency while maintaining a favorable tolerability and safety profile. Preclinical data has shown that combining PH-762 and PH-894 in a single formulation elicited complete cure of tumors in a liver cancer model and outperformed the efficacy of the small molecule and antibody control treatments toward the same targets. In addition, local INTASYL therapy was shown to induce a systemic anti-tumor response with the clearance of distant untreated tumors. We believe that these data demonstrate that the use of INTASYL to target multiple genes may provide a durable and systemic anti-tumor immune response that can combat tumor growth.

Intellectual Property

INTASYL compounds have a single-stranded phosphorothioate region, a short duplex region, and contain a variety of nuclease-stabilizing and lipophilic chemical modifications that we believe combines the beneficial properties of both conventional RNAi and antisense technologies. 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.

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	9	46
Canada	6	4
Europe	12	39
Japan	9	16
Other Markets	11	14

Our portfolio includes 119 issued patents, 87 of which cover our INTASYL platform. There are 17 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 2040. Furthermore, there are 47 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 2040, 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).

Key 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.

Advanced RNA Technologies, LLC (“Advirna”). In September 2011, the Company entered into an agreement with Advirna, pursuant to which Advirna assigned to us its existing patent and technology rights related to the INTASYL technology in exchange for an annual maintenance fee, a one-time milestone payment upon the future issuance of the first patent with valid claims covering the assigned patent and technology rights and the issuance of shares of common stock of the Company equal to 5% of the Company’s fully-diluted shares outstanding at the time of issuance. In 2012, we issued shares of common stock of the Company to Advirna equal to 5% of our fully-diluted shares outstanding at the time of issuance and paid \$350,000 to Advirna upon the issuance of the first patent in 2014. Additionally, we also pay to Advirna an annual maintenance fee of \$100,000 and are required to pay low single-digit royalties on any licensing revenue received by us with respect to future licensing of the assigned Advirna patent and technology rights. To date, any royalties owed to Advirna under the agreement 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) included in the 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. Further, the Company also granted back to Advirna a license under the assigned patent and technology rights for fields of use outside human therapeutics.

Manufacturing and Supply

We do not have any manufacturing capability and therefore we currently rely on and intend to continue to rely on contract manufacturing organizations to produce our product candidates in accordance with regulatory requirements.

We currently rely on and contract with third parties for the manufacture of drug substances and drug products for use in our preclinical studies and clinical trials in accordance with regulatory requirements. We intend that we will continue to rely on and contract with third parties to manufacture our product candidates in the future.

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. Many of these companies are larger than us and have greater financial resources and human capital to develop competing products.

Government Regulation

Review and Approval of Drugs in the United States

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, preclinical studies 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 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 of the FDA’s staff.

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 utilizing 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, failure to comply with the applicable requirements could result in administrative or judicial enforcement action, which could include refusal to permit clinical trials, refusal to approve an application, withdrawal of an approval, issuance of a warning letter, product recall, product seizure, suspension of production or distribution, fines, refusals of government contracts, and restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

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.

In order to market any pharmaceutical product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions governing, among other things, research and development, testing, manufacturing, quality control, safety, efficacy, clinical trials, marketing authorization, packaging, storage, record keeping, reporting, export and import, advertising and other promotional practices involving pharmaceutical products, as well as commercial sales, distribution and post-approval monitoring and reporting of our products. Whether or not it obtains FDA approval for a pharmaceutical product, the company would need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical trials or marketing of the pharmaceutical product in those countries or jurisdictions. The approval process ultimately varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer and far more difficult than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

The United Kingdom (“UK”) formally left the European Union (“EU”) on January 31, 2020 and the transition period, during which EU laws continued to apply to the UK, expired on December 31, 2020. This means EU laws now only apply to the UK in respect of Northern Ireland as laid out in the Protocol on Ireland and Northern Ireland. Following the end of the transition period, the EU and the UK concluded a trade and cooperation agreement (“TCA”), which applied provisionally from January 1, 2021 and entered into force on May 1, 2021.

The TCA includes provisions affecting the life sciences sector (including on customs and tariffs) but areas for further discussion between the EU and the UK remain. In addition, there are some specific provisions concerning pharmaceuticals. These include the mutual recognition of Good Manufacturing Practice (“GMP”) and issued GMP documents. The TCA does not, however, contain wholesale mutual recognition of UK and EU pharmaceutical regulations and product standards.

Since January 1, 2021, the EU laws which have been transposed into UK law through secondary legislation continue to be applicable in the UK as “retained EU law”. As there is no general power to amend these regulations, the UK government has enacted the Medicines and Medical Devices Act 2021. The purpose of the act is to enable the existing regulatory frameworks in relation to human medicines, clinical trials of human medicines, veterinary medicines and medical devices to be updated. The powers under the act may only be exercised in relation to specified matters and must safeguard public health.

Specified provisions of the Medicines and Medical Devices Act 2021 entered into force on February 11, 2021. The remaining provisions came into effect within two months of February 11, 2021 or will otherwise come into effect as stipulated in subsequent statutory instruments. The Medicines and Medical Devices Act 2021 supplements the UK Medical Devices Regulations 2002 (the “UK Regulations”), which are based on the EU Medical Devices Directive as amended to reflect the UK’s post-Brexit regulatory regime. Notably, the UK Regulations do not include any of the revisions that have been made by the EU Medical Devices Regulation (EU) 2017/745, which, since May 26, 2021, now applies in all EU Member States.

The UK’s Medicines and Healthcare products Regulatory Agency conducted a comprehensive consultation between September and November 2021 on proposals to develop a new UK regime for medical devices in the UK. The proposals include more closely aligning definitions for medical devices and in vitro medical devices with internationally recognized definitions and changing the classification of medical devices according to levels or risk. The proposals are intended to improve patient and public safety and increase the appeal of the UK market. The new regime is planned to come into force on July 1, 2023, which will align with the date from which the UK is due to stop accepting CE marked medical devices and require UKCA (UK Conformity Assessed) marking. It is envisaged that, in Northern Ireland, the amended regime could run in parallel with any existing or future EU rules in accordance with the Protocol on Ireland and Northern Ireland.

Drug Development Process

The conduct of clinical trials is currently governed by the EU Clinical Trials Directive 2001/20/EC (the “**Clinical Trials Directive**”), and will be gradually replaced by the EU Clinical Trials Regulation (EU) No. 536/2014 (“CTR”). The CTR introduces a complete overhaul of the existing regulation of clinical trials for medicinal products in the EU. It entered into force on January 31, 2022.

Under the current regime, which will expire after a transition period of one or three years, respectively, as outlined below in more detail, before a clinical trial can be initiated, it must be approved in each EU Member State in which the clinical trial is to be conducted. The approval must be obtained from two separate entities: the National Competent Authority (“NCA”) and one or more Ethics Committees. The NCA of the EU Member States in which the clinical trial will be conducted must authorize the conduct of the trial, and the independent Ethics Committee must grant a positive opinion in relation to the conduct of the clinical trial in the relevant EU Member State before the commencement of the trial. Any substantial changes to the trial protocol or other information submitted with the clinical trial applications must be submitted to or approved by the relevant NCA and Ethics Committees. Under the current regime all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial must be reported to the NCA and to the Ethics Committees of the EU Member State where they occur.

A more unified procedure applies under the new CTR, which came into force on January 31, 2022. A sponsor is able to submit a single application for approval of a clinical trial through a centralized EU clinical trials portal. One national regulatory authority (the reporting EU Member State proposed by the applicant) takes the lead in validating and evaluating the application, and will consult and coordinate with the other concerned Member States. If an application is rejected, it may be amended and resubmitted through the EU clinical trials portal. If an approval is issued, the sponsor may start the clinical trial in all concerned Member States. However, a concerned EU Member State may in limited circumstances declare an “opt-out” from an approval and prevent the clinical trial from being conducted in such Member State. The CTR also aims to streamline and simplify the rules on safety reporting, and introduces enhanced transparency requirements such as mandatory submission of a summary of the clinical trial results to the EU Database (“CTIS”). While Member States will work in CTIS immediately after the system has gone live, the CTR provides for two transition periods for sponsors: For one year, until January 31, 2023, clinical trial sponsors can still choose whether to submit an initial clinical trial application in line with the current system (Clinical Trials Directive) or via CTIS. From January 31, 2023, submission of initial clinical trial applications via CTIS becomes mandatory, and by January 31, 2025, all ongoing trials approved under the current Clinical Trials Directive will be governed by the new Regulation and have to be transitioned to CTIS.

Under both the current regime and the new CTR, national laws, regulations, and the applicable Good Clinical Practice and Good Laboratory Practice standards must also be respected during the conduct of the trials, including the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use guidelines on Good Clinical Practice (“GCP”) and the ethical principles that have their origin in the Declaration of Helsinki.

Marketing Authorization Procedures

In the EU and in Iceland, Norway and Liechtenstein (together, the European Economic Area or “EEA”), after completion of all required clinical testing, pharmaceutical products may only be placed on the market after obtaining a Marketing Authorization (“MA”). To obtain a MA of a drug under EU regulatory systems, an applicant can submit a Marketing Authorization Application (“MAA”) through, amongst others, a centralized or decentralized procedure.

The centralized procedure provides for the grant of a single MA by the European Commission (“EC”) that is valid for all EU Member States and, after respective national implementing decisions, in the three additional EEA Member States. The centralized procedure is compulsory for specific medicinal products, including for medicines developed by means of certain biotechnological processes, products designated as orphan medicinal products, advanced therapy medicinal products (“ATMP”) and medicinal products with a new active substance indicated for the treatment of certain diseases (AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases).

For medicinal products containing a new active substance not yet authorized in the EEA before May 20, 2004 and indicated for the treatment of other diseases, medicinal products that constitute significant therapeutic, scientific or technical innovations or for which the grant of a MA through the centralized procedure would be in the interest of public health at EU level, an applicant may voluntarily submit an application for a marketing authorization through the centralized procedure.

Under the centralized procedure, the Committee for Medicinal Products for Human Use (“CHMP”), established at the European Medicines Agency (“EMA”), is responsible for conducting the initial assessment of a drug. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing marketing authorization. Under the centralized procedure, the timeframe for the evaluation of a MAA by the EMA’s CHMP is, in principle, 210 days from receipt of a valid MAA. However, this timeline excludes clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP, so the overall process typically takes a year or more, unless the application is eligible for an accelerated assessment. Accelerated assessment might be granted by the CHMP in exceptional cases when a medicinal product is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. On request, the CHMP can reduce the time frame to 150 days if the applicant provides sufficient justification for an accelerated assessment. The CHMP will provide a positive opinion regarding the application only if it meets certain quality, safety and efficacy requirements. However, the EC has final authority for granting the MA within 67 days after receipt of the CHMP opinion.

The decentralized procedure permits companies to file identical MA applications for a medicinal product to the competent authorities in various EU Member States simultaneously if such medicinal product has not received marketing approval in any EU Member State before. This procedure is available for pharmaceutical products not falling within the mandatory scope of the centralized procedure.

The competent authority of a single EU Member State, known as the reference EU Member State, is appointed to review the application and provide an assessment report. Under this procedure, an applicant submits an application based on identical dossiers and related materials, including a draft summary of product characteristics, and draft labeling and package leaflet, to the reference EU Member State and concerned EU Member States. The reference EU Member State prepares a draft assessment report and drafts of the related materials within 120 days after receipt of a valid application. Subsequently, each concerned EU Member State must decide whether to approve the assessment report and related materials. If an EU Member State cannot approve the assessment report and related materials on the grounds of potential serious risk to public health, the disputed points are subject to a dispute resolution mechanism and may eventually be referred to the EC, whose decision is binding for all EU Member States.

All new MAAs must include a Risk Management Plan (“RMP”), describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. RMPs and Periodic Safety Update Reports are routinely available to third parties requesting access, subject to limited redactions.

Marketing Authorizations have an initial duration of five years. After these five years, the authorization may subsequently be renewed on the basis of a reevaluation of the risk-benefit balance. Once renewed, the MA is valid for an unlimited period unless the EC or the national competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with only one additional five-year renewal. Applications for renewal must be made to the EMA at least nine months before the five-year period expires.

Data and Market Exclusivity in the European Union

As in the United States, it may be possible to obtain a period of market and/or data exclusivity in the EU that would have the effect of postponing the entry into the marketplace of a competitor’s generic, hybrid or biosimilar product (even if the pharmaceutical product has already received a MA) and prohibiting another applicant from relying on the MA holder’s pharmacological, toxicological and clinical data in support of another MA for the purposes of submitting an application, obtaining MA or placing the product on the market.

New medicinal products authorized in the European Union, qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. The overall ten-year period of market exclusivity can be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

The data exclusivity period prevents generic or biosimilar applicants from relying on the preclinical and clinical trial data contained in the dossier of the reference medicinal product when applying for a generic or biosimilar marketing authorization in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until 10 years have elapsed from the initial authorization of the reference product in the EU.

Post-approval Regulation

Similar to the United States, both marketing authorization holders and manufacturers of pharmaceutical products are subject to comprehensive regulatory oversight by the EMA, the EC and/or the competent regulatory authorities of the EU Member States.

The holder of an EU marketing authorization for a pharmaceutical product must also comply with EU pharmacovigilance legislation and its related regulations and guidelines, which entail many requirements for conducting pharmacovigilance, or the assessment and monitoring of the safety of pharmaceutical products.

Failure by us or by any of our third-party partners, including suppliers, manufacturers and distributors to comply with EU laws and the EU Member State laws implementing Directive 2001/83/EC on pharmaceutical products for human use and other core legislation relating to pharmaceutical products, and other EU Member State laws that apply to the conduct of clinical trials, manufacturing approval, marketing authorization of pharmaceutical products and marketing of such products, both before and after grant of marketing authorization, manufacturing of pharmaceutical products, statutory health insurance, bribery and anti-corruption or with other applicable regulatory requirements may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials or to grant marketing authorization, product withdrawals and

recalls, product seizures, suspension, withdrawal or variation of the marketing authorization, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

European Union Data Laws

The collection and use of personal health data and other personal information in the EU is governed by the provisions of the General Data Protection Regulation (“**GDPR**”), which came into force in May 2018, and related implementing laws in individual EU Member States. In addition, following the UK’s formal departure from the EU on January 31, 2020 and the end of the transition period on December 31, 2020, the United Kingdom has become a “third country” for the purposes of EU data protection law. A “third country” is a country other than the EU Member States and the three additional European Economic Area countries (Norway, Iceland and Liechtenstein) that have adopted a national law implementing the GDPR. However, the TCA includes a provision, whereby the transfer of personal data from the EU to the UK will not be considered as a transfer to a “third country” for a period of four months starting from the entry into force of the TCA. This period will be extended by two further months, unless the EU or the UK objects. Under the GDPR, personal data can only be transferred to third countries in compliance with specific conditions for cross-border data transfers. Appropriate safeguards are required to enable transfers of personal data from the EU Member States. This status has a number of significant practical consequences, in particular for international data transfers, competent supervisory authorities and enforcement of the GDPR. The GDPR increased responsibility and liability in relation to personal data that we process.

The GDPR imposes a number of strict obligations and restrictions on the ability to process (processing includes collection, analysis and transfer of) personal data, including health data from clinical trials and adverse event reporting. The GDPR also includes requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals prior to processing their personal data or personal health data, notification of data processing obligations to the national data protection authorities and the security and confidentiality of the personal data. The GDPR also prohibits the transfer of personal data to countries outside of the EU that are not considered by the EU to provide an adequate level of data protection, except if the data controller meets very specific requirements. These countries include the United States, and following the end of the six month period as laid out in the TCA, it may include the UK if no adequacy decision is given prior to this. Following the Schrems II decision of the Court of Justice of the European Union on July 16, 2020, there is uncertainty as to the general permissibility of international data transfers under the GDPR. In light of the implications of this decision we may face difficulties regarding the transfer of personal data from the EU to third countries. The European Data Protection Board has adopted draft recommendations for data controllers and processors who export personal data to third countries regarding supplementary measures to ensure compliance with the GDPR when transferring personal data outside of the EU. These recommendations were submitted to public consultation until December 21, 2020, however it is unclear when and in which form these recommendations will be published in final form.

Failure to comply with the requirements of the GDPR and the related national data protection laws of the EU Member States may result in significant monetary fines, other administrative penalties and a number of criminal offenses (punishable by uncapped fines) for organizations and in certain cases their directors and officers as well as civil liability claims from individuals whose personal data was processed. Data protection authorities from the different EU Member States may still implement certain variations, enforce the GDPR and national data protection laws differently, and introduce additional national regulations and guidelines, which adds to the complexity of processing personal data in the EU. Guidance developed at both EU level and at the national level in individual EU Member States concerning implementation and compliance practices are often updated or otherwise revised.

There is, moreover, a growing trend towards required public disclosure of clinical trial data in the EU which adds to the complexity of obligations relating to processing health data from clinical trials. Such public disclosure obligations are provided in the new EU Clinical Trials Regulation, EMA disclosure initiatives and voluntary commitments by industry. Failing to comply with these obligations could lead to government enforcement actions and significant penalties against us, harm to our reputation, and adversely impact our business and operating results. The uncertainty regarding the interplay between different regulatory frameworks, such as the Clinical Trials Regulation and the General Data Protection Regulation, further adds to the complexity that we face with regard to data protection regulation.

New Legislation and Regulations

From time to time, legislation is drafted, introduced and passed in the EU, its Member States and other states of Europe that could significantly change the statutory provisions governing the testing, approval, manufacturing, marketing, coverage and reimbursement of pharmaceutical products. In addition to new legislation, pharmaceutical regulations and policies are often revised or interpreted by the EMA and national agencies in ways that may significantly affect our business and our products.

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. However, to date, compliance with such environmental laws and regulations has not had a material impact on our capital expenditures.

Human Capital Management

As of December 31, 2022, we had nine full-time employees and one part-time employee 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 2023 to increase our expertise and resources available in our clinical development and administrative areas. We continually evaluate our business needs and weigh the use of in-house expertise and capacity with outsourced expertise and capacity. We currently outsource substantially all 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, we offer a total rewards package consisting of base salary and cash target bonus, 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 payouts are based on performance.

A 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

Effective January 26, 2023, the Company completed a 1-for-12 reverse stock split of the Company's outstanding common stock. The reverse stock split did not reduce the number of authorized shares of the Company's common or preferred stock. 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, we changed our name to Phio Pharmaceuticals Corp., to reflect our 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, compensation, nominating and governance committees, as well as our corporate code of ethics and conduct.

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 this website, and our website, 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

We are dependent on the success of our INTASYL technology platform, and our product candidates based on this platform, which is unproven and may never lead to approved and marketable products.

Our efforts have been focused on the development of product candidates based on our INTASYL technology platform. We have invested, and we expect to continue to invest, significant financial resources and efforts developing our product candidates. Our ability to eventually generate revenue is highly dependent on the successful development, regulatory approval and commercialization of our INTASYL product candidates by us or by collaborative partners, which may not occur for the foreseeable future, if ever, and is highly uncertain and depends on a number of factors, many of which are beyond our control. 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 will spend large amounts of money developing our INTASYL platform technology and may never succeed in obtaining regulatory approval. In addition, our research methodology may be unsuccessful in identifying product candidates and results from preclinical studies and clinical trials 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 or impossible to manufacture, receive regulatory approval or commercialize. 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.

Our product candidates are in an early stage of development and we may fail, experience significant delays, never advance clinical development or not be successful in our efforts to identify or discover additional product candidates, which may materially and adversely impact our business.

Our success depends heavily on the successful development of our product candidates, which may never occur. Our product candidates, which are in early stages of development, could be delayed, not advance into the clinic, or unexpectedly fail at any stage of development. Our ability to identify, develop and commercialize product candidates is dependent on extensive preclinical and other non-clinical tests in order to support an IND application in the United States, or the equivalent with regulatory authorities in other jurisdictions. These research programs to identify new product candidates require substantial financial and human resources, are difficult to design and can take many years to complete.

We cannot be certain of the outcome of our research studies and clinical trials and the results from these studies and clinical trials may not predict the results that will be obtained in later stages of development and we may focus our efforts and resources on product candidates that may prove to be unsuccessful. There is no assurance that we will be able to successfully develop our product candidates, and we may forego opportunities with certain product candidates or for indications that later prove to have greater commercial potential. If we are not able to successfully develop our product candidates, we may be forced to abandon or delay our development efforts, which may materially and adversely affect our business, financial condition, and results of operations.

Further, the FDA, or equivalent foreign regulatory authority, may not accept the results of our preclinical studies or clinical trials and may require us to complete additional studies or impose stricter approval conditions than we expect, which could impact the value of a particular program, the approvability or commercialization of the particular product candidate or product and our Company in general. 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 studies or clinical trials 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 such preclinical studies or clinical trials.

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

We are dependent on third parties that have direct access to the patient or donor cells used in cell therapy 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 other research agreements with 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, their corporate objectives may not align with ours, and 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, and 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, and results of operations could be materially and adversely affected.

If we experience delays or difficulties in identifying and enrolling subjects in clinical trials, it may lead to delays in generating clinical data and the receipt of necessary regulatory approvals.

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, which could materially and adversely impact our business and financial condition. We may experience slower than expected subject enrollment, including as a result of the coronavirus pandemic, in our current or future clinical trials. In addition, clinical trials for drug candidates that treat the same indications as our product candidates may result in subjects who would otherwise be eligible for our clinical trials instead enrolling in clinical trials for other drug candidates.

Topline data may not accurately reflect or may materially differ from the complete results of a clinical trial.

From time to time, we may publicly disclose topline or interim data from our clinical trials based on a preliminary analysis of then-available data, of which the results, related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. Preliminary observations made in early stages of clinical trials are not necessarily indicative of results that will be obtained when full data sets are analyzed or in subsequent clinical trials. As a result, topline data may differ from future results from the same studies or different conclusions may qualify such results once additional data has been received and evaluated. Topline or interim data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data that we publicly disclose and should be viewed with caution until the complete data is available. If the topline data we report differs from future analysis of results, or if others, including regulatory authorities, disagree with the conclusions reached, our business, financial condition, and results of operations could be materially and adversely affected.

We rely upon third-parties to conduct our clinical trials and other studies for our product candidates, and if they do not successfully fulfill their obligations, the development of our product candidates may be materially impacted.

We depend upon third-party CROs, medical institutions, clinical investigators, consultants and other third-parties to support and conduct our clinical trials and rely on these third-party CROs for the execution of certain of our preclinical studies and expect to continue to do so. 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. We and our CROs are responsible for ensuring that our clinical trials are conducted in accordance with applicable regulations and protocols. If we or our CROs fail to comply with these applicable regulations, the FDA, or equivalent foreign regulatory authority, may not accept these data and may require us to complete additional preclinical studies and clinical trials, which could result in significant additional costs and delays to us.

As we only control certain aspects of their activities, we cannot guarantee that these partners will fulfill their obligations to us under these arrangements. If these third-parties do not successfully carry out their responsibilities, as well as within a timely fashion, our clinical trials and preclinical studies may be delayed, unsuccessful or otherwise adversely affected. If we have to enter into alternative arrangements it may delay or adversely affect the development of our product candidates and our business operations. This could be difficult, costly or impossible, and our preclinical studies or clinical trials may need to be extended, delayed, terminated or repeated, and we may not be able to obtain regulatory approval in a timely fashion, or at all, for the applicable drug candidate, or to commercialize such drug candidate being tested in such studies or trials.

France adopted the General Data Protection Regulation, a data privacy regulation, and as we are conducting a clinical trial in France we are required to follow this law, which, if violated, could subject us to significant fines.

The collection and use of personal health data and other personal information in the European Union is governed by the provisions of the GDPR, which came into force in May 2018 and related implementing laws in individual EU Member States.

The GDPR imposes a number of strict obligations and restrictions on the ability to process (processing includes collection, analysis and transfer of) personal data of individuals within the EU and in the EEA, including health data from clinical trials and adverse event reporting. The GDPR also includes requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals prior to processing their personal data or personal health data, notification of data processing obligations to the national data protection authorities and the security and confidentiality of the personal data. EU Member States may also impose additional requirements in relation to health, genetic and biometric data through their national implementing legislation.

Under the GDPR, personal data can only be transferred within the EU Member States and the three additional EEA countries (Norway, Iceland and Liechtenstein) that have adopted a national law implementing the GDPR. Appropriate safeguards are required to enable cross-border transfers of personal data from the EU and EEA Member States to a “third country” (a country outside the EU or EEA). This status has a number of significant practical consequences, in particular for international data transfers, competent supervisory authorities and enforcement of the GDPR.

The GDPR prohibits the transfer of personal data to countries outside of the EU/EEA (including the United States) that are not considered by the EC to provide an adequate level of data protection, except if the data controller meets very specific requirements such as the use of standard contractual clauses (“SCCs”), issued by the EC. In this respect recent legal developments in Europe have created complexity and compliance uncertainty regarding certain transfers of personal data from the EU/EEA. For example, following the Schrems II decision of the Court of Justice of the EU on July 16, 2020, in which the Court invalidated the Privacy Shield under which personal data could be transferred from the EU/EEA to United States entities who had self-certified under the Privacy Shield scheme, there is uncertainty as to the general permissibility of international data transfers under the GDPR. The Court did not invalidate the then current SCCs, but ruled that data exporters relying on these SCCs are required to verify, on a case-by-case basis, if the law of the third country ensures an adequate level of data protection that is essentially equivalent to that guaranteed in the EU/EEA. In light of the implications of this decision we may face difficulties regarding the transfer of personal data from the EU/EEA to third countries, such as the United States. However, on June 4, 2021 the EC issued a new set of SCCs for data transfers from controllers or processors in the EU/EEA to controllers or processors established outside the EU/EEA. These SCCs replace the old sets of SCCs that were adopted under the previous European Data Protection Directive 95/46. Since September 27, 2021, it is no longer possible to conclude contracts incorporating these previous versions of the SCCs. In addition, for contracts concluded before September 27, 2021, it is still possible to rely on the previous SCCs until the end of an additional 15 months transitional period (until December 27, 2022), provided that the processing operations which are the subject matter of the contract remain unchanged and reliance on previous SCCs ensures that the transfer is subject to appropriate safeguards. On November 11, 2021, the European Data Protection Board adopted recommendations on such appropriate safeguards that supplement transfer mechanisms. These recommendations aim to assist data exporters with their duty to identify and implement appropriate supplementary measures where they are needed to ensure an essentially equivalent level of protection to the personal data they transfer to third countries.

Failure to comply with the requirements of the GDPR and the related national data protection laws of the EU Member States may result in significant monetary fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater, other administrative penalties and a number of criminal offenses (punishable by uncapped fines) for organizations and in certain cases their directors and officers as well as civil liability claims from individuals whose personal data was processed. Data protection authorities from the different EU Member States may still implement certain variations, enforce the GDPR and national data protection laws differently, and introduce additional national regulations and guidelines, which adds to the complexity of processing personal data in the EU. Guidance developed at both EU level and at the national level in individual EU Member States concerning implementation and compliance practices are often updated or otherwise revised. Ensuring compliance with GDPR is time-intensive and may increase the cost of doing business, and failure to comply with these laws may have a material impact on our operations and financial condition.

There is, moreover, a growing trend towards required public disclosure of clinical trial data in the EU which adds to the complexity of obligations relating to processing health data from clinical trials. Such public disclosure obligations are provided in the new EU Clinical Trials Regulation, EMA disclosure initiatives and voluntary commitments by industry. Failing to comply with these obligations could lead to government enforcement actions and significant penalties against us, harm to our reputation, and adversely impact our business and operating results. The uncertainty regarding the interplay between different regulatory frameworks, such as the Clinical Trials Regulation and the GDPR, further adds to the complexity that we face with regard to data protection regulation.

On June 28, 2021 the European Commission adopted two adequacy decisions for the UK – one under the GDPR and the other for the Law Enforcement Directive. Personal data may now freely flow from the EU to the UK since the UK is deemed to have an adequate data protection level. Additionally, following the UK's withdrawal from the EU and the EEA, companies also have to comply with the UK's data protection laws (including the UK GDPR, which is based on the EU GDPR), the latter regime having the ability to separately fine up to the greater of £17.5 million or 4% of global turnover. The adequacy decisions include a 'sunset clause' which entails that the decisions will automatically expire four years after their entry into force.

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, or foreign equivalent. 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 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.

Preclinical studies and clinical trials are lengthy and expensive, and their outcome is highly uncertain. Historical failure rates are high due to a 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 clinical trial and refusing to approve a particular drug candidate for any or all indications of use.

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.

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 ongoing 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. Any delay or failure in obtaining required approvals may prevent us from completing our preclinical studies or clinical trials 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, which could have a material impact on our business, financial condition, and results of operations.

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

The biotechnology and pharmaceutical industries have intense competition and contain a high degree of risk and there are many other companies actively engaged in the discovery, development and commercialization of products that may compete with our product candidates. 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.

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.

We have a small core management team and are particularly dependent on them. Accordingly, 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 an employment agreement with our Chief Executive Officer, 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.

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

The use of our product candidates in clinical trials and, if any of our product candidates receive regulatory approval, the sale of our product candidates for commercial use expose us to the risk of product liability claims. Product liability claims may be brought against us by patients, healthcare providers, consumers or others who come into contact with our product candidates or approved products. 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. However, 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 of our product candidates and the marketing of those product candidates, if approved. 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. If we cannot successfully defend against product liability claims, we could incur substantial liabilities. 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 of these outcomes could materially impact our business and financial condition.

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

We rely on third-party suppliers and manufacturers to provide us with the materials and services to manufacture our product candidates for certain preclinical studies and for our clinical trials, and we expect that we will continue to rely on third-party manufacturers for the supply of our product candidates in the future. We have limited in-house manufacturing capabilities and resources, and we do not own or lease manufacturing facilities or have our own supply source for the required materials to manufacture our compounds. Further, we have limited current good manufacturing practice (“cGMP”) manufacturing capabilities and limited experience in scale-up of clinical supply as our internal capabilities are limited to small-scale production of research material. Accordingly, we are dependent upon third-party suppliers and contract manufacturers to obtain supplies and manufacture our product candidates and we will need to either develop, contract for, or otherwise arrange for the necessary manufacturers for these supplies.

There are a limited number of manufacturers that make oligonucleotides and we currently contract with multiple manufacturers for the supply of our product candidates to reduce the risk of supply interruption or availability. However, there is no assurance that our supply of our product candidates will not be limited, interrupted, of satisfactory quality or be available at acceptable prices. For example, constraints on the supply chain and availability of resources due to the ongoing coronavirus pandemic have resulted in delays and shortages at manufacturing facilities. While we have engaged with multiple manufacturers for the supply of our product candidates in order to mitigate the impact of the loss or delay of any one manufacturer, there can be no assurance that our efforts will be successful. 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. If we or any of these manufacturers are unable or unwilling to increase its manufacturing capacity or if we are unable to establish alternative arrangements on a timely basis or on acceptable terms, the development and commercialization of such an approved product may be delayed or there may be a shortage in supply. Any inability to manufacture our product candidates or future approved drugs in sufficient quantities when needed would seriously harm our business.

Approval of any of our product candidates will not occur unless the manufacturing facilities are in compliance with the FDA's cGMP regulations, or a foreign equivalent's regulations, in order to ensure that drug products are safe and that they consistently meet applicable requirements and specifications. These requirements are enforced by the FDA and other regulatory authorities through periodic inspections of the manufacturing facilities and can result in enforcement action, such as warning letters, fines and suspension of production if they are found to not be in compliance with the regulations. 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 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.

Unstable market and economic conditions, including elevated and sustained inflation, may have serious adverse consequences on our business, financial condition and stock price.

As has been widely reported, we are currently operating in a period of economic uncertainty and capital markets disruption, which has been significantly impacted by domestic and global monetary and fiscal policy, geopolitical instability, an ongoing military conflict between Russia and Ukraine, and historically high domestic and global inflation. In particular, the conflict in Ukraine has exacerbated market disruptions, including significant volatility in commodity prices, as well as supply chain interruptions, and has contributed to record inflation globally. The U.S. Federal Reserve and other central banks may be unable to contain inflation through more restrictive monetary policy and inflation may increase or continue for a prolonged period of time. Inflationary factors, such as increases in the cost of clinical supplies, interest rates, overhead costs and transportation costs may adversely affect our operating results. We continue to monitor these events and the potential impact on our business. Although we do not believe that inflation has had a material impact on our financial position or results of operations to date, we may be adversely affected in the future due to domestic and global monetary and fiscal policy, supply chain constraints, consequences associated with the coronavirus pandemic and the ongoing conflict between Russia and Ukraine, and such factors may lead to increases in the cost of manufacturing our product candidates and delays in initiating studies. In addition, global credit and financial markets have experienced extreme volatility and disruptions in the past several years and the foregoing factors have led to and may continue to cause diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, uncertainty about economic stability and increased inflation.

There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals.

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 preparing and filing 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.

Risks Relating to Our Intellectual Property

We may be involved in litigation to protect our patents and intellectual property rights and our ability to protect our patents and intellectual property rights is uncertain and may subject us to potential liabilities.

We have filed patent applications, have pending patents that we have licensed and those that we own and expect to continue to file patent applications. We may also need to license patents and patent applications from research sponsored by us with third-parties. 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 patent granting authorities have upheld stringent standards for the RNAi patents that have been prosecuted so far and, 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.

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 patents 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. Our efforts to enforce and maintain our intellectual property rights may not be successful and may result in substantial costs and diversion of management and key employee's time. If we are unable to defend our licensed or owned intellectual property, it may have a materially and adverse impact on our business, results of operations and financial condition.

Third-parties may claim that we infringe their patents, which may result in substantial liabilities and prevent us from pursuing the development of our product candidates.

Because the field we operate in is constantly changing and patent applications are still being processed by government patent offices around the world, 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 field we operate. Further, many patents in the fields we are pursuing have already been exclusively licensed to third-parties, including our competitors. It is possible that we may become a party to such proceedings.

If a claim should be brought against us and we are found to infringe the rights of others, we may be required to pay substantial damages, be forced to stop the development of product candidates affected by the claim, and/or establish licenses or similar arrangements. Furthermore, any such licenses may not be available when needed, on commercially reasonable terms or at all. Whether an infringement claim is successful or not, the cost of these proceedings may be significant and divert the attention of management and other key employees. As a result, we cannot be certain that our patents or those we license will not be challenged by others, which could have a material adverse effect on our business, results of operations and financial condition.

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

Our success depends upon our ability to obtain and maintain intellectual property protection for our product candidates. 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 develop our product candidates freely. 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. Because of the extensive time required for development, testing, and regulatory review of a potential product, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thus reducing any advantage provided by the patent. Further, 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. If we are unable to derive value from our licensed or owned intellectual property, it may have a materially and adverse impact on our business, results of operations and financial condition.

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. If there is any dispute or issue of non-performance between us and the respective licensing partner regarding the rights or obligations under the license agreements, the ability to develop and commercialize the affected product candidate may be adversely affected. Moreover, if any of our existing licenses are terminated, the development of the product candidates 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. 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.

Risks Relating to Our Financial Condition

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. 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 product candidates;
- To obtain regulatory approval for our product candidates;
- 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.

We are dependent on obtaining funding from third parties, such as proceeds from the issuance of debt, sale of equity or strategic opportunities, in order to maintain our operations. We cannot assure you that additional 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 or improve our technology. 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.

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.

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. 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. 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, perhaps substantially. The issuance of a significant amount of shares of common stock could cause the market price of our common stock to decline or become highly volatile.

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.

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. The Company has limited cash resources, has reported recurring losses from operations since inception and has not yet received product revenues. These factors raise substantial doubt regarding the Company's ability to continue as a going concern, and the Company's current cash resources may not provide sufficient capital to fund operations for at least the next 12 months from the date of the release of these financial statements. The continuation of the Company as a going concern depends upon the Company's ability to raise additional capital through an equity offering, debt offering or strategic opportunity to fund its operations. There can be no assurance that the Company will be successful in accomplishing these plans in order 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 ability to utilize net operating loss carryforwards and other tax benefits may be limited.

We have historically incurred net losses and may never achieve or sustain profitability. 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. Net operating losses incurred in tax years beginning after December 31, 2017 may be carried forward indefinitely, but are limited to offset up to 80% of future taxable income. Certain of our net operating loss carryforwards predating December 31, 2017 could expire unused before offsetting potential future income tax liabilities.

Additionally, an ownership change, as defined by Section 382 and 383 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. Pursuant to Section 382 and 383 of the code, if the Company has experienced a change of control at any time since inception, utilization of the Company's net operating loss or tax credit carryforwards then in existence would be subject to an annual limitation. Any limitation may result in expiration of a portion of the net operating loss or tax credit carryforwards before utilization.

During 2021, the Company completed an assessment of the available net operating loss and tax credit carryforwards under Section 382 and 383 and determined that the Company underwent multiple ownership changes during the period from 2012 to 2021. As a result, our net operating losses and tax credit carryforwards are subject to substantial annual limitations under Section 382 and 383 due to these ownership changes. The Company has adjusted its net operating loss and tax credit carryforwards to address the impact of the ownership changes. The Company assesses the need to conduct an ownership change analysis to determine whether any changes occurred in ownership that would limit net operating loss or tax credit carryforwards on an annual basis. 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 and tax credit carryforwards is materially limited, it could 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 and could result in the loss of all or part of your investment. In addition, the limited trading volume of our stock may contribute to its volatility. Moreover, if we are unable to trade above \$1.00 for a certain period of time, or fulfill the other continued listing standards, The Nasdaq Stock Market may delist our common stock. Delisting our common stock from Nasdaq would adversely affect our trading volume and would likely negatively impact our trading price.

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 and as of the year ended December 31, 2022 had one share of Series D Preferred Stock outstanding, which was subsequently redeemed in full in January 2023 and is no longer outstanding. Our Board of Directors (the “**Board**”) 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.

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 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 is expressly authorized to adopt, alter or repeal our bylaws; and
- Establish advance notice requirements for nominations for election to our Board 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, 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, which is responsible for appointing the members of our management.

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

On December 17, 2013, we entered into a lease (the “Lease”), as subsequently amended on January 22, 2019, 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 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 had the option to terminate the lease on March 31, 2021, paying the non-terminating party six months’ rent as a penalty or on March 31, 2022, paying the non-terminating party three months’ rent as a penalty. The option to terminate the Lease early was not exercised by either party and has expired.

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. To our knowledge, we are not currently a party to any actual or threatened material legal proceedings.

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 9, 2023, 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 (the "**Board**") and will depend upon, among other things, our results of operations, financial condition, cash requirements, prospects and other factors that our Board may deem relevant.

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, 2022 or 2021.

ITEM 6. **RESERVED**

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. ("**Phio**," "**we**," "**our**" or the "**Company**") is a clinical stage biotechnology company whose proprietary INTASYL™ self-delivering RNAi technology platform is designed to make immune cells more effective in killing tumor cells. We are developing therapeutics that are designed to leverage INTASYL to precisely target specific proteins that reduce the body's ability to fight cancer, without the need for specialized formulations or drug delivery systems. We are committed to discovering and developing innovative cancer treatments for patients by creating new pathways toward a cancer-free future.

Our development efforts are based on our proprietary INTASYL self-delivering RNAi technology platform. INTASYL compounds are designed to precisely target specific proteins that reduce the body's ability to fight cancer, without the need for specialized formulations or drug delivery systems, and are designed to make immune cells more effective in killing tumor cells. Our efforts are focused on developing immuno-oncology therapeutics using our INTASYL platform. We have demonstrated preclinical efficacy in both direct-to-tumor injection and adoptive cell therapy ("**ACT**") applications with our INTASYL compounds.

PH-762

PH-762 is an INTASYL compound designed to reduce the expression of cell death protein 1 (“**PD-1**”). PD-1 is a protein that inhibits T cells’ ability to kill cancer cells and is a clinically validated target in immunotherapy. Decreasing the expression of PD-1 can thereby increase the capacity of T cells, which protect the body from cancer cells and infections, to kill cancer cells.

Preclinical studies conducted by the Company have demonstrated that direct-to-tumor application of PH-762 resulted in potent anti-tumoral effects and have shown that direct-to-tumor treatment with PH-762 inhibits tumor growth in a dose dependent fashion in PD-1 responsive and refractory models. Importantly, direct-to-tumor administration of PH-762 resulted in activity against distant untreated tumors, indicative of a systemic anti-tumor response. We believe these data further support the potential for PH-762 to provide a strong local immune response without the dose immune-related adverse effects seen with systemic antibody therapy.

PH-762 is currently being evaluated in a Phase 1b dose escalation clinical trial in France that is expected to enroll up to 21 subjects with advanced melanoma. PH-762 will be administered as a neoadjuvant monotherapy intratumorally once a week, for a total of four injections, across five escalating dose levels. Dosing will be followed by tumoral excision after an additional two weeks. The primary study objectives are to evaluate the safety and tolerability, and pharmacokinetics of PH-762; to determine the potential immunologic and pathologic tumor responses; and to determine the recommended dose for later clinical trials. Safety data from the initial cohort of three subjects in the clinical trial was evaluated by a Data Monitoring Committee in the first quarter of 2023. The safety data review disclosed no dose-limiting toxicity, and no drug-related severe or serious adverse events, and the Data Monitoring Committee recommended proceeding to the enrollment of the subsequent dose cohort. The next cohort is now open for enrollment of subjects.

In addition to the French clinical trial, we expect to commence a U.S. Phase 1b clinical trial with PH-762 in the second half of 2023. The U.S. trial is expected to focus on the application of PH-762 to treat cutaneous squamous cell carcinoma (“**cSCC**”) and other selected cutaneous malignancies.

Due to INTASYL’s ease of administration, we have shown that our compounds can easily be incorporated into current ACT manufacturing processes. In ACT, T cells are usually taken from a patient’s own blood or tumor tissue, grown in large numbers in a laboratory, and then given back to the patient to help the immune system fight cancer. By treating T cells with our INTASYL compounds while they are being grown in the laboratory, we believe our INTASYL compounds can improve these immune cells to make them more effective in killing cancer. Preclinical data generated in collaboration with AgonOx, Inc. (“**AgonOx**”), a private company developing a pipeline of novel immunotherapy drugs targeting key regulators of the immune response to cancer, demonstrated that treating AgonOx’s “double positive” tumor infiltrating lymphocyte (“**DP TIL**”) with PH-762 increased by two-fold their tumor killing activity.

In March 2021, we entered into a clinical co-development collaboration agreement (the “**Clinical Co-Development Agreement**”) with AgonOx to conduct a Phase 1 clinical trial using DP TIL and PH-762. Under the Clinical Co-Development Agreement, we paid AgonOx \$0.3 million as an upfront payment in December 2022 and have agreed to provide up to \$4 million in total financial support to AgonOx to conduct a Phase 1 clinical trial of PH-762 treated DP TIL. Phio is also eligible to receive certain future development milestones and low single-digit sales-based royalty payments from AgonOx’s licensing of its DP TIL technology.

PH-762 treated DP TILs are expected to be evaluated in a Phase 1 clinical trial in the United States with up to 18 subjects with advanced melanoma and other advanced solid tumors. The primary study objectives are to evaluate the safety and to study the potential for enhanced therapeutic benefit from the administration of PH-762 treated DP TILs. Enrollment of subjects is expected to commence in the second quarter of 2023.

PH-894

PH-894 is an INTASYL compound that is designed to silence BRD4, a protein that controls gene expression in both T cells and tumor cells, thereby effecting the immune system as well as the tumor. Intracellular and/or commonly considered “undruggable” targets, such as BRD4, represent a challenge for small molecule and antibody therapies. Therefore, what sets this compound apart is its dual mechanism: PH-894 suppression of BRD4 in T cells results in T cell activation, and suppression of BRD4 in tumor cells results in tumors becoming more sensitive to being killed by T cells.

Preclinical studies conducted have demonstrated that PH-894 resulted in a strong, concentration dependent and durable silencing of BRD4 in T cells and in various cancer cells. Similar to PH-762, preclinical studies have also shown that direct-to-tumor application of PH-894 resulted in potent and statistically significant anti-tumoral effects and demonstrated a systemic anti-tumor response. These preclinical data indicate that PH-894 can reprogram T cells and other cells in the tumor microenvironment to provide enhanced immunotherapeutic activity. The Company has completed the investigational new drug (“IND”)-enabling studies and is in the process of finalizing the study reports required for an IND submission with PH-894. As a result of the reprioritization to advance the Company’s clinical trial with PH-762 in the U.S., the Company has elected to defer the IND submission for PH-894.

Impact of the Coronavirus Pandemic

The Company continues to respond to and monitor the ongoing coronavirus pandemic. The Company believes that the coronavirus pandemic has not had a significant impact on our financial condition and results of operations, however, the extent to which the coronavirus pandemic may materially impact our financial results and operations will depend on a number of factors, including the availability of supplies and services we rely on, the ability to enroll subjects in our clinical trials, the emergence of variant strains of the coronavirus, the development, availability, and public acceptance of effective treatments and vaccines, and the duration of the coronavirus pandemic, which remain difficult to predict and are highly uncertain.

Impact of Inflation

Inflation has increased during the period covered by this Annual Report and is expected to continue to remain at elevated levels or even increase in the near future. Inflation generally affects us by increasing our cost of labor and third party contract costs. We do not believe inflation has had a material effect on our results of operations during year ended December 31, 2022.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are 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 Note 1 to our consolidated financial statements included elsewhere in this Annual Report, we believe the following addresses the Company’s 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 that we have received for which vendors have not yet billed us. 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, 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 our actual costs. Due to the nature of estimates, we cannot provide assurance that we will not make changes to our estimates in the future as we become aware of additional information about the conduct of our research activities.

Collaborative Arrangements

The Company follows the provisions of the Financial Accounting Standards Board (the “FASB”) Accounting Standards Codification (“ASC”) Topic 808, “*Collaborative Arrangements*,” (“**Topic 808**”) when collaboration agreements involve joint operating activities in which both parties are active participants and that are also both exposed to significant risks and rewards. The Company also considers the guidance in the FASB ASC Topic 606, “*Revenue from Contracts with Customers*,” (“**Topic 606**”) in determining the appropriate treatment for activities between the Company and our collaborative partners that are more reflective of a vendor-customer relationship and therefore, within the scope of Topic 606. Under Topic 808, we determine an appropriate recognition method, either by analogy to appropriate accounting literature or by applying a reasonable accounting policy election. Generally, the classification of transactions under the collaborative arrangement is determined based on the nature and contractual terms of the arrangement along with the nature of the operations of the participants. The Company recognizes its share of costs arising from research and development activities performed by collaborators in the period its collaborators incur such expense. Payments or reimbursements that are the result of a collaborative relationship instead of a customer relationship, such as co-development activities, are evaluated on a quarterly basis and recorded as an offset to research and development expense incurred.

Financial Operations Overview

Revenues

To date, we have primarily generated revenues through government grants. We have not generated any commercial product revenue and do not expect to do so in the foreseeable future.

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 expenses have been a significant portion of our total operating expenses and are expected to constitute 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 (Expense) Income, net

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

Results of Operations

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

	Years Ended December 31,		Dollar Change
	2022	2021	
Operating expenses	\$ 11,462	\$ 13,511	\$ (2,049)
Operating loss	(11,462)	(13,511)	2,049
Net loss	\$ (11,480)	\$ (13,287)	\$ 1,807

Comparison of the Years Ended December 31, 2022 and 2021

Operating Expenses

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

	Years Ended December 31,		Dollar Change
	2022	2021	
Research and development	\$ 7,012	\$ 8,886	\$ (1,874)
General and administrative	4,450	4,625	(175)
Total operating expenses	\$ 11,462	\$ 13,511	\$ (2,049)

Research and Development Expenses

Research and development expenses for the year ended December 31, 2022 decreased 21% compared with the year ended December 31, 2021. The decrease in research and development expenses was primarily driven by manufacturing related costs of approximately \$2,000,000 for our PH-762 and PH-894 compounds and approximately \$195,000 in preclinical studies with PH-762 that were required for the Company's clinical trial in France, both of which were completed in the prior year period, offset by increases in clinical-related costs for the Company's clinical trials with PH-762 in France and in ACT with our partner AgonOx of approximately \$334,000.

The Company anticipates research and development expenses to increase as a result of clinical-related activities as our pipeline programs progress in clinical development.

General and Administrative Expenses

General and administrative expenses for the year ended December 31, 2022 decreased 4% compared with the year ended December 31, 2021. The decrease in general and administrative expenses was primarily due to decreases in total payroll-related expenses of approximately \$156,000 as a result of the departure of our former Chief Executive Officer and a reduction in the use of consultants and outside professional services of approximately \$141,000 offset by approximately \$55,000 in executive search fees.

Total Other (Expense) Income

Total other income for the year ended December 31, 2022 decreased by \$242,000 as compared with the year ended December 31, 2021, primarily due to the full forgiveness of our Paycheck Protection Program ("PPP") loan in 2021.

Liquidity and Capital Resources

Historically, our primary source of funding has been through the sale of our 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, 2022, we had cash of \$11,781,000 as compared with \$24,057,000 at December 31, 2021.

In August 2019, we entered into a purchase agreement (the "**Purchase Agreement**") with Lincoln Park Capital, LLC ("**LPC**"), pursuant to which we had the right to sell to LPC up to \$10,000,000 in shares of our common stock, subject to certain limitations and conditions set forth in the Purchase Agreement. The Purchase Agreement expired in May 2022 and no shares of common stock were sold to LPC under the Purchase Agreement.

The Company has limited cash resources, has reported recurring losses from operations since inception and has not yet received product revenues. These factors raise substantial doubt regarding the Company's ability to continue as a going concern, and the Company's current cash resources may not provide sufficient capital to fund operations for at least the next 12 months from the date of the release of the financial statements included elsewhere in this Annual Report. The continuation of the Company as a going concern depends upon the Company's ability to raise additional capital through equity offerings, debt offerings or strategic opportunities to fund its operations. There can be no assurance that the Company will be successful in accomplishing any of these plans in order to continue as a going concern. The financial statements included elsewhere in this Annual Report do not include any adjustments to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

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

	Years Ended December 31,	
	2022	2021
Net cash used in operating activities	\$ (12,129)	\$ (11,858)
Net cash used in investing activities	(121)	(51)
Net cash (used in) provided by financing activities	(26)	21,722
Net (decrease) increase in cash and restricted cash	<u>\$ (12,276)</u>	<u>\$ 9,813</u>

Net Cash Flow from Operating Activities

Net cash used in operating activities for the year ended December 31, 2022 increased as compared with the year ended December 31, 2021, primarily due to an increase of \$2,246,000 in the changes in operating assets and liabilities primarily due to payments made for the preclinical studies conducted for PH-894 and for the manufacturing of our PH-762 and PH-894 compounds and an increase of \$168,000 in non-cash related items primarily as a result of the full forgiveness of the Company's PPP loan in the prior year period offset by a decrease in net loss of \$1,807,000.

Net Cash Flow from Investing Activities

Net cash used in investing activities for the year ended December 31, 2022 increased as compared with the year ended December 31, 2021, primarily due to an increase of \$70,000 in laboratory and computer equipment purchases for the Company's facility as compared to the prior year period.

Net Cash Flow from Financing Activities

Net cash from financing activities for the year ended December 31, 2022 decreased as compared with the year ended December 31, 2021, primarily due to the net proceeds of \$21,722,000 received by the Company from capital raising activities and warrant exercises in the comparable prior year period.

Contractual Obligations

Commitments

In March 2021, we entered into a Clinical Co-Development Agreement with AgonOx to develop a T cell-based therapy using PH-762, and AgonOx's DP TIL technology. Under the Clinical Agreement, we committed to make future payments of up to \$4,000,000 to reimburse AgonOx for expenses incurred to support the Phase 1 clinical trial with PH-762 treated DP TIL. During the year ended December 31, 2022, the Company paid AgonOx \$250,000 as an upfront payment. No amounts were paid to AgonOx during the year ended December 31, 2021 under the Clinical Co-Development Agreement.

License Commitments

We enter 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 progress through clinical trials, upon approval of the product by a regulatory agency and/or upon a percentage of sales of the product pursuant to such agreements. The expenditures required under these arrangements may be material individually in relation to any product candidates covered by the intellectual property licensed under any such arrangement, and material in the aggregate in the unlikely event that milestones for multiple products covered by these arrangements were reached in the same period. During the years ended December 31, 2022 and 2021, we did not trigger any milestone payments.

Our contractual license obligations that will require future cash payments as of December 31, 2022 are \$700,000, which result from payments expected in connection with annual license fees.

Lease Commitments

Future lease payments under our non-cancellable operating lease are expected to be approximately \$175,000 over the remaining duration of our lease, or through March 31, 2024.

For further information regarding our future cash commitments see Note 8 to our consolidated financial statements.

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

Shareholders 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”) as of December 31, 2022 and 2021, the related consolidated statements of operations, preferred stock and stockholders’ equity, and cash flows for each of the years then ended, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2022 and 2021, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company does not generate revenues and continues to suffer recurring losses from operations that raise substantial doubt about its ability to continue as a going concern. Management’s plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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

Critical audit matters are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

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

/s/ BDO USA, LLP

Boston, Massachusetts
March 22, 2023

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

	<u>December 31, 2022</u>	<u>December 31, 2021</u>
ASSETS		
Current assets:		
Cash	\$ 11,781	\$ 24,057
Restricted cash	50	50
Prepaid expenses and other current assets	615	620
Total current assets	12,446	24,727
Right of use asset	161	283
Property and equipment, net	183	133
Other assets	24	27
Total assets	<u>\$ 12,814</u>	<u>\$ 25,170</u>
LIABILITIES, PREFERRED STOCK AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 779	\$ 283
Accrued expenses	1,025	2,660
Lease liability	135	125
Total current liabilities	1,939	3,068
Lease liability, net of current portion	35	170
Total liabilities	1,974	3,238
Commitments and contingencies (Footnote 8)		
Series D Preferred Stock, \$0.0001 par value; 1 and 0 shares authorized, issued and outstanding at December 31, 2022 and December 31, 2021, respectively	2	—
Stockholders' equity:		
Common stock, \$0.0001 par value, 100,000,000 shares authorized; 1,139,024 and 1,127,917 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively	—	—
Additional paid-in capital	139,218	138,832
Accumulated deficit	(128,380)	(116,900)
Total stockholders' equity	10,838	21,932
Total liabilities, preferred stock and stockholders' equity	<u>\$ 12,814</u>	<u>\$ 25,170</u>

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,	
	2022	2021
Operating expenses:		
Research and development	\$ 7,012	\$ 8,886
General and administrative	4,450	4,625
Total operating expenses	<u>11,462</u>	<u>13,511</u>
Operating loss	(11,462)	(13,511)
Total other (expense) income, net	<u>(18)</u>	<u>224</u>
Loss before income taxes	(11,480)	(13,287)
Provision for income taxes	<u>—</u>	<u>—</u>
Net loss	<u>\$ (11,480)</u>	<u>\$ (13,287)</u>
Net loss per common share:		
Basic	<u>\$ (10.10)</u>	<u>\$ (12.43)</u>
Diluted	<u>\$ (10.10)</u>	<u>\$ (12.43)</u>
Weighted average number of common shares outstanding		
Basic	<u>1,136,566</u>	<u>1,069,234</u>
Diluted	<u>1,136,566</u>	<u>1,069,234</u>

See accompanying notes to consolidated financial statements.

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

	Series D Preferred Stock		Common Stock		Additional	Accumulated	Total
	Shares	Amount	Shares	Amount	Paid-in Capital	Deficit	
Balance at December 31, 2020	—	\$ —	481,749	\$ —	\$ 116,630	\$ (103,613)	\$ 13,017
Issuance of common stock, pre-funded warrants and warrants in connection with private placement, net of offering costs	—	—	368,405	—	12,669	—	12,669
Issuance of common stock in registered direct offering, net of offering costs	—	—	187,232	—	6,908	—	6,908
Issuance of common stock upon the exercise of warrants	—	—	90,276	—	2,146	—	2,146
Issuance of common stock upon vesting of restricted stock units	—	—	279	—	—	—	—
Shares withheld for payroll taxes	—	—	(24)	—	(1)	—	(1)
Stock-based compensation expense	—	—	—	—	480	—	480
Net loss	—	—	—	—	—	(13,287)	(13,287)
Balance at December 31, 2021	—	\$ —	1,127,917	\$ —	\$ 138,832	\$ (116,900)	\$ 21,932
Issuance of common stock upon vesting of restricted stock units	—	—	14,043	—	—	—	—
Shares withheld for payroll taxes	—	—	(2,936)	—	(28)	—	(28)
Issuance of preferred stock	1	2	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	414	—	414
Net loss	—	—	—	—	—	(11,480)	(11,480)
Balance at December 31, 2022	<u>1</u>	<u>\$ 2</u>	<u>1,139,024</u>	<u>\$ —</u>	<u>\$ 139,218</u>	<u>\$ (128,380)</u>	<u>\$ 10,838</u>

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,	
	2022	2021
Cash flows from operating activities:		
Net loss	\$ (11,480)	\$ (13,287)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	71	75
Amortization of right of use asset	122	117
Non-cash stock-based compensation	414	480
Forgiveness of debt	—	(233)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	8	241
Accounts payable	496	(445)
Accrued expenses	(1,635)	1,310
Lease liability	(125)	(116)
Net cash used in operating activities	(12,129)	(11,858)
Cash flows from investing activities:		
Cash paid for purchase of property and equipment	(121)	(51)
Net cash used in investing activities	(121)	(51)
Cash flows from financing activities:		
Net proceeds from the issuance of common stock and warrants	—	19,577
Net proceeds from the exercise of warrants	—	2,146
Payments of taxes for net share settled restricted stock unit issuances	(28)	(1)
Net proceeds from the issuance of preferred stock	2	—
Net cash (used in) provided by financing activities	(26)	21,722
Net (decrease) increase in cash and restricted cash	(12,276)	9,813
Cash and restricted cash at the beginning of period	24,107	14,294
Cash and restricted cash at the end of period	<u>\$ 11,831</u>	<u>\$ 24,107</u>

The following table provides a reconciliation of cash and restricted cash reported within the consolidated balance sheets to the totals above:

	December 31,	
	2022	2021
Cash	\$ 11,781	\$ 24,057
Restricted cash	50	50
Total cash and restricted cash	<u>\$ 11,831</u>	<u>\$ 24,107</u>

See accompanying notes to consolidated financial statements.

PHIO PHARMACEUTICALS CORP.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Significant Accounting Policies

Nature of Operations

Phio Pharmaceuticals Corp. (“Phio,” “we,” “our” or the “Company”) is a clinical stage biotechnology company whose proprietary INTASYL™ self-delivering RNAi technology platform is designed to make immune cells more effective in killing tumor cells. We are developing therapeutics that are designed to leverage INTASYL to precisely target specific proteins that reduce the body’s ability to fight cancer, without the need for specialized formulations or drug delivery systems. We are committed to discovering and developing innovative cancer treatments for patients by creating new pathways toward a cancer-free future.

The Company continues to respond to and monitor the ongoing coronavirus pandemic. The Company believes that the coronavirus pandemic has not had a significant impact on its financial condition and results of operations, however, the extent to which the coronavirus pandemic may materially impact our financial results and operations will depend on a number of factors, including the availability of supplies and services we rely on, the ability to enroll subjects in our clinical trials, the emergence of variant strains of the coronavirus, the development, availability, and public acceptance of effective treatments and vaccines, and the duration of the coronavirus pandemic, which remain difficult to predict and are highly uncertain.

Liquidity

The Company has reported recurring losses from operations since its inception and expects to continue to have negative cash flows from operations for the foreseeable future. Historically, the Company’s primary source of funding has been from sales 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, which may be adversely impacted by the coronavirus pandemic, rates of inflation and the ongoing conflict between Russia and Ukraine. 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.

The Company has limited cash resources, has reported recurring losses from operations since inception and has not yet received product revenues. These factors raise substantial doubt regarding the Company’s ability to continue as a going concern, and the Company’s current cash resources may not provide sufficient capital to fund operations for at least the next 12 months from the date of the release of these financial statements. The continuation of the Company as a going concern depends upon the Company’s ability to raise additional capital through an equity offering, debt offering or strategic opportunity to fund its operations. There can be no assurance that the Company will be successful in accomplishing these plans in order to continue as a going concern. These financial statements do not include any adjustments to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

Basis of Presentation

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

Principles of Consolidation

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

Reverse Stock Split

Effective January 26, 2023, the Company completed a 1-for-12 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.

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 as of 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, accruals for research and development expenses, useful lives of property and equipment, income taxes, and the 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. 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 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	Lesser of remaining lease term or 5 years

Impairment of Long-Lived Assets

The Company reviews long-lived assets for impairment annually or whenever an event or change in circumstance occurs in which 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. As of December 31, 2022 and 2021, the Company believes no impairment existed.

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, including scheduled increases, 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.

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, research activities under our research collaborations, 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.

Collaborative Arrangements

The Company follows the provisions of the Financial Accounting Standards Board (the "FASB") Accounting Standards Codification ("ASC") Topic 808, "Collaborative Arrangements," ("Topic 808") when collaboration agreements involve joint operating activities in which both parties are active participants and that are also both exposed to significant risks and rewards. The Company also considers the guidance in the FASB ASC Topic 606, "Revenue from Contracts with Customers," ("Topic 606") in determining the appropriate treatment for activities between the Company and its collaborative partners that are more reflective of a vendor-customer relationship and therefore, within the scope of Topic 606. Under Topic 808, the Company determines an appropriate recognition method, either by analogy to appropriate accounting literature or by applying a reasonable accounting policy election. Generally, the classification of transactions under the collaborative arrangements is determined based on the nature and contractual terms of the arrangement along with the nature of the operations of the participants. The Company recognizes its share of costs arising from research and development activities performed by collaborators in the period its collaborators incur such expense. Payments or reimbursements that are the result of a collaborative relationship instead of a customer relationship, such as co-development activities, are evaluated on a quarterly basis and recorded as an offset to research and development expense incurred.

Patents and Patent Application Costs

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

Stock-based Compensation

The Company follows the provisions of the FASB ASC Topic 718, "Compensation — Stock Compensation" ("ASC 718"), which requires the measurement and recognition of compensation expense for all stock-based payment awards. The fair value of restricted stock units ("RSUs") is based upon the Company's closing stock price at the grant date. 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. Stock-based compensation expense is recognized on a straight-line basis 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 award 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 or to the extent that actual forfeitures differ from our estimates, is recorded as a cumulative adjustment in the period the estimates are 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. Valuation allowances are established if, based on the weight of available evidence, it is more likely than not that all or a portion of a deferred tax asset will not be realized. The provision for income taxes, if any, represents the tax payable for the period and the change in deferred income tax assets and liabilities during the period.

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 loss 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, RSUs and stock options.

Recent Accounting Pronouncements

In May 2021, the FASB issued Accounting Standards Update 2021-04, “Earnings per Share (Topic 260), Debt – Modifications and Extinguishments (Subtopic 470-50), Compensation – Stock Compensation (Topic 718), and Derivatives and Hedging – Contracts in Entity’s Own Equity (Subtopic 815-40)” (“ASU 2021-04”). The amendments in the updates are intended to clarify and reduce diversity in an issuer’s accounting for modifications or exchanges of freestanding equity-classified written call options that remain equity classified after modification or exchange. The amendments in ASU 2021-04 are effective for all entities for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. An entity should apply the amendments prospectively to modifications or exchanges occurring on or after the effective date of the amendments. The Company adopted ASU 2021-04 on January 1, 2022. The adoption of this standard had no impact on the Company’s consolidated financial statements.

2. Collaboration and License Agreements

AgonOx, Inc. (“AgonOx”)

In March 2021, the Company entered into a clinical co-development collaboration agreement (the “Clinical Agreement”) with AgonOx, a private company developing a pipeline of novel immunotherapy drugs targeting key regulators of the immune response to cancer. Under the Clinical Agreement, Phio and AgonOx are working to develop a T cell-based therapy using the Company’s lead product candidate, PH-762, and AgonOx’s “double positive” TIL (“DP TIL”) technology. Per the terms of the Clinical Agreement, the Company committed to make future payments of up to \$4,000,000 to reimburse AgonOx for expenses incurred to support the Phase 1 clinical trial with the DP TIL technology and PH-762.

The Company will recognize its share of costs arising from research and development activities performed by AgonOx in the Company’s financial statements in the period AgonOx incurs such expense. Phio will be entitled to certain future development milestones and low single-digit sales-based royalty payments from AgonOx’s licensing of its DP TIL technology. The Company recognized approximately \$130,000 of expense in connection with these efforts during the year ended December 31, 2022. No expense under the Clinical Agreement was recognized during the year ended December 31, 2021. There was approximately \$120,000 recorded as prepaid expenses and other current assets as of December 31, 2022.

Advanced RNA Technologies, LLC (“Advirna”)

In September 2011, the Company entered into an agreement with Advirna, pursuant to which Advirna assigned to us its existing patent and technology rights related to the INTASYL technology in exchange for an annual maintenance fee of \$100,000, a one-time milestone payment upon the future issuance of the first patent with valid claims covering the assigned patent and technology rights and the issuance of shares of common stock of the Company equal to 5% of the Company’s fully-diluted shares outstanding at the time of issuance. The one-time milestone payment and the issuance of shares of common stock in the Company were completed in 2014 and 2012, respectively. Additionally, the Company is required to pay low single-digit royalties to Advirna on any licensing revenue received by the Company with respect to future licensing of the assigned Advirna patent and technology rights. To date, any royalties owed to Advirna under the agreement have been minimal.

Phio’s 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 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. Further, the Company also granted back to Advirna a license under the assigned patent and technology rights for fields of use outside human therapeutics.

3. Fair Value of Financial Instruments

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

Level 1 – quoted prices in active markets for identical assets or liabilities.

Level 2 – other significant observable inputs for the assets or liabilities through corroboration with market data at the measurement date.

Level 3 – significant unobservable inputs that reflect management’s best estimate of what market participants would use to price the assets or liabilities at the measurement date.

At December 31, 2022 and 2021, the Company categorized its restricted cash of \$50,000 as Level 2 hierarchy. The assets classified as Level 2 have initially been valued at the applicable transaction price and subsequently valued, at the end of each reporting period, using other market observable data. Observable market data points include quoted prices, interest rates, reportable trades and other industry and economic events.

The carrying amounts of cash, accounts payable and accrued expenses of the Company approximate their fair values due to their short-term nature.

4. Property and Equipment

The following table summarizes the Company’s major classes of property and equipment, in thousands:

	December 31,	
	2022	2021
Computer equipment	\$ 116	\$ 108
Machinery & equipment	1,077	1,035
Furniture & fixtures	119	49
Leasehold improvements	46	46
Total gross fixed assets	1,358	1,238
Less: accumulated depreciation and amortization	(1,175)	(1,105)
Property and equipment, net	<u>\$ 183</u>	<u>\$ 133</u>

Depreciation and amortization expense for the years ended December 31, 2022 and 2021 was \$71,000 and \$75,000, respectively.

5. Accrued Expenses

Accrued expenses consist of the following, in thousands:

	December 31,	
	2022	2021
Compensation and benefits	\$ 408	\$ 572
Professional fees	97	102
Research and development costs	501	1,986
Other	19	—
Total accrued expenses	<u>\$ 1,025</u>	<u>\$ 2,660</u>

6. Leases

In January 2019, the Company amended the lease for its corporate headquarters and primary research facility in Marlborough, Massachusetts. The lease is for a total of 7,581 square feet of office and laboratory space and will expire on March 31, 2024. The lease contains an option to terminate after two 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 was not included in the lease liability on the Company's balance sheet. The Company did not exercise its option to terminate in either the second or third year of the lease, and the option to terminate has expired. Additionally, the lease agreement did not contain information to determine the borrowing 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 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 the lease term (number of years) and discount rate:

	December 31,	
	2022	2021
Assets		
Right of use asset	<u>\$ 161</u>	<u>\$ 283</u>
Liabilities		
Lease liability, current	135	125
Lease liability, non-current	35	170
Total lease liability	<u>\$ 170</u>	<u>\$ 295</u>
Lease Term and Discount Rate		
Weighted average remaining lease term	1.25	2.25
Weighted average discount rate	4.70%	4.70%

Operating lease costs included in operating expense were \$132,000 for the years ended December 31, 2022 and 2021, respectively.

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 statements of cash flows was \$135,000 and \$132,000 for the years ended December 31, 2022 and 2021, 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, 2022 is as follows, in thousands:

2023	\$ 140
2024	35
Total lease payments	<u>175</u>
Less: Imputed interest	(5)
Total operating lease liabilities (includes current portion)	<u>\$ 170</u>

7. Debt

In May 2020, the Company received loan proceeds pursuant to the Paycheck Protection Program (the “PPP”) under the Coronavirus Aid, Relief, and Economic Security Act. 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 the PPP loan proceeds received and accrued interest over the term of the loan. The Company believed it used the loan proceeds for eligible purposes and applied for full loan forgiveness. In February 2021, the Small Business Administration approved the Company’s application for full loan forgiveness, and the full amount of the PPP loan was remitted to the lender for forgiveness. Upon loan forgiveness, the Company recognized a gain on the extinguishment of debt of \$233,000 for the loan proceeds received and interest accrued in the consolidated statements of operations for the year ended December 31, 2021.

8. Commitments and Contingencies

Commitments

In March 2021, the Company entered into a Clinical Agreement with AgonOx to develop a T cell-based therapy using the Company’s lead product candidate, PH-762, and AgonOx’s DP TIL technology. Per the terms of the Clinical Agreement, the Company committed to make future payments of up to \$4,000,000 to reimburse AgonOx for expenses incurred to support the Phase 1 clinical trial with the DP TIL technology and PH-762. Refer to Note 2 for further details on the Clinical Agreement with AgonOx.

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.

Refer to Note 6 for more information about the Company’s obligations under its non-cancellable lease for its corporate headquarters.

License Commitments

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 progress through clinical trials, upon approval of the product by a regulatory agency and/or upon a percentage of sales of the product pursuant to such agreements. The expenditures required under these arrangements may be material individually in relation to any product candidates covered by the intellectual property licensed under any such arrangement, and material in the aggregate in the unlikely event that milestones for multiple products covered by these arrangements were reached in the same period. Due to the contingent nature of these payments, they are not included in the table of contractual obligations shown below.

During the years ended December 31, 2022 and 2021, the Company did not trigger any milestone payments.

The Company’s contractual license obligations that will require future cash payments as of December 31, 2022, which result from payments expected in connection with annual license fees, are as follows, in thousands:

Year Ending December 31,	
2023	\$ 100
2024	100
2025	100
2026	100
2027	100
Thereafter	200
Total	<u>\$ 700</u>

Litigation

From time to time, the Company may become a party to various legal proceedings and complaints arising in the ordinary course of business. To the Company’s knowledge, it is not currently a party to any actual or threatened material legal proceedings. Accordingly, there were no contingent liabilities recorded as of the year ended December 31, 2022.

9. Preferred Stock

The Company has authorized up to 10,000,000 shares of preferred stock, \$0.0001 par value per share, for issuance. The Company's Board of Directors is authorized under the Company's Amended and Restated Articles of Incorporation, to designate the authorized preferred stock into one or more series and to fix and determine such rights, preferences, privileges and restrictions of any series of preferred stock, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, as shall be determined by the Company's Board of Directors upon its issuance. At December 31, 2022, the Company had designated one share of preferred stock as Series D Preferred Stock and the remaining authorized shares were undesignated.

On November 16, 2022, the Company issued and sold one share of the Company's Series D Preferred Stock, par value \$0.0001 per share (the "**Series D Preferred Stock**") to Robert Bitterman, then its interim Executive Chairman and current Chief Executive Officer, for \$1,750. The Series D Preferred Stock was entitled to 17,500,000 votes per share exclusively with respect to any proposal to amend the Company's Amended and Restated Certificate of Incorporation (as may be amended and/or restated from time to time, the "**Amended Certificate**") to effect a reverse stock split of the Company's common stock ("**Reverse Stock Split**"). The terms of the Series D Preferred Stock provided that it would be voted, without action by the holder, on any such proposal in the same proportion as shares of the Company's common stock were voted. The Series D Preferred Stock otherwise had no voting rights except as otherwise required by the General Corporation Law of the State of Delaware.

The Series D Preferred Stock was not convertible into, or exchangeable for, shares of any other class or series of stock or other securities of the Company. The Series D Preferred Stock had no rights with respect to any distribution of assets of the Company, including upon a liquidation, bankruptcy, reorganization, merger, acquisition, sale, dissolution or winding up of the Company, whether voluntarily or involuntarily. The holder of the Series D Preferred Stock was not entitled to receive dividends of any kind.

Under its terms, the outstanding share of Series D Preferred Stock was to be redeemed in whole, but not in part, at any time: (i) if such redemption was approved by the Board of Directors in its sole discretion or (ii) automatically and effective upon the approval by the Company's stockholders of a Reverse Stock Split. Upon such redemption, the holder of the Series D Preferred Stock was entitled to receive consideration of \$1,750 in cash.

The Series D Preferred Stock has been classified outside of permanent equity (within the mezzanine section between liabilities and equity on the balance sheets) as the Company may not be able to control the actions necessary to provide for a redemption in full of the then outstanding Series D Preferred Stock.

The Series D Preferred Stock was redeemed in whole on January 4, 2023, upon the approval by the Company's stockholders of a Reverse Stock Split.

10. Stockholders' Equity

January 2021 Private Placement — In January 2021, the Company completed a private placement of 368,405 shares of the Company's common stock at a purchase price per share of \$36.84, pre-funded warrants to purchase an aggregate of 11,672 shares of the Company's common stock at a purchase price per pre-funded warrant of \$36.828 and warrants to purchase an aggregate of 285,061 shares of the Company's common stock with an exercise price of \$36.00 per warrant (the "**Private Placement**"). In connection with the Private Placement, the Company issued warrants to the placement agent, H.C. Wainwright & Co., LLC ("**HCW**"), to purchase a total of 28,509 shares of the Company's common stock at an exercise price of \$46.05 per warrant. Net proceeds to the Company from the Private Placement were \$12,669,000 after deducting placement agent fees and offering expenses.

February 2021 Registered Direct Offering — In February 2021, the Company completed a registered direct offering of 187,232 shares of the Company's common stock at a purchase price of \$41.04 per share (the "**Offering**"). In connection with the Offering, the Company issued warrants to the placement agent, HCW, to purchase a total of 14,044 shares of the Company's common stock at an exercise price of \$51.30 per warrant. Net proceeds to the Company from the Offering were \$6,908,000 after deducting placement agent fees and offering expenses.

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 from the warrants issued by the Company, the outstanding warrants are outside the scope of ASC 480.

The Company then applies and follows the applicable accounting guidance in the FASB ASC Topic 815, “*Derivatives and Hedging*.” Financial instruments are accounted for as either derivative liabilities or equity instruments depending on the specific terms of the agreement. The warrants issued by the Company 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, the Company’s warrants are classified within stockholders’ equity.

The following table summarizes the Company’s outstanding equity-classified warrants at December 31, 2022:

Description	Exercise Price	Expiration Date	Balance December 31, 2021	Warrants Issued	Warrants Exercised	Warrants Expired	Balance December 31, 2022
April 2018 Warrants	\$ 2,079.00	5/31/2023	1,720	—	—	—	1,720
April 2018 Placement Agent Warrants	\$ 2,676.00	4/9/2023	117	—	—	—	117
October 2018 Warrants	\$ 125.40	10/3/2025	32,486	—	—	—	32,486
October 2018 Underwriter Warrants	\$ 156.72	10/1/2023	2,438	—	—	—	2,438
November 2019 Placement Agent Warrants	\$ 82.50	11/18/2024	1,138	—	—	—	1,138
February 2020 Registered Direct Warrants	\$ 104.52	8/6/2025	16,425	—	—	—	16,425
February 2020 Placement Agent Warrants	\$ 132.45	2/4/2025	1,233	—	—	—	1,233
February 2020 Warrants	\$ 48.00	2/13/2025	110,557	—	—	—	110,557
February 2020 Underwriter Warrants	\$ 60.00	2/11/2025	12,501	—	—	—	12,501
April 2020 Warrants	\$ 26.52	10/2/2025	35,691	—	—	—	35,691
April 2020 Placement Agent Warrants	\$ 35.0256	3/31/2025	3,481	—	—	—	3,481
January 2021 Warrants	\$ 36.00	7/27/2026	285,061	—	—	—	285,061
January 2021 Placement Agent Warrants	\$ 46.05	7/27/2026	28,509	—	—	—	28,509
February 2021 Placement Agent Warrants	\$ 51.30	2/12/2026	14,044	—	—	—	14,044
			<u>545,401</u>	<u>—</u>	<u>—</u>	<u>—</u>	<u>545,401</u>

No warrants were exercised during the year ended December 31, 2022. The Company received net proceeds of \$2,146,000 from the exercise of warrants during the year ended December 31, 2021.

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, RSU 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, 2022, there were an aggregate of 105,640 shares of common stock reserved under the 2020 Plan, including 141 shares subject to outstanding stock options and 47,328 shares subject to unvested RSUs and 43,807 shares available for future grants. RSUs granted by the Company to employees vest annually over 3 years after the grant date, stock options 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 2020 Plan to new employees. RSUs are generally subject to graded vesting and the satisfaction of service requirements. Upon vesting, each outstanding RSU will be settled 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, 2022:

	Number of Shares	Weighted- Average Grant Date Fair Value Per Share
Unvested units at December 31, 2021	30,592	\$ 38.52
Granted	61,250	10.08
Vested	(14,043)	39.72
Forfeited	(30,471)	17.40
Unvested units at December 31, 2022	47,328	\$ 15.00

The weighted-average fair value of RSUs granted during the years ended December 31, 2022 and 2021 was \$10.08 and \$35.28, respectively.

Stock-based compensation expense related to RSUs was \$401,000 and \$443,000 for the years ended December 31, 2022 and 2021, respectively.

The aggregate fair value of awards that vested during the years ended December 31, 2022 and 2021 was \$138,000 and \$9,000, which represents the market value of the Company's common stock on the date that the RSUs vested.

As of December 31, 2022, the compensation expense for all unvested RSUs in the amount of approximately \$458,000 will be recognized in the Company's results of operations over a weighted average period of 1.60 years.

Stock Options

Stock options are available for issuance under the 2020 Plan or as inducement grants issued outside of the 2020 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 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 Company did not grant stock options during the years ended December 31, 2022 and 2021. The following table summarizes the activity of the Company's stock option plan for the year ended December 31, 2022:

	Total Number of Shares	Weighted- Average Exercise Price Per Share	Weighted- Average Remaining Contractual Term	Aggregate Intrinsic Value
Balance at December 31, 2021	208	\$ 40,822.80		
Granted	—	—		
Exercised	—	—		
Unvested shares cancelled	(6)	1,181.40		
Vested shares cancelled	(61)	93,016.68		
Balance at December 31, 2022	141	\$ 19,761.12	5.18 years	\$ —
Exercisable at December 31, 2022	141	\$ 19,761.12	5.18 years	\$ —

Stock-based compensation expense related to stock options for the years ended December 31, 2022 and 2021 was \$13,000 and \$37,000, respectively.

As of December 31, 2022, the compensation expense for all unvested stock options was recognized in the Company's results of operations.

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.

Compensation Expense Related to Equity Awards

The following table sets forth total stock-based compensation expense for the years ended December 31, 2022 and 2021, in thousands:

	December 31,	
	2022	2021
Research and development	\$ 154	\$ 117
General and administrative	260	363
Total stock-based compensation	\$ 414	\$ 480

12. Income Taxes

The provision for income taxes for the years ended December 31, 2022 and 2021 are as follows, in thousands:

	Years Ended December 31,	
	2022	2021
Current		
Federal	\$ —	\$ —
State	—	—
Total current	—	—
Deferred		
Federal	(1,733)	(3,016)
State	(553)	(1,329)
Total deferred	(2,286)	(4,345)
Valuation allowance	2,286	4,345
Total provision for income taxes	\$ —	\$ —

The following table presents a reconciliation of the U.S. statutory tax rate to the Company's actual effective income tax rate:

	Years Ended December 31,	
	2022	2021
Federal statutory rate	21.0%	21.0%
State income taxes, net of federal benefit	7.4	8.5
Non-deductible expenses	(0.8)	0.2
Income tax credits	3.2	4.3
Valuation allowance	(30.8)	(34.0)
Effective tax rate	0.0%	0.0%

The Company recognizes deferred tax assets and liabilities to reflect the tax effects of temporary differences between the tax basis of assets or liabilities and their reported amounts in the financial statements in accordance with ASC 740. These temporary differences will result in taxable or deductible amounts in future years when the reported amounts of the assets or liabilities are recovered or settled.

ASC 740 requires that a valuation allowance be established when management determines that it is more likely than not that all or a portion of a deferred asset will not be realized. The Company evaluates the realizability of its net deferred income tax assets and valuation allowances as necessary, at least on an annual basis. During this evaluation, the Company reviews its forecasts of income in conjunction with other positive and negative evidence surrounding the realizability of its deferred income tax assets to determine if a valuation allowance is required. Adjustments to the valuation allowance will increase or decrease the Company's income tax provision or benefit.

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

	Years Ending December 31,	
	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	\$ 11,808	\$ 10,150
Tax credit carryforwards	1,227	946
Stock-based compensation	435	1,363
Capitalized research and development expenses	1,662	—
License fees	1,680	2,018
Lease liability	46	79
Other timing differences	120	169
Deferred tax assets	16,978	14,725
Deferred tax liabilities:		
Right of use asset	(43)	(76)
Deferred tax liability	(43)	(76)
Valuation allowance	(16,935)	(14,649)
Net deferred tax asset	\$ —	\$ —

The Tax Cuts and Jobs Act of 2017 included a provision that requires the capitalization and amortization of research and development costs incurred in tax years beginning after December 31, 2021. Under this provision, U.S.-based research and development expenses are amortized over a period of five years and non-U.S.-based research and development expenses are amortized over a period of 15 years. The deferred tax assets as of December 31, 2022 included capitalized research and development expenses of \$1,662,000.

The Company evaluated the realizability of its net deferred tax assets and concluded that, in accordance with the applicable accounting standards, that it is more likely than not that the Company may not realize the benefit of all of its deferred tax assets. Accordingly, a valuation allowance against 100% of its deferred tax assets has been recorded. Significant judgment is required in the evaluation of deferred tax benefits and differences in future results from our estimates could result in material differences in the realization of these assets.

As of December 31, 2022, the Company had federal net operating loss (“NOL”) carryforwards of approximately \$49,200,000 and state NOL carryforwards of approximately \$23,200,000 to reduce future taxable income. The utilization of the federal carryforwards as an available offset to future taxable income is subject to limitations under federal income tax laws. Under current federal income tax law, the Company’s federal NOLs generated in tax years beginning after December 31, 2017, totaling approximately \$48,879,000, may be carried forward indefinitely, but are limited to offset up to 80% of future taxable income. The remaining federal NOLs generated, totaling approximately \$321,000, will begin to expire in 2037 and the Company’s available state NOL carryforwards will begin to expire in 2038. In addition, the Company had federal and state research and development credits of approximately \$819,000 and \$517,000, respectively, which will begin to expire in 2041 and 2036, respectively.

Ownership changes may limit the amount of NOL carryforwards or tax credit carryforwards that can be utilized to offset future taxable income or tax liability. Pursuant to Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the “Code”), NOL and tax credit carryforwards may be subject to annual limitations in the event a cumulative change in ownership of more than 50% occurs within a three-year period. Any limitation may result in expiration of a portion of the NOL carryforwards or tax credit carryforwards before utilization.

During 2021, the Company completed an assessment of the available NOL and tax credit carryforwards under Sections 382 and 383 of the Code and determined that the Company underwent six ownership changes during the period from 2012 to 2021. As a result, NOL and tax credit carryforwards attributable to the pre-ownership changes are subject to substantial annual limitations under Section 382 and 383 of Code due to the ownership changes. The Company adjusted its NOL and tax credit carryforwards to address the impact of the ownership changes. For the years ended prior to December 31, 2021, federal and state NOLs of \$55,000,000 and \$70,000,000, respectively, were reduced and federal and state tax credit carryforwards of \$1,400,000 and \$700,000, respectively, were also reduced.

The Company assesses the need to conduct an ownership change analysis to determine whether any changes occurred in ownership that would limit NOL or tax credit carryforwards on an annual basis. Due to the minimal number of share issuances during the year, the Company did not conduct an ownership change analysis in 2022. The Company may experience ownership changes in the future as a result of subsequent shifts in stock ownership, some of which may be outside of the Company’s control.

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. The Company has not recorded any uncertain tax positions as of December 31, 2022 or 2021. 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.

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 2014 through 2022.

13. Net Loss per Share

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

	December 31,	
	2022	2021
Options to purchase common stock	141	208
Unvested restricted stock units	47,328	30,592
Warrants to purchase common stock	545,401	545,401
Total	<u>592,870</u>	<u>576,201</u>

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Principal Executive Officer (who is also acting as our Principal Financial Officer), evaluated the effectiveness of disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (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 Principal Executive Officer (who is also acting as our Principal Financial Officer), concluded that our disclosure controls and procedures were effective at the reasonable assurance level 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, 2022. 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 Principal Executive Officer (who is also acting as our Principal Financial Officer), concluded that, as of December 31, 2022, 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 our 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 fiscal quarter ended December 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

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

Board of Directors

The size of the Board is currently set at six directors. Biographical and other information regarding our directors, whose terms expire at the 2023 Annual Meeting of Stockholders, is set forth below.

Director Name and Year First Became a Director	Age	Position(s) with the Company
Robert J. Bitterman (2012)	72	President, Chief Executive Officer and Chairman of the Board of Directors
Patricia A. Bradford (2022)	72	Director
Geert Cauwenbergh, Dr. Med. Sc. (2012)	69	Director
Robert L. Ferrara (2019)	71	Director
Jonathan E. Freeman, Ph.D. (2017)	54	Director
Curtis A. Lockshin, Ph.D. (2013)	62	Director

Robert J. Bitterman has served as a member and the Chairman of our Board since 2012 and as our President and Chief Executive Officer since February 2023. Mr. Bitterman served as the Interim Executive Chairman of the Company from September 2022 to February 2023 until his appointment to President and Chief Executive Officer. Mr. Bitterman served as the President and Chief Executive Officer of Cutanea Life Sciences, Inc., a private company he founded in 2005 that focused on developing innovative technologies to treat diseases and disorders of the skin and subcutaneous tissue, until its acquisition by Biofrontera, Inc., USA in March 2019. Since leaving Cutanea, Mr. Bitterman was retired until commencing the Interim Executive Chairman role with the Company in September 2022. Prior to his role at Cutanea Life Sciences, Inc., Mr. Bitterman also held the position of President and Chief Executive Officer of Isolagen, Inc., President and General Manager of Dermik Laboratories and various positions of increasing responsibility in financial and commercial capacities within Aventis S.A. Mr. Bitterman holds an A.B. degree in Economics from The College of the Holy Cross and a Master of Business Administration degree from Boston University. He also holds a Doctor of Humane Letters (Honoris Causa) from the New York College of Podiatric Medicine.

Patricia A. Bradford has served as a member of our Board since 2022. Ms. Bradford served as Senior Vice President Global Human Resources at Unisys Corporation, a global information technology solutions company, where her total service at Unisys spanned from 1982 until her retirement in 2013. In her role at Unisys, Ms. Bradford strategically led all global human resource programs and initiatives, including talent management, at multiple levels of the organization. Ms. Bradford's roles at Unisys progressively included all areas of human resources, including an overseas assignment at the Unisys European headquarters where she provided human resources leadership to the region. Prior to Unisys, Ms. Bradford was employed by Deloitte, an audit, consulting, tax, and advisory services firm, from 1978 to 1982. Since 2014, Ms. Bradford has maintained a consulting practice focused on individual coaching for senior executives and high potential employees recommended by management. Ms. Bradford received a B.S. degree with an emphasis on accounting and statistics from Walsh College and is a Certified Public Accountant.

Geert Cauwenbergh, Dr. Med. Sc. has served as a member of our Board since 2012 and served as our Interim Principal Executive and Financial Officer from May 2022 to September 2022. He previously served as our President and Chief Executive Officer from April 2012 to November 2018, and as our Chief Executive Officer from November 2018 until his retirement in March 2019. Dr. Cauwenbergh served as Chairman and Chief Executive Officer of RHEI Pharmaceuticals, Inc., a private company that develops and commercializes proprietary drug therapies, from 2008 to 2011. In 2001, Dr. Cauwenbergh founded Barrier Therapeutics, Inc., a biopharmaceutical company focused on dermatology drug development, until its acquisition by Stiefel Laboratories, Inc. in 2008. Prior to Barrier Therapeutics, Inc. Dr. Cauwenbergh was employed by Johnson & Johnson for 23 years where he held a number of ascending senior management positions. He currently serves as a director of Legacy Health Care (Switzerland). Dr. Cauwenbergh received his Doctorate in Medical Sciences from the Catholic University of Leuven, Faculty of Medicine (Belgium), where he also completed his masters and undergraduate work.

Robert L. Ferrara has served as a member of our Board since 2019 and currently serves as our Lead Independent Director. He most recently served as the Chief Financial Officer of Cutanea Life Sciences, Inc., a private company focused on developing innovative technologies to treat diseases and disorders of the skin and subcutaneous tissue, from January 2012 to his retirement in June 2019. Prior to Cutanea, Mr. Ferrara served as the Chief Financial Officer of Storeroom Solutions Inc., a venture capital financed, technology enhanced, integrated supply chain solutions company, from 2004 to 2011, and NER Data Products, Inc., an IT service management company, from 2000 to 2003, as well as holding other senior level financial positions in national and international public companies in the greater Philadelphia area. Mr. Ferrara received a B.S. in Accounting from Lehigh University and is a Certified Public Accountant.

Jonathan E. Freeman, Ph.D. has served as a member of our Board since 2017. Dr. Freeman currently serves as the Chief Operating Officer of Anthos Therapeutics Inc., a clinical-stage biopharmaceutical company developing therapies for cardiovascular patients, a position he has held since July 2021. Anthos Therapeutics Inc. was launched by Novartis and Blackstone Life Sciences, a private investment firm, where Dr. Freeman has also served as a Senior Advisor since July 2018. From 2017 to June 2018, Dr. Freeman held the position of Chief Business Officer of Vedanta Biosciences, a clinical-stage company developing therapies for immune-mediated diseases. Prior to his role with Vedanta Biosciences, Dr. Freeman was the Senior Vice President of Strategy and Portfolio Management and Head of Business Development and Licensing at Merck KGaA, a leading science and technology company, from 2008 to 2016. Dr. Freeman received a Ph.D. in Molecular Pharmacology and Drug Metabolism from the Imperial Cancer Research Fund (now CRUK), an M.A. and First Class Honours in Biochemistry from Cambridge University and a MBA with a finance major from Webster, St. Louis.

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

Executive Officers

As of the date of this Annual Report on Form 10-K, we have only one executive officer, Robert Bitterman, who serves as our President and Chief Executive Officer. Certain biographical information regarding Mr. Bitterman is set forth above. There are no family relationships among any of our directors or executive officers.

Audit Committee

We have a separately-designated standing audit committee established in accordance with Section 3(a)(58)(A) of the Exchange Act. The Audit Committee is comprised of Mr. Ferrara (Chairman), Ms. Bradford and Dr. Freeman. The Board has determined that all members of the Audit Committee satisfy the current independence and experience requirements of Rule 10A-3 of the Securities Exchange Act of 1934, as amended, (the “**Exchange Act**”) and the current Nasdaq independence standards, and the Board has determined that Mr. Ferrara is an “audit committee financial expert,” as the Securities and Exchange Commission (the “**SEC**”) has defined that term in Item 407 of Regulation S-K.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics that applies to all employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. Our Code of Business Conduct and Ethics, as well as other corporate governance materials, is located on our website at www.phioharma.com. Waivers of our Code of Business Conduct and Ethics may only be granted by the Board. We intend to disclose on our website any amendments to, or waivers from, the Code of Business Conduct and Ethics that are required to be disclosed pursuant to the disclosure requirements of Item 5.05 of Form 8-K within four business days following the date of the amendment or waiver.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires the Company's directors, executive officers and greater-than-10% stockholders to file forms with the SEC to report their ownership of Company securities and any changes in ownership. We have reviewed all forms filed electronically with the SEC. Based on that review and on written information given to us by our officers and directors, we believe that all of our directors, officers and greater-than-10% stockholders filed the required reports on a timely basis under Section 16(a) during 2022, except for director Patricia Bradford, who on September 26, 2022 filed a Form 4 that was due August 11, 2022.

ITEM 11. EXECUTIVE COMPENSATION

The following describes the compensation earned by each of the executive officers identified below in the Summary Compensation Table, who are referred to collectively as our “named executive officers.” Our named executive officers with respect to the fiscal year that ended on December 31, 2022 are Robert J. Bitterman, Geert Cauwenbergh, Dr. Med. Sc., our former interim Principal Executive and Financial officer and Gerrit Dispersyn, Dr. Med. Sc., our former President and Chief Executive Officer.

Summary Compensation Table

Name and principal position	Year	Salary (\$)	Stock awards (\$) ⁽¹⁾	Non-equity incentive plan compensation	All other compensation	Total (\$)
				(\$) ⁽²⁾	(\$) ⁽³⁾	
Robert J. Bitterman ⁽⁴⁾	2022	77,885	31,464	—	31	109,380
President and Chief Executive Officer	2021	47,500	30,800	—	—	78,300
Geert Cauwenbergh, Dr. Med. Sc. ⁽⁵⁾	2022	68,750	8,612	—	—	77,362
Former interim Principal Executive and Financial Officer	2021	27,500	30,800	—	—	58,300
Gerrit Dispersyn, Dr. Med. Sc. ⁽⁶⁾	2022	178,514	108,511	—	202,744	489,769
Former President and Chief Executive Officer	2021	403,390	210,826	136,688	575	751,479

- (1) The amounts shown reflect the grant date fair value of restricted stock units (“RSUs”) computed in accordance with the Financial Accounting Standards Board (the “FASB”) Accounting Standards Codification (“ASC”) Topic 718, “Compensation — Stock Compensation” for the indicated year.
- (2) The amounts shown reflect the annual cash bonus earned for performance for each respective year under the Company’s Incentive Bonus Program. The annual cash bonus for fiscal years 2022 and 2021 was paid in March of the subsequent year, respectively.
- (3) Represents amounts for the dollar value of life insurance premiums paid, except as noted in footnote 6 below.
- (4) Mr. Bitterman has served as a member of the Company’s Board of Directors since 2012 and served as the Company’s Interim Executive Chairman from September 2022 to February 2023 and was appointed as our President and Chief Executive Officer in February 2023. The amounts listed in fiscal year 2021 reflect the compensation paid to Mr. Bitterman as a member of our Board of Directors. The amounts listed in fiscal year 2022 reflect the compensation paid to Mr. Bitterman as a member of our Board of Directors, totaling \$46,112, and as our Interim Executive Chairman, totaling \$63,268.
- (5) Dr. Cauwenbergh has served as a member of the Company’s Board of Directors since 2012 and served as the Company’s interim Principal Executive and Financial Officer from May 2022 to September 2022. Dr. Cauwenbergh was paid \$37,500 in compensation in fiscal year 2022 as the Company’s interim Principal Executive and Financial Officer, which is included within the “Salary” heading of the Summary Compensation Table. All other compensation listed in the Summary Compensation Table reflects the compensation paid to Dr. Cauwenbergh as a member of our Board of Directors.
- (6) Dr. Dispersyn served as the Company’s President and Chief Executive Officer from March 2019 to May 2022. Included within the “All Other Compensation” heading of the Summary Compensation Table is \$202,500 in severance payments made to Dr. Dispersyn in connection with his termination consistent with and subject to the conditions set forth in his employment agreement.

Outstanding Equity Awards at Fiscal Year-End

The following table shows information regarding outstanding equity awards as of December 31, 2022 for our named executive officers:

Name	Grant Date	Option Awards				Stock Awards			
		Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested	Market Value of Shares or Units of Stock That Have Not Vested (\$)	Equity Incentive Plan Awards: Number of Shares or Units of Stock That Have Not Vested (#)	Equity Incentive Plan Awards: Market Value of Unearned Shares or Units of Stock That Have Not Vested (\$) ⁽¹⁾
Robert J. Bitterman ⁽²⁾	6/7/2013	1	—	396,000.00	6/7/2023	—	—	—	—
	6/2/2014	1	—	188,100.00	6/2/2024	—	—	—	—
	6/1/2015	1	—	25,080.00	6/1/2025	—	—	—	—
	2/10/2016	1	—	18,876.00	2/10/2026	—	—	—	—
	2/1/2017	1	—	4,151.40	2/1/2027	—	—	—	—
	2/15/2022	—	—	—	—	—	—	834	3,720
	10/1/2022	—	—	—	—	—	—	3,334	14,870
Geert Cauwenbergh, Dr. Med. Sc. ⁽³⁾	6/7/2013	3	—	396,000.00	6/7/2013	—	—	—	—
	6/2/2014	3	—	188,100.00	6/2/2014	—	—	—	—
	6/1/2015	3	—	25,080.00	6/1/2025	—	—	—	—
	2/10/2016	3	—	18,876.00	2/10/2026	—	—	—	—
	2/1/2017	2	—	4,151.40	2/1/2027	—	—	—	—
	8/1/2018	32	—	1,181.40	8/1/2028	—	—	—	—
	2/15/2022	—	—	—	—	—	—	834	3,720
Gerrit Dispersyn, Dr. Med. Sc.	—	—	—	—	—	—	—	—	—

⁽¹⁾ Value is based on the closing price of \$4.46 of the Company's common stock on December 31, 2022.

⁽²⁾ The equity awards granted to Mr. Bitterman vest in one installment on the first anniversary of the grant date.

⁽³⁾ The equity awards granted to Dr. Cauwenbergh from 2013 and 2018 vested over four years commencing on the first anniversary of the grant date. The equity award granted to Dr. Cauwenbergh in 2022 vests in one installment on the first anniversary of the grant date.

Base Salary

When reviewing and approving our executive compensation arrangements, including the base salaries paid to our executive officers, the Compensation Committee of the Company's Board of Directors (the "**Compensation Committee**") considers a number of factors, including, but not limited to: the performance of the executive officer to the Company's overall performance, the performance of the executive officer against the Company's corporate objectives, the executive officer's skills, experience and qualifications in such executive officer's role, review of compensation surveys of base salaries paid by comparable organizations and market compensation data. These factors provide the framework for decisions regarding the base salary compensation for each executive officer. No single factor is determinative in setting base salary levels, nor was the impact of any factor on the determination of pay levels quantifiable.

Incentive Compensation

Annual Incentive Bonus

Annual bonuses are based on the achievement of corporate goals typically comprised of a mix of clinical development, discovery, financial, business development, and investor relations related performance objectives. The corporate goals are approved by the Board on an annual basis at the start of each year. Annual bonuses for all employees, including executive officers, take into account the achievement of specified business objectives and individual performance objectives, with the exception of the Company's President and Chief Executive Officer, whose annual bonus is determined solely by the achievement of business objectives. The Compensation Committee reviews our achievements against these corporate goals and their assessment of the goals and recommendations regarding funding is presented to our full Board for approval. The Compensation Committee maintains full discretion in determining overall performance under the annual bonus and may adjust bonus payouts based on factors it deems relevant. Annual incentive bonus payouts to our named executive officers are disclosed in the Summary Compensation Table above.

Equity Incentive

We maintain our 2020 Long Term Incentive Plan (“**2020 Plan**”) pursuant to which we currently grant RSU awards to eligible participants. Grants of restricted stock units under this plan to our named executive officers are disclosed in the Summary Compensation Table and Outstanding Equity Awards at Fiscal Year-End table above.

Employment and Change of Control Agreements

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

Robert J. Bitterman

Mr. Bitterman was appointed President and Chief Executive Officer and entered into an employment agreement, dated February 20, 2023, pursuant to which he will be entitled to an initial annual base salary of \$440,000 and will be eligible to receive an annual bonus of up to 40% of his annual base salary, based on the achievement of certain performance goals established annually by the Board. In connection with his appointment, the Company granted Mr. Bitterman RSUs settleable for 11,000 shares of the Company's common stock under the Company's 2020 Plan. The RSUs will vest in two equal annual installments, commencing on the first anniversary of the date of grant, subject to Mr. Bitterman's continuous service with the Company through each such vesting date.

If Mr. Bitterman's employment is terminated by the Company due to death or disability, the Company shall pay to Mr. Bitterman or to his estate, as applicable, any earned, but unpaid, base salary and any amounts owed to Mr. Bitterman for reimbursement of expenses properly incurred which are reimbursable, in each case as earned or incurred, as applicable through the date of termination (the “**Accrued Benefits**”), as well as pay any accrued but unpaid bonus then due to Mr. Bitterman and all equity awards that have been granted will immediately vest on a pro-rata basis. If Mr. Bitterman's employment is terminated by the Board for cause or by Mr. Bitterman without good reason, the Company shall pay to Mr. Bitterman the Accrued Benefits through the date of termination. If Mr. Bitterman's employment is terminated by Mr. Bitterman for good reason or by the Company other than as a result of death or disability and other than for cause, then the Company shall pay to Mr. Bitterman the Accrued Benefits through the date of termination, continue to pay Mr. Bitterman his base salary for three months from the date of separation, pay any accrued but unpaid bonus and if, and only if, such termination occurs within one year of a change in control all equity awards that have been granted but are not exercisable at the time of such termination shall immediately become exercisable in full.

Mr. Bitterman is eligible to participate in the Company's 2020 Plan and other benefits available to the Company's executive officers.

Geert Cauwenbergh, Dr. Med. Sc.

In connection with his appointment as the Company's interim Principal Executive Officer and Principal Financial Officer, Dr. Cauwenbergh received a monthly cash payment of \$7,500.

Gerrit Dispersyn, Dr. Med. Sc.

We entered into an employment agreement with Dr. Dispersyn effective April 24, 2017 as our Chief Development Officer. As Chief Development Officer, Dr. Dispersyn was entitled to receive an initial base salary of \$285,000 per annum, as well as a performance bonus of up to 30% of his base salary, subject to the achievement of performance goals to be established annually. In connection with Dr. Dispersyn's appointment to Chief Development Officer, he received a stock option entitling him to purchase 14 shares of the Company's common stock, which were subject to vesting in equal monthly installments over four years following the date of grant.

Dr. Dispersyn served as the Company's President and Chief Executive Officer from March 2019 to May 2022. As President and Chief Executive Officer, Dr. Dispersyn was entitled to an initial base salary of \$380,000 per annum, as well as a performance bonus of up to 50% of his base salary, subject to the achievement of performance goals to be established annually. As a one-time award in connection with his appointment on March 1, 2019, Dr. Dispersyn received RSUs settleable for 617 shares of the Company's common stock, which was subject to vesting in equal annual installments over four years.

Dr. Dispersyn's employment agreement provided that, upon termination of Dr. Dispersyn's employment without cause by us, he would be entitled to payment of: (1) any accrued but unpaid salary and unused vacation as of the date of his termination; (2) six months of salary from the date of termination; and (3) continued participation, at our expense, during the applicable six-month severance period in our sponsored group medical and dental plans. Effective May 5, 2022, Dr. Dispersyn's employment with the Company ended, which was treated as a termination without "cause," and Dr. Dispersyn became entitled to receive severance benefits totaling \$202,500 consistent with the above and subject to the conditions set forth in the separation agreement between Dr. Dispersyn and the Company.

Director Compensation

Non-Employee Director Compensation Policy

We compensate our non-employee directors for their service as a member of our Board. Each non-employee director is entitled to receive an annual cash retainer of \$35,000. The chairs of our Board and Audit Committee are entitled to receive an additional annual cash retainer of \$15,000 and the chairs of the Compensation, Governance and Nominating Committees are entitled to receive an additional cash retainer of \$7,500. In addition, the Lead Independent Director, if any, is entitled to receive an additional annual cash retainer of \$12,500. Each non-employee director is also entitled to receive 1,667 RSUs, which vest in full on the one-year anniversary of the respective date of grant.

The Compensation Committee and the Board reassess the appropriate levels of cash and equity compensation for non-employee directors on an annual basis.

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

Non-Employee Director Compensation Table

The following table shows the compensation to the Company's non-employee directors in fiscal year 2022. We compensate our non-employee directors for their service as a member of our Board. Compensation paid to Robert J. Bitterman, the Company's President, Chief Executive Officer and Chairman of the Board, and Geert Cauwenbergh, Dr. Med. Sc., who served as the Company's interim Principal Executive Officer and interim Principal Financial Officer from May 2022 to September 2022, in connection with their service as directors of the Company is set forth above in the Summary Compensation Table due to Mr. Bitterman and Dr. Cauwenbergh's status as named executive officers of the Company.

Name	Fees Earned or Paid in Cash (\$)	Stock Awards (\$)⁽¹⁾	Total (\$)
Patricia A. Bradford	27,292	15,000	42,292
H. Paul Dorman ⁽²⁾	16,667	8,612	25,279
Robert L. Ferrara	49,375	8,612	57,987
Jonathan E. Freeman, Ph.D.	31,250	8,612	39,862
Curtis A. Lockshin, Ph.D.	38,750	8,612	47,362

⁽¹⁾ The amounts shown reflect the grant date fair value of RSUs computed in accordance with the FASB ASC Topic 718, "Compensation — Stock Compensation".

⁽²⁾ Mr. Dorman did not stand for reelection at the 2022 Annual Stockholder Meeting held on August 8, 2022 and served as a director until the end of his term.

As of December 31, 2022, the aggregate number of shares underlying stock options and RSUs by our non-employee directors is as follows: Patricia A. Bradford — 1,667 RSUs, Robert L. Ferrara — 834 RSUs, Jonathan E. Freeman, Ph.D. — 1 option award and 834 RSUs, and Curtis A. Lockshin, Ph.D. — 5 option awards and 834 RSUs. Mr. Bitterman and Dr. Cauwenbergh's outstanding equity awards are also included in the Outstanding Equity Awards at Fiscal Year-End table above due to their status as named executive officers during the fiscal year ended December 31, 2022.

Upon his appointment to President and Chief Executive Officer of the Company effective February 20, 2023, Mr. Bitterman ceased receiving compensation in connection with his positions as a director of the Company, including as Chairman of the Board.

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

Security Ownership of Certain Beneficial Owners and Management

Based on information available to us and filings with the SEC, the following table sets forth certain information regarding the beneficial ownership (as defined by Rule 13d-3 under the Exchange Act) of our outstanding common stock for (i) each of our directors, (ii) each of our named executive officers, (iii) all of our directors and executive officers as a group and (iv) persons known to us to beneficially own more than 5% of our outstanding common stock. The following information is presented as of February 28, 2023 or such other date as may be reflected below.

Beneficial ownership and percentage ownership are determined in accordance with the rules of the SEC and include voting or investment power with respect to shares of stock. This information does not necessarily indicate beneficial ownership for any other purpose. Under these rules, shares of common stock not outstanding but deemed beneficially owned by virtue of the right of a person to acquire them as of February 28, 2023, or within 60 days of February 28, 2023, are deemed outstanding for the purpose of computing the percentage ownership of each person, but are not deemed outstanding for the purpose of computing the percentage ownership of any other person.

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

Name and Address of Beneficial Owner	Shares Beneficially Owned	
	Number ⁽¹⁾	Percent of Class ⁽²⁾
Greater than 5% Holders		
Intracoastal Capital LLC ⁽³⁾	67,654	5.6%
Directors and Named Executive Officers:		
Robert J. Bitterman ⁽⁴⁾	2,883	*
Patricia A. Bradford	—	*
Geert Cauwenbergh, Dr. Med. Sc. ⁽⁵⁾	2,782	*
Robert Ferrara	2,500	*
Jonathan E. Freeman, Ph.D. ⁽⁶⁾	1,698	*
Curtis A. Lockshin, Ph.D. ⁽⁷⁾	1,702	*
All current directors and executive officers as a group (six persons)	11,565	1.02%

* Indicates less than 1%.

⁽¹⁾ Represents shares of common stock held as of February 28, 2023 plus shares of common stock that may be acquired upon the exercise of options and warrants within 60 days of February 28, 2023.

⁽²⁾ Based on 1,137,318 shares of common stock that were issued and outstanding as of February 28, 2023. Shares not outstanding but deemed beneficially owned by virtue of the right of a person to acquire them as of February 28, 2023, or within 60 days of February 28, 2023, are treated as outstanding only when determining the ownership and voting power for each person (or all directors and executive officers as a group).

⁽³⁾ Based solely on information set forth in a Schedule 13G/A filed with the SEC on February 8, 2023 by Intracoastal Capital LLC ("**Intracoastal**"), Mitchell P. Kopin ("**Mr. Kopin**") and Daniel B. Asher ("**Mr. Asher**"). Each of Intracoastal, Mr. Kopin and Mr. Asher may be deemed to have beneficial ownership of 67,654 shares of common stock consisting of (i) 17,845 shares of common stock issuable upon exercise of a warrant held by Intracoastal ("**Intracoastal Warrant 1**"), (ii) 19,271 shares of common stock issuable upon exercise of a second warrant held by Intracoastal ("**Intracoastal Warrant 2**"), (iii) 30,538 shares of common stock issuable upon exercise of a third warrant held by Intracoastal ("**Intracoastal Warrant 3**"), and all such shares of common stock represented beneficial ownership of approximately 5.6% of the common stock, based on (1) 1,138,997 shares of common stock outstanding as of November 17, 2022, as reported by the Issuer, plus (2) 17,845 shares of common stock issuable upon exercise of Intracoastal Warrant 1, (3) 19,271 shares of common stock issuable upon exercise of Intracoastal Warrant 2 and (4) 30,538 shares of common stock issuable upon exercise of Intracoastal Warrant 3. The foregoing excludes (I) 4,625 shares of common stock issuable upon exercise of a fourth warrant held by Intracoastal ("**Intracoastal Warrant 4**") because Intracoastal Warrant 4 contains a blocker provision under which the holder thereof does not have the right to exercise Intracoastal Warrant 4 to the extent (but only to the extent) that such exercise would result in beneficial ownership by the holder thereof, together with the holder's affiliates, and any other persons acting as a group together with the holder or any of the holder's affiliates, of more than 4.99% of the common stock and (II) 342 shares of common stock issuable upon exercise of a fifth warrant held by Intracoastal ("**Intracoastal Warrant 5**") because Intracoastal Warrant 5 contains a blocker provision under which the holder thereof does not have the right to exercise Intracoastal Warrant 5 to the extent (but only to the extent) that such exercise would result in beneficial ownership by the holder thereof, together with the holder's affiliates, and any other persons acting as a group together with the holder or any of the holder's affiliates, of more than 4.99% of the common stock. Without such blocker provisions, each of the Reporting Persons may have been deemed to have beneficial ownership of 72,621 shares of common stock. The principal business office of Mr. Kopin and Intracoastal is 245 Palm Trail, Delray Beach, Florida 33483. The principal business office of Mr. Asher is 111 W. Jackson Boulevard, Suite 2000, Chicago, Illinois 60604.

⁽⁴⁾ Includes 5 stock options exercisable within 60 days of February 28, 2023.

⁽⁵⁾ Includes 46 stock options exercisable within 60 days of February 28, 2023.

⁽⁶⁾ Includes 1 stock option exercisable within 60 days of February 28, 2023.

⁽⁷⁾ Includes 5 stock options exercisable within 60 days of February 28, 2023.

Equity Compensation Plan Information

The following table sets forth certain information, as of December 31, 2022, about the securities authorized for issuance under our equity compensation plans, which consisted of our 2020 Plan and our 2013 Employee Stock Purchase Plan. Upon adoption of the 2020 Plan, shares that remained available for grant under our prior Phio Pharmaceuticals Corp. 2012 Long-Term Incentive Plan (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.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in First Column)
Equity compensation plans approved by security holders ⁽¹⁾	47,469	\$ 19,761.12	43,807
Equity compensation plans not approved by security holders	—	—	—
Total	47,469	\$ 19,761.12	43,807

(1) Includes options outstanding representing 141 shares of common stock under the 2020 Plan. Also includes 47,328 RSUs subject to the 2020 Plan.

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

Our Board, with the assistance of the Audit Committee, reviews and approves all transactions with directors, officers and holders of more than 5% of our voting securities and their affiliates. Prior to the Board’s consideration of a transaction with such a related party, the material facts as to the related party’s relationship or interest in the transaction must be disclosed to the Board, and the transaction will not be considered approved by the Board unless a majority of the directors who are not interested in the transaction (if applicable) approve the transaction. Furthermore, when stockholders are entitled to vote on a transaction with a related party, the material facts of the related party’s relationship or interest in the transaction must be disclosed to the stockholders, who must approve the transaction in good faith.

Since the past two years, there has not been, nor is there currently proposed, any transaction or series of related transactions to which we were or will be a party in which the amount involved exceeded or will exceed the lesser of (i) \$120,000 or (ii) one percent of the average of Company’s total assets at yearend for the last two completed fiscal years and in which the other parties included or will include any of our directors, executive officers, holders of 5% or more of our voting securities, or any member of the immediate family of any of the foregoing persons, other than compensation arrangements with directors and executive officers, which are described where required in Item 11. Executive Compensation of this Annual Report on Form 10-K.

Indemnification Agreements

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

Director Independence

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

In addition, Nasdaq listing standards require that, subject to specified exceptions, each member of our Audit, Compensation, Governance and Nominating Committees be independent and that our Audit Committee members also satisfy independence criteria set forth in Rule 10A-3 under the Exchange Act. Our Board has determined that all members of the Audit Committee, Compensation Committee, Governance Committee, and Nominating Committee are independent under the applicable Nasdaq listing standards and the Exchange Act.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following is a summary of the fees billed and expected to be billed to the Company by BDO USA, LLP (“**BDO**”), our independent registered public accounting firm, for professional services rendered for the fiscal years ended December 31, 2022 and 2021. All fees incurred in fiscal years 2022 and 2021 for services rendered by BDO were approved in accordance with the pre-approval policies and procedures described below.

	2022	2021
Audit Fees	\$ 215,974	\$ 187,352
Audit-Related Fees	—	—
Tax Fees	—	36,250
All Other Fees	—	—
Total All Fees:	<u>\$ 215,974</u>	<u>\$ 223,602</u>

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

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

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

All Other Fees consist of the aggregate fees billed for products and services provided by BDO and not otherwise included in Audit Fees, Audit-Related Fees or Tax Fees.

Pre-Approval Policies and Procedures

Under the Sarbanes-Oxley Act of 2002, all audit and permissible non-audit services provided by our auditors must be approved in advance by our Audit Committee to ensure that such services do not impair the auditors’ independence from us. Accordingly, the Audit Committee reviews and pre-approves all audit and non-audit services performed by its independent registered public accounting firm, as well as the fees charged for such services. In its review of non-audit service fees, the Audit Committee considers, among other things, the possible impact of the performance of such services on the auditor’s independence.

PART IV

ITEM 15. *EXHIBITS AND FINANCIAL STATEMENT SCHEDULES*

Financial Statements

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

Financial Statement Schedules

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

Exhibits

Exhibit Number	Description	Incorporated by Reference Herein	
		Form	Date
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	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 25, 2023
3.4	Certificate of Designation of Series D Preferred Stock, dated November 16, 2022.	Current Report on Form 8-K (File No. 001-36304)	November 16, 2022
3.5	Amended and Restated Bylaws of Phio Pharmaceutical Corp.	Current Report on Form 8-K (File No. 001-36304)	May 2, 2022
4.1	Form of Warrant.	Current Report on Form 8-K (File No. 001-36304)	April 11, 2018
4.2	Form of Placement Agent Warrant.	Current Report on Form 8-K (File No. 001-36304)	April 11, 2018
4.3	Form of Warrant.	Amendment No. 1 to the Registration Statement on Form S-1 (File No. 333- 221173)	September 28, 2018
4.4	Form of Underwriter Warrant.	Current Report on Form 8-K (File No. 001-36304)	October 5, 2018
4.5	Form of Placement Agent Warrant.	Current Report on Form 8-K (File No. 001-36304)	November 19, 2019
4.6	Form of Warrant.	Current Report on Form 8-K (File No. 001-36304)	February 6, 2020
4.7	Form of Warrant.	Current Report on Form 8-K (File No. 001-36304)	February 13, 2020
4.8	Form of Underwriter Warrant.	Current Report on Form 8-K (File No. 001-36304)	February 13, 2020
4.9	Form of Warrant.	Current Report on Form 8-K (File No. 001-36304)	April 2, 2020

4.10	Form of Common Stock Warrant.	Current Report on Form 8-K (File No. 001-36304)	January 25, 2021
4.11	Form of Placement Agent Warrant.	Current Report on Form 8-K (File No. 001-36304)	February 17, 2021
4.12	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 Advima, LLC, effective as of September 24, 2011.	Registration Statement on Form S-1 (File No. 333-177498)	October 25, 2011
10.2	Clinical Co-development Agreement, dated February 26, 2021, by and between Phio Pharmaceuticals Corp. and AgonOx, Inc.*+		
10.3	Phio Pharmaceuticals Corp. 2020 Long Term Incentive Plan.#	Registration Statement on Form S-8 (File No. 333-251670)	December 23, 2020
10.4	Form of Restricted Stock Unit Award under the Company's 2020 Long Term Incentive Plan.#	Annual Report on Form 10-K (File. 001-36304)	March 25, 2021
10.5	Phio Pharmaceuticals Corp. 2012 Long Term Incentive Plan.#	Quarterly Report on Form 10-Q (File No. 001-36304)	November 12, 2019
10.6	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
10.7	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
10.8	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
10.9	RXi Pharmaceuticals Corporation Employee Stock Purchase Plan.#	Registration Statement on Form S-8 (File No. 333-277013)	August 24, 2018
10.10	Form of Indemnification Agreement.#	Amendment No. 3 to the Registration Statement on Form S-1 (File No. 333-177498)	January 23, 2012
10.11	Separation Agreement, date May 5, 2022, by and between Phio Pharmaceuticals Corp. and Gerrit Dispersyn, Dr. Med. Sc.#*		
10.12	Employment Agreement, dated February 20, 2023, by and between Phio Pharmaceuticals Corp. and Robert Bitterman.#	Current Report on Form 8-K (File No. 001-36304)	February 22, 2023
10.13	Subscription and Investment Representation Agreement, dated November 16, 2022, by and between Phio Pharmaceuticals Corp. and Robert Bitterman.	Current Report on Form 8-K (File No. 001-36304)	November 16, 2022

10.14	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
10.15	First Amendment to Lease dated January 22, 2019.	Current Report on Form 8-K (File No. 001-36304)	January 28, 2019
10.16	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
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 Act Section 906 Certification of Principal Executive Officer and Principal Financial Officer.**		
101.INS	Inline XBRL Instance Document.*		
101.SCH	Inline XBRL Taxonomy Extension Schema Document.*		
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.*		
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.*		
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.*		
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.*		
104	The cover page for this report, formatted in Inline XBRL (included in Exhibit 101).*		

* Filed herewith.

** Furnished herewith.

Indicates a management contract or compensatory plan or arrangement.

+ Certain portions of this Exhibit have been redacted pursuant to Item 601(b)(10) of Regulation S-K. The Company agrees to furnish supplementally an unredacted copy of this Exhibit to the SEC upon request.

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/ Robert J. Bitterman
 Robert J. Bitterman
 President and Chief Executive Officer
 (as Principal Executive and Financial Officer)

Date: March 22, 2023

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/ Robert J. Bitterman Robert J. Bitterman	President, Chief Executive Officer and Director (Principal Executive Officer and Principal Financial Officer)	March 22, 2023
/s/ Caitlin Kontulis Caitlin Kontulis	Vice President of Finance and Administration and Secretary (Principal Accounting Officer)	March 22, 2023
/s/ Patricia Bradford Patricia Bradford	Director	March 22, 2023
/s/ Geert Cauwenbergh Geert Cauwenbergh, Dr. Med. Sc.	Director	March 22, 2023
/s/ Robert L. Ferrara Robert L. Ferrara	Director	March 22, 2023
/s/ Jonathan E. Freeman Jonathan E. Freeman, Ph.D.	Director	March 22, 2023
/s/ Curtis A. Lockshin Curtis A. Lockshin, Ph.D.	Director	March 22, 2023

Board of Directors

Robert J. Bitterman, Chair
President & CEO, Phio Pharmaceuticals Corp.

Patricia A. Bradford
Former Senior Vice President Global Human Resources, Unisys Corporation

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

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

Robert J. Bitterman
President & CEO

Linda Mahoney
Senior Vice President of Development

James Cardia, Ph.D.
Vice President of Discovery

Caitlin Kontulis
Vice President of Finance & Administration

Transfer Agent

Computershare Trust Company, N.A.

By Regular Mail:

P.O. Box 43078
Providence, RI 02940-3078

By Overnight Delivery:

150 Royall Street, Suite 101
Canton, MA 02021

Securities Listing

The Nasdaq Capital Market

Ticker: PHIO

Corporate Counsel

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Philadelphia, PA

Auditors

BDO USA, LLP

Boston, MA

Corporate Headquarters

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