2023

Phio Pharmaceuticals Corp.

Annual Report

Dear Shareholder:

On behalf of the Phio Board of Directors and management team, I want to thank you for your investment in our Company. Our objective is to drive shareholder value for you as we continue on our mission to eliminate cancer in ways that others cannot. We strive to execute our strategy effectively and efficiently, leveraging our patented INTASYL™ technology platform which is designed to make immune cells more effective at killing cancer cells.

Last year I described our plan to transition our primary business model from discovery research to human drug development. Our goal at that time was to deploy our INTASYL technology in a human clinical trial. Having established preclinical safety and proof of concept in various types of solid tumor models, we elected to target skin cancer, and in particular cutaneous squamous cell carcinoma (cSCC). We successfully demonstrated that in preclinical studies our lead compound PH-762 silences the production of the PD-1 protein, which disguises tumor cells from our body's innate T-cell tumor killing action. The role of PD-1 in disguising solid tumors was initially substantiated by a few large pharma companies with their monoclonal antibody (mAB) biologics. The systemic infusion of mAB's could attack PD-1 already present on the surface of the cell. In contrast, we established that Phio's PH-762 compound could shut down or silence the production of PD-1 at its source within the T-cell before it could migrate to the cell surface. Moreover, PH-762 could be administered by intralesional injection direct to the tumor site instead of through systemic infusion. Phio's form of administration essentially reduces the risk of off target side effects, in particular, auto immune reactions common with mAB systemic infusion. Phio's administration by injection would also provide convenience to physician and patient, allowing for treatment in the physician's office.

In April of 2023 we submitted an IND (Investigational New Drug Application) to the FDA with a goal to receive approval to commence the first in human Phase 1b dose escalation study to treat late stages of melanoma, Merkel cell and cutaneous squamous cell carcinoma with PH-762. Approximately one month later we received clearance to commence a study in the late stages of these diseases, but were also granted clearance to treat early stages I&II of cSCC for which there is no drug currently approved in the U.S. The current standard of care is surgical intervention. This approval to study early stages of cSCC opened a significant market opportunity. Cutaneous squamous cell carcinoma represents the 2nd largest incidence of solid tumors in the U.S. in the human body, only exceeded by basal cell carcinoma. Cutaneous squamous cell carcinoma represents approximately 1.8 million incidences of which Stages I&II comprise over 75% of these tumors. The capture of just a modest single digit market share in this segment aligned with a per treatment regimen price point acceptable to drug reimbursement plans could reasonably yield revenue dollars in excess of $1 billion annually.

With FDA approval to proceed with our study, we sought out and successfully concluded agreements with 4 clinical investigation sites, geographically dispersed, representing a combination of prestigious universities, medical centers and private clinics. Today I am happy to report we are treating the last patient in the first dosing cohort of 5 increasing-dose cohorts of patients. It is our goal to advance through the 4 additional cohorts over the next 12 months to complete the enrollment of the clinical trial sometime in 2nd quarter 2025.

In parallel with conducting the clinical trial, we initiated cost improvement and operational efficiency programs. On March 31st of this year, we terminated our lease on a 7,600 square foot facility in Marlborough MA., serving both research and administration needs. With a reduction of

6 discovery scientists, we transferred a more focused activity to a smaller footprint consisting of 2 scientists in a 321 square foot incubator space in the city of Worcester. Our administrative staff of 2 individuals now conduct their activities virtually. Development personnel also work virtually. Clinical trial activity is supported by 2 senior in-house experts with combined experience exceeding 50 years. They, along with a lean but experienced network of specifically skilled individual consultants drive the development program. We have the added benefit of these individuals having worked together cross functionally in a prior pharma company. In this manner we deploy personnel as needed to maximize cost efficiencies.

We are also rationalizing our intellectual property portfolio, broadening protections on our primary and backup compounds, and strengthening claims on compounds which we have targeted for out-license to 3rd parties. Currently, the proprietary protections on our lead and backup compounds extend beyond the year 2040 with the inclusion of patent term restoration. Our out-license efforts target companies in the biotech and dermatology space to offer license opportunities for INTASYL compounds that are not of our primary focus, but which may be complimentary to their technologies and not directly competitive to our core business targets.

As we progress through this fiscal year we will continue to enhance our visibility to shareholders, industry and medical societies. We recently initiated a one-minute Phio infomercial campaign across a number of cable and streaming services which portrays our medical/research focus in the field of solid tumors. We are also presenting various medical abstracts and study posters at many of the prestigious medical society meetings which address cancer and dermatology. We believe these actions will expand our reach to a broader base of investors and potential corporate business development partners.

In summary, I wish to thank you for your interest and continued support as we strive to realize our vision: ‘discovering new pathways toward a cancer free future’. I hope this short update has been helpful to you in understanding our strategy and progress. We look forward to exceeding your expectations.

Sincerely,

Robert Bitterman

Chairman, 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, 2023

Or

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

For the transition period from _____ to _____

Commission File Number 001-36304

PHIO PHARMACEUTICALS CORP.

(Exact name of registrant as specified in its charter)

Delaware	**45-3215903**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

11 Apex Drive, Suite 300A PMB 2006, 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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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, 2023, was approximately $5.7 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 15, 2024, the registrant had 4,591,700 shares of Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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PHIO PHARMACEUTICALS CORP.
ANNUAL REPORT ON FORM 10-K
For the Fiscal Year Ended December 31, 2023

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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;
- 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;
- our business and operations would suffer in the event of computer system failures, cyberattacks or a deficiency in our cybersecurity;
- 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;
- we may not be able to regain compliance with the continued listing requirements of The Nasdaq Capital Market; 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.

In 2023, the Company implemented a cost rationalization program driven by its transition from discovery research to product development. This resulted in a decision not to renew the lease for office and laboratory space in Marlborough, Massachusetts, which will expire on March 31, 2024. Beginning in April of 2024, we expect to continue operations as a remote business with a small laboratory facility in Worcester, Massachusetts for 321 square feet of space that commenced on March 1, 2024. Additionally, we rationalized discovery research personnel resulting in headcount reduction by approximately 36%. Expense reductions have been redirected to funding the Phase 1b clinical trial with PH-762 directed toward skin cancer.

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.

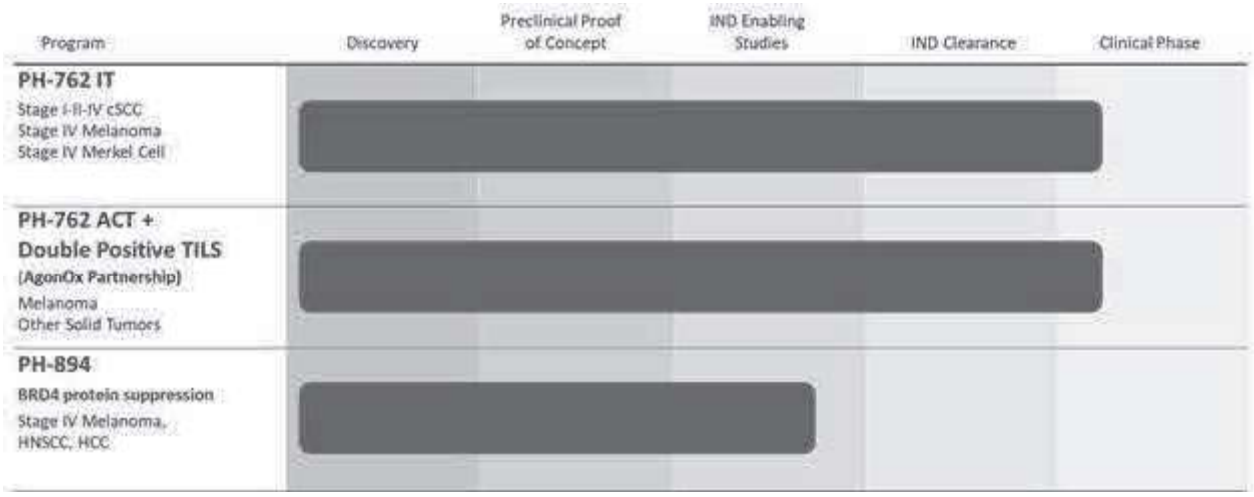
We believe that our INTASYL platform provides the following benefits including, but not limited to:

- 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.



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.

Our preclinical studies 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 U.S. multi-center Phase 1b dose-escalating clinical trial through the intratumoral injection of PH-762 for the treatment of patients with cutaneous squamous cell carcinoma, melanoma and Merkel cell carcinoma. The trial is designed to evaluate the safety and tolerability of neoadjuvant use of intratumorally injected PH-762, assess the tumor response, and determine the dose or dose range for continued study of PH-762 and is expected to enroll up to 30 patients. In November 2023, we announced the dosing of the first patient and the trial is currently open for the continued enrollment of patients.

Given our intention to focus our efforts and resources on our U.S. clinical trial with PH-762, we have completed the winding down process for our first-in-human clinical trial for PH-762 in France, which was limited to the treatment of patients with metastatic melanoma. Safety data from the initial cohort of three patients in the French clinical trial were 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.

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 lymphocytes ("**DP TIL**") with PH-762 increased their tumor killing activity by two-fold.

In February 2021, we entered into a clinical co-development collaboration agreement (the "**Clinical Co-Development Agreement**") with AgonOx to develop a T cell-based therapy using PH-762 and AgonOx's DP TIL. Under the Clinical Co-Development Agreement, we agreed to reimburse AgonOx up to $4 million in expenses incurred to conduct a Phase 1 clinical trial of PH-762 treated DP TIL in patients with advanced melanoma and other advanced solid tumors. As of December 31, 2023, there was approximately $2.8 million of remaining costs not yet incurred under the Clinical Co-Development Agreement. We are 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 TIL are being evaluated in a Phase 1 clinical trial in the U.S. with up to 18 patients with advanced melanoma and other advanced solid tumors by AgonOx. The primary trial objectives are to evaluate the safety and to study the potential for enhanced therapeutic benefit from the administration of PH-762 treated DP TIL. We announced the first patient was dosed in August 2023 and the trial is open for the continued enrollment of patients.

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 against distant untreated tumors, indicative of 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. We have completed the investigational new drug application ("**IND**")-enabling studies and are in the process of continuing to finalize the study reports required for an IND submission with PH-894. As a result of the reprioritization to advance our clinical trial with PH-762 in the U.S., we have elected to defer the IND submission for PH-894.

Synergies With Other Therapies

Preclinical studies with our INTASYL compounds in combination with antibodies resulted in enhanced potency in vivo. The combination of INTASYL with antibodies may also increase the number of addressable drug targets. Unlike other antibody combination approaches, INTASYL can target multiple protein drug targets in a specific therapeutic dose, thereby enhancing potency while maintain a favorable tolerability and safety profile.

We have demonstrated preclinical efficacy with INTASYL in ACT applications. In preclinical studies, INTASYL was shown to enhance the activity of ACT therapies, including with tumor infiltrating lymphocytes and natural killer cells. As demonstrated in these preclinical studies, INTASYL is easily incorporated into current ACT manufacturing processes.

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 combine 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 U.S. 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	14	33
Canada	3	2
Europe	6	26
Japan	7	12
Other Markets	10	8

Our portfolio includes 81 issued patents, 73 of which cover our INTASYL platform. There are 13 patent families broadly covering both the composition and methods of use of our self-delivering INTASYL platform technology and uses of our INTASYL compounds targeting immune checkpoint, cellular differentiation and metabolism targets for *ex vivo* cell-based cancer immunotherapies. The INTASYL platform patents are scheduled to expire between 2029 and 2038.

Furthermore, there are 40 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 that may issue from these pending patent applications will, if issued, be set to expire between 2029 and 2042, 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.

In September 2011, the Company entered into an agreement with Advanced RNA Technologies, LLC ("**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 Advirna 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 Advirna agreement or (ii) the abandonment of the last-to-be abandoned of such patents, unless earlier terminated in accordance with the provisions of the Advirna 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 expect 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 through an IND, must become effective before human clinical trials may commence. Preclinical studies generally involve evaluation of product characteristics and animal studies to assess the efficacy and safety of the product candidate. Many of these studies must be conducted in accordance with the FDA's current Good Laboratory Practices, the Animal Welfare Act, and other applicable regulations.

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 to approve a 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 agency resources.

The FDA maintains several programs to facilitate and expedite the development and review of applications that are intended for the treatment of a serious or life-threatening disease or condition that meet certain other criteria, including Fast Track Designation, Breakthrough Designation, Priority Review, and the Accelerated Approval pathway.

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 and certain state agencies 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 state and local requirements governing the manufacturing and distribution of pharmaceutical products. In addition, we 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.

In the future, we may also be subject to a variety of regulations governing clinical trials and sales of our products outside the U.S. 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 U.S.

European Union Data Laws For Review and Approval of Drugs in the European Union Including France

The collection and use of personal health data and other personal information in the European Union ("**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 United Kingdom's ("**UK**") formal departure from the EU on January 31, 2020 and the end of the transition period on December 31, 2020, the UK 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 trade and cooperation agreement ("**TCA**") entered into between the EU and UK following the end of the transition period 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.

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, 2023, we had eight 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 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 in the United States, or the equivalent with regulatory authorities in other jurisdictions, if applicable. 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 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 drug or biologic 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 partner for the successful development of our adoptive cell therapy product candidate.

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 our third-party collaborator to support the clinical development of our ACT product candidate. We have entered into a clinical co-development collaboration agreement with AgonOx, Inc. to conduct a Phase 1 clinical trial of the evaluation of PH-762 treated "double positive" tumor infiltrating lymphocytes in patients with advanced melanoma and other advanced solid tumors. The success of our collaboration depends upon the efforts of our collaboration partner, and their performance in achieving the development activities to the extent they are responsible under our collaboration agreement. Our partner 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 partner works 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 collaboration is not successful or our 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 this collaborator 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 patients 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 or biologic candidate require the enrollment of a sufficient number of patients, including patients who are suffering from the disease or condition the drug or biologic candidate is intended to treat and who meet other eligibility criteria. Rates of patient enrollment are affected by many factors, and delays in patient 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 patient enrollment in our current or future clinical trials. In addition, clinical trials for drug or biologic candidates that treat the same indications as our product candidates may result in patients who would otherwise be eligible for our clinical trials instead enrolling in clinical trials for other drug or biologic 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 rely upon third-party CROs, medical institutions, collaborators, clinical investigators, consultants and other third-parties to support and conduct our clinical trials and we 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, our collaborators, and our CROs are responsible for ensuring that our clinical trials are conducted in accordance with applicable regulations and protocols. If we, our collaborators, or our CROs fail to comply with these applicable regulations, the FDA 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 or biologic candidate, or to commercialize such drug or biologic candidate being tested in such studies or trials.

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

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

- Delays in filing or acceptance of INDs, NDAs, or BLA for our product candidates;
- Difficulty in securing centers to conduct clinical trials;
- Conditions imposed on us by the FDA 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 patients 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 or biologic 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, for example, 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 or expectations for testing during the course of that testing;

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

- Adverse results obtained by other companies developing similar drugs.

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 or biologic 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 are intensely competitive, 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. Many of our competitors 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 such product candidates. 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.

We also face competition acquiring technologies complementary to our INTASYL technology. Further, 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, he 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 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 have, and will seek to obtain, clinical trial insurance for current and any future 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 cGMP manufacturing capabilities and limited experience scaling 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 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 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 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 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, ongoing military conflicts, and high domestic and global inflation. 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 military conflicts, 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 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 financings 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.

Our business and operations would suffer in the event of computer system failures, cyberattacks or a deficiency in our cybersecurity.

Despite the implementation of security measures, our internal computer systems and those of our third-party contractors and collaborators are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures, cyberattacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. Such an event could cause interruption of our operations. As part of our business, we and our third-party contractors and collaborators maintain large amounts of confidential information, including non-public personal information on patients and our employees. Breaches in security could result in the loss or misuse of this information, which could, in turn, result in potential regulatory actions or litigation, including material claims for damages, interruption to our operations, damage to our reputation or otherwise have a material adverse effect on our business, financial condition and operating results. We expect to have appropriate information security policies and systems in place in order to prevent unauthorized use or disclosure of confidential information, including non-public personal information, but there can be no assurance that such use or disclosure will not occur.

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 or biologic candidates. Even if we are able to successfully commercialize our drug or biologic 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. We have limited cash resources, have reported recurring losses from operations since inception, negative operating cashflows and have not yet received product revenues. These factors raise substantial doubt regarding our 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 consolidated financial statements included elsewhere in this Annual Report. The continuation of the Company as a going concern depends upon our ability to raise additional capital through equity offerings, debt offerings and/or strategic opportunities to fund our operations. There can be no assurance that we 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.

We have completed multiple assessments of the available net operating loss and tax credit carryforwards under Sections 382 and 383 of the Code through the year ended December 31, 2023 and determined that we underwent multiple ownership changes during the period from inception to 2023. As a result, our net operating losses and tax credit carryforwards are subject to substantial annual limitations under Sections 382 and 383 of the Code 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. We assess 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;
- 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; 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 these 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 ("**Nasdaq**") 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.

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

On January 24, 2024, we received notice (the "**Notification Letter**") from Nasdaq notifying us that we are not in compliance with the minimum bid price requirements set forth in Nasdaq Listing Rule 5550(a)(2) for continued listing on The Nasdaq Capital Market. Nasdaq Listing Rule 5550(a)(2) requires listed securities to maintain a minimum bid price of $1.00 per share, and Listing Rule 5810(c)(3)(A) provides that a failure to meet the minimum bid price requirement exists if the deficiency continues for a period of 30 consecutive business days. Based on the closing bid price of our common stock for the 30 consecutive business days prior to the date of the Notification Letter, we no longer meet the minimum bid price requirement.

The Notification Letter does not impact our listing on The Nasdaq Capital Market at this time. The Notification Letter states that we have 180 calendar days, or until July 22, 2024, to regain compliance. To regain compliance, the bid price of our common stock must have a closing bid price of at least $1.00 per share for a minimum of 10 consecutive business days at any time prior to July 22, 2024. In the event that we do not regain compliance by July 22, 2024, we may be eligible for additional time to reach compliance with the minimum bid price requirement. However, if we fail to regain compliance with the minimum bid price listing requirement or fail to maintain compliance with all other applicable continued listing requirements and Nasdaq determines to delist our common stock, the delisting could adversely impact us by, among other things, reducing the liquidity and market price of our common stock; reducing the number of investors willing to hold or acquire our common stock; limiting our ability to issue additional securities in the future; and limiting our ability to fund our operations.

Our Board of Directors has the authority to issue shares of "blank check" preferred stock and the terms of the preferred stock may reduce the value of our common stock.

We are authorized to issue up to 10,000,000 shares of preferred stock in one or more series. Our Board of Directors (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 1C. *CYBERSECURITY*

We are increasingly dependent on sophisticated software applications and computing infrastructure to conduct key operations. We depend on both our own systems, networks, and technology as well as the systems, networks and technology of our contractors, consultants, vendors and other business partners.

Cybersecurity Program

Given the importance of cybersecurity to our business, we maintain a robust cybersecurity program to support both the effectiveness of our systems and our preparedness for information security risks. This program includes a number of safeguards, such as: continuous monitoring for internal and external threats; regular evaluations of our cybersecurity program, including periodic external reviews; and industry benchmarking. We also require cybersecurity trainings when onboarding new employees, as well as cybersecurity awareness training for our employees. Our program leverages standard industry frameworks to strengthen our program effectiveness and reduce cybersecurity risks.

We use a risk-based approach with respect to our use and oversight of third-party service providers, tailoring processes according to the nature and sensitivity of the data accessed, processed, or stored by such third-party service provider. We use a number of means to assess and manage cyber risks related to our third-party service providers, including conducting due diligence in connection with onboarding new vendors and seeking to include appropriate security terms in our contracts where applicable.

Process for Assessing, Identifying and Managing Material Risks from Cybersecurity Threats

In the event of a cybersecurity incident, designated personnel are responsible for assessing the severity of an incident and associated threat, containing the threat, remediating the threat, including recovery of data and access to systems, analyzing any reporting obligations associated with the incident, and performing post-incident analysis and program enhancements. We maintain a disaster recovery plan in the event of a significant cybersecurity incident.

We have relationships with a number of third-party service providers to assist with cybersecurity containment and remediation efforts, including insurance providers and various law firms.

Governance

Management Oversight

The controls and processes employed to assess, identify and manage material risks from cybersecurity threats are implemented and overseen by the use of consultants as the Company does not have a full-time dedicated cybersecurity position in the Company. Our consultant has over 20 years of experience in information technology matters and is responsible for the day-to-day management of the cybersecurity program, including the prevention, detection, investigation, response to, and recovery from cybersecurity threats and incidents, and are regularly engaged to help ensure the cybersecurity program functions effectively in the face of evolving cybersecurity threats.

Board Oversight

The Board of Directors (the "**Board**") has overall responsibility for risk oversight and cybersecurity risk matters. The Board is responsible for discussing with management the Company's data privacy, information technology and security and cybersecurity risk exposures, including: (i) the potential impact of those exposures on the Company's business, financial results, operations and reputation; (ii) the programs implemented by management to monitor and mitigate any exposures; and (iii) major legislative and regulatory developments that could materially impact the Company's data privacy and cybersecurity risk exposure.

Cybersecurity Risks

Our cybersecurity risk management processes are integrated into our overall information technology ("**IT**") processes. As part of our IT process, we identify, assess and evaluate risks impacting our operations across the Company, including those risks related to cybersecurity. We also maintain cybersecurity insurance providing coverage for certain costs related to cybersecurity-related incidents that impact our own systems, networks, and technology or the systems, networks and technology of our contractors, consultants, vendors and other business partners.

As of December 31, 2023, we are not aware of any material risks from cybersecurity threats, including as a result of any previous cybersecurity incidents, that have materially affected the business strategy, results of operations or financial condition of the Company or are reasonably likely to have such a material effect. While we maintain a robust cybersecurity program, the techniques used to infiltrate information technology systems continue to evolve. Accordingly, we may not be able to timely detect threats or anticipate and implement adequate security measures. For additional information, see "Item 1A—Risk Factors."

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.

The Company does not intend to renew the Lease, which will expire on March 31, 2024. Beginning in April of 2024, we expect to continue operations as a remote business with a laboratory facility located at 17 Briden Street, Worcester, Massachusetts, covering 321 square feet. The term of the laboratory facility commenced on March 1, 2024 and expires on September 1, 2024. The total base rent for the premises over the term is expected to be $15,000.

ITEM 3. *LEGAL PROCEEDINGS*

From time to time, the Company 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 of which we are aware.

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 15, 2024, 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.

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, 2023 or 2022.

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. 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.

In 2023, the Company implemented a cost rationalization program driven by its transition from discovery research to product development. This resulted in a decision not to renew the lease for office and laboratory space in Marlborough, Massachusetts, which will expire on March 31, 2024. Beginning in April of 2024, we expect to continue operations as a remote business with a small laboratory facility in Worcester, Massachusetts for 321 square feet of space that commenced on March 1, 2024. Additionally, we rationalized discovery research personnel resulting in headcount reduction by approximately 36%. Expense reductions have been redirected to funding the Phase 1b clinical trial with PH-762 directed toward skin cancer.

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.

Our preclinical studies 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 U.S. multi-center Phase 1b dose-escalating clinical trial through the intratumoral injection of PH-762 for the treatment of patients with cutaneous squamous cell carcinoma, melanoma and Merkel cell carcinoma. The trial is designed to evaluate the safety and tolerability of neoadjuvant use of intratumorally injected PH-762, assess the tumor response, and determine the dose or dose range for continued study of PH-762 and is expected to enroll up to 30 patients. In November 2023, we announced the dosing of the first patient under a previously cleared Investigational New Drug application ("**IND**") application by the Food and Drug Administration and the trial is currently open for the continued enrollment of patients.

Given our intention to focus our efforts and resources on our U.S. clinical trial with PH-762, we have completed the winding down process for our first-in-human clinical trial for PH-762 in France, which was limited to the treatment of patients with metastatic melanoma. Safety data from the initial cohort of three patients in the French clinical trial were 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.

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 lymphocytes ("**DP TIL**") with PH-762 increased their tumor killing activity by twofold.

In February 2021, we entered into a clinical co-development collaboration agreement (the "**Clinical Co-Development Agreement**") with AgonOx to develop a T cell-based therapy using PH-762 and AgonOx's DP TIL. Under the Clinical Co-Development Agreement, we agreed to reimburse AgonOx up to $4 million in expenses incurred to conduct a Phase 1 clinical trial of PH-762 treated DP TIL in patients with advanced melanoma and other advanced solid tumors. We are 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 TIL are being evaluated in a Phase 1 clinical trial in the United States with up to 18 patients with advanced melanoma and other advanced solid tumors by AgonOx. The primary trial objectives are to evaluate the safety and to study the potential for enhanced therapeutic benefit from the administration of PH-762 treated DP TIL. We announced the first patient was dosed in August 2023 and the trial is open for the continued enrollment of patients.

As of December 31, 2023, there is approximately $2,757,000 of remaining costs not yet incurred under the Clinical Co-Development Agreement.

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 against distant untreated tumors, indicative of 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. We have completed the IND-enabling studies and are in the process of continuing to finalize the study reports required for an IND submission with PH-894. As a result of the reprioritization to advance our clinical trial with PH-762 in the U.S., we have elected to defer the IND submission for PH-894.

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 our accounting policies to be the most critical in understanding the judgments and estimates we use in preparing our consolidated financial statements.

Research and Development Expenses

Research and development expenses are charged to expense as incurred. Payments made by us 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 we have 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 our reported results. Our historical accrual estimates have not been materially different from our actual costs. Due to the nature of estimates, we cannot provide assurance that we will not make changes to our estimates in the future as we become aware of additional information about the conduct of our research activities.

Collaborative Arrangements

We follow 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. We also consider the guidance in the FASB ASC Topic 606, "*Revenue from Contracts with Customers*," ("**Topic 606**") in determining the appropriate treatment for activities between us and our collaborative partners that are more reflective of a vendor-customer relationship and therefore, within the scope of Topic 606, as well as other accounting literature. 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. We recognize our share of costs arising from research and development activities performed by collaborators in the period our collaborators incur such expense. 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. Payments in excess of our collaboration expense will be recorded as revenue.

Derivative Financial Instruments

During the normal course of business we may issue warrants as part of a debt or equity financing. Warrants and other derivative financial instruments are accounted for either as equity or as an asset or liability, depending on the characteristics of each derivative financial instrument. 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. Financial instruments that meet the definition of a derivative are classified as an asset or liability are measured at fair value on the issuance date and are revalued on each subsequent balance sheet date. The changes in the fair value are recognized as current period income or loss.

Financial Operations Overview

Revenues

To date, we have primarily generated revenues through government grants. We have not generated any commercial product revenue 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 we 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 collaboration, 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 and patent-related activities, 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
	2023	2022	
Operating expenses	$ 10,824	$ 11,462	$ (638)
Operating loss	$ (10,824)	$ (11,462)	$ 638
Net loss	$ (10,826)	$ (11,480)	$ 654

Comparison of the Years Ended December 31, 2023 and 2022

Operating Expenses

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

	Years Ended December 31,		Dollar Change
	2023	2022	
Research and development	$ 6,332	$ 7,012	$ (680)
General and administrative	4,366	4,450	(84)
Impairment of property and equipment	126	–	126
Total operating expenses	$ 10,824	$ 11,462	$ (638)

Research and Development Expenses

Research and development expenses for the year ended December 31, 2023 decreased 10% as compared to the year ended December 31, 2022. The decrease was primarily due to a decrease in costs related to the completion of our IND-enabling preclinical studies for PH-894 of approximately $1,979,000 and reduced lab supplies of approximately $298,000 as a result of a decrease in lab personnel and a shift in focus on clinical development and, partially offset by an increase in clinical-related costs of approximately $1,580,000 for the two U.S. PH-762 Phase 1 clinical trials as compared to the prior year period.

General and Administrative Expenses

General and administrative expenses for the year ended December 31, 2023 decreased 2% as compared to the year ended December 31, 2022. The decrease was primarily due to decreases in personnel-related expenses of approximately $230,000 due to departmental organizational changes and one-time executive search-related fees of approximately $78,000 for the Company's President & CEO and reduced D&O insurance premiums of $92,000, partially offset by increased legal fees of approximately $302,000.

Impairment of Property and Equipment

Loss on impairment of property and equipment for the year ended December 31, 2023 increased 100% as compared to the year ended December 31, 2022. The impairment charge to our long-lived assets was associated with our non-renewal of our office lease to operate as a remote business. The carrying value of these assets totaling $126,000 was deemed no longer recoverable and an impairment charge of $126,000 was recorded to adjust those assets to their fair value.

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, 2023, we had cash of $8,490,000 as compared with $11,781,000 at December 31, 2022.

During the year ended December 31, 2023, we completed the April 2023 Financing, June 2023 Financing and December 2023 Financing (each as defined in Note 9 to our consolidated financial statements included elsewhere in this Annual Report) and received total net proceeds of $7,452,000 after deducting placement agent fees and offering expenses. For further information regarding the April 2023 Financing, June 2023 Financing and December 2023 Financing, see Note 9 to our consolidated financial statements included elsewhere in this Annual Report.

We have limited cash resources, have reported recurring losses from operations since inception, negative operating cash flows and have not yet received product revenues. These factors raise substantial doubt regarding our ability to continue as a going concern, and our 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 consolidated financial statements included elsewhere in this Annual Report. Our continuation as a going concern depends upon our ability to raise additional capital through equity offerings, debt offerings and/or strategic opportunities to fund our operations. There can be no assurance that we will be successful in accomplishing any of these plans in order to continue as a going concern. The consolidated 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 we 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,	
	2023	2022
Net cash used in operating activities	$ (10,749)	$ (12,129)
Net cash used in investing activities	(5)	(121)
Net cash provided by (used in) financing activities	7,413	(26)
Net decrease in cash and restricted cash	$ (3,341)	$ (12,276)

Net Cash Flow from Operating Activities

Net cash used in operating activities for the year ended December 31, 2023 decreased 11% as compared to the year ended December 31, 2022, primarily due to decreased cash outflows from changes in operating assets and liabilities of $720,000 as a result of liabilities owed for the payments related to the IND-enabling studies with PH-894 and clinical supply manufacturing of PH-762 and PH-894 in the prior year period and a decrease in net loss of $654,000.

Net Cash Flow from Investing Activities

Net cash used in investing activities for the year ended December 31, 2023 decreased 96% as compared to the year ended December 31, 2022, primarily due to changes in laboratory and computer equipment purchases for our facility over the comparative period.

Net Cash Flow from Financing Activities

Net cash provided by financing activities for the year ended December 31, 2023 increased as compared to the net cash used in financing activities for the year ended December 31, 2022, primarily due to the Company's capital raise activities over the comparative period (see Note 9 to our consolidated annual consolidated financial statements included elsewhere in this Annual Report).

Contractual Obligations

Commitments

In February 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. Details of our obligations under the Clinical Co-Development Agreement as of December 31, 2023 can be found in Note 2 of the consolidated financial statements included elsewhere in this Annual Report. As of December 31, 2023, there is approximately $2,757,000 of remaining costs not yet incurred 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, 2023 and 2022, we did not trigger any milestone payments.

Our contractual license obligations that will require future cash payments as of December 31, 2023 are $600,000, 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 $35,000 over the remaining duration of our lease, or through March 31, 2024. We do not intend to renew the lease for our corporate headquarters and primary research facility in Marlborough, Massachusetts, which will expire on March 31, 2024. Beginning in April of 2024, we expect to continue operations as a remote business with a small laboratory facility. The term of the laboratory facility commenced on March 1, 2024 and has a 6-month term, with lease payments expected to be $15,000 over the term of the lease.

For further information regarding our future cash commitments see Note 7 to our consolidated financial statements included elsewhere in this Annual Report.

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

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

ITEM 8. *FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA*

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

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, 2023 and 2022, 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, 2023 and 2022, 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 has suffered recurring losses from operations and negative cash flows 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

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

Accounting for Certain Warrants Issued in 2023

As described in Note 9 to the consolidated financial statements, the Company completed each of two registered direct offerings of common stock and concurrent private placement offerings of warrants to purchase common stock in April and June 2023 (the "April 2023 Financing" and "June 2023 Financing", respectively). In December 2023, the Company issued additional warrants to purchase common stock to certain holders of existing warrants in connection with an Inducement Letter Agreement (the "December 2023 Financing"). The Company assessed the warrants issued in the April 2023 Financing, June 2023 Financing and December 2023 Financing to determine whether the warrants should be accounted for as either liabilities or equity instruments depending on the specific terms of the agreements. The Company determined that the warrants issued in the April 2023 Financing, June 2023 Financing and December 2023 Financing were classified within stockholders' equity.

We identified the assessment of the accounting for certain warrants to purchase common stock issued in connection with the April 2023 Financing, June 2023 Financing and December 2023 Financing as a critical audit matter. Determining whether the certain warrants issued should be accounted for as either liabilities or equity instruments requires significant judgment due to the application of complex technical accounting guidance. Auditing this element required especially challenging and complex auditor judgement due to the nature and extent of the audit effort required to address the matter, including the need for specialized knowledge and skill in assessing elements of the agreements.

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

- Reading and analyzing agreements related to the certain warrants issued to identify relevant terms and conditions that affect whether the certain warrants issued should be accounted for as either liabilities or equity instruments.

- Evaluating whether the certain warrants issued should be accounted for as either liabilities or equity instruments.

- Utilizing personnel with specialized knowledge and skill in the relevant technical accounting guidance to evaluate the appropriateness of the Company's application of the relevant technical accounting guidance in determining whether the certain warrants issued should be accounted for as either liabilities or equity instruments.

/s/ BDO USA, P.C.

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

Boston, Massachusetts

April 1, 2024

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

	December 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash	$ 8,490	$ 11,781
Restricted cash	–	50
Prepaid expenses and other current assets	832	615
Total current assets	9,322	12,446
Right of use asset	33	161
Property and equipment, net	6	183
Other assets	3	24
Total assets	$ 9,364	$ 12,814
LIABILITIES, PREFERRED STOCK AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 657	$ 779
Accrued expenses	942	1,025
Lease liability	35	135
Total current liabilities	1,634	1,939
Lease liability, net of current portion	–	35
Total liabilities	1,634	1,974
Commitments and contingencies (Footnote 7)		
Series D Preferred Stock, $0.0001 par value; 0 and 1 shares authorized, issued and outstanding at December 31, 2023 and December 31, 2022, respectively	–	2
Stockholders' equity:		
Common stock, $0.0001 par value, 100,000,000 shares authorized; 3,747,329 and 1,139,024 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively	–	–
Additional paid-in capital	146,936	139,218
Accumulated deficit	(139,206)	(128,380)
Total stockholders' equity	7,730	10,838
Total liabilities, preferred stock and stockholders' equity	$ 9,364	$ 12,814

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,	
	2023	**2022**
Operating expenses:		
Research and development	$ 6,332	$ 7,012
General and administrative	4,366	4,450
Loss on impairment of property and equipment	126	–
Total operating expenses	10,824	11,462
Operating loss	(10,824)	(11,462)
Total other expense, net	(2)	(18)
Net loss	$ (10,826)	$ (11,480)
Net loss per common share:		
Basic and diluted	$ (5.20)	$ (10.10)
Weighted average number of common shares outstanding		
Basic and diluted	2,083,569	1,136,566

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 Paid-in	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Deficit	Total
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	1	$ 2	1,139,024	$ –	$ 139,218	$ (128,380)	$ 10,838
Cash-in-lieu of fractional shares for reverse stock split	–	–	(1,706)	–	(11)	–	(11)
Redemption of preferred stock	(1)	(2)	–	–	–	–	–
Issuance of common stock and warrants, net of offering costs	–	–	1,963,511	–	7,452	–	7,452
Issuance of common stock upon exercise of warrants	–	–	628,935	–	–	–	–
Issuance of common stock upon vesting of restricted stock units	–	–	23,414	–	–	–	–
Shares withheld for payroll taxes	–	–	(5,849)	–	(26)	–	(26)
Stock-based compensation expense	–	–	–	–	303	–	303
Net loss	–	–	–	–	–	(10,826)	(10,826)
Balance at December 31, 2023	–	$ –	3,747,329	$ –	$ 146,936	$ (139,206)	$ 7,730

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (10,826)	$ (11,480)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	56	71
Amortization of right of use asset	128	122
Impairment of property and equipment	126	–
Stock-based compensation	303	414
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(196)	8
Accounts payable	(122)	496
Accrued expenses	(83)	(1,635)
Lease liability	(135)	(125)
Net cash used in operating activities	(10,749)	(12,129)
Cash flows from investing activities:		
Cash paid for purchase of property and equipment	(5)	(121)
Net cash used in investing activities	(5)	(121)
Cash flows from financing activities:		
Net proceeds from the issuance of common stock and warrants	7,452	–
Net proceeds from the issuance of preferred stock	–	2
Cash-in-lieu of fractional shares for reverse stock split	(11)	–
Redemption of Series D Preferred Stock	(2)	–
Payment of taxes on net share settlements of restricted stock units	(26)	(28)
Net cash provided by (used in) financing activities	7,413	(26)
Net decrease in cash and restricted cash	(3,341)	(12,276)
Cash and restricted cash at the beginning of period	11,831	24,107
Cash and restricted cash at the end of period	$ 8,490	$ 11,831

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

	December 31,	
	2023	**2022**
Cash	$ 8,490	$ 11,781
Restricted cash	–	50
Total cash and restricted cash	$ 8,490	$ 11,831

See accompanying notes to consolidated financial statements.

1. Organization and Significant Accounting Policies

Nature of Operations

Phio Pharmaceuticals Corp. ("**Phio**" 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. The Company is 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.

Phio was incorporated in the state of Delaware in 2011 as RXi Pharmaceuticals Corporation. On November 19, 2018, the Company changed its name to Phio Pharmaceuticals Corp., to reflect its transition from a platform company to one that is fully committed to developing groundbreaking immuno-oncology therapeutics.

Basis of Presentation

The accompanying consolidated 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 the Company and its wholly-owned subsidiary, MirImmune, LLC. All material intercompany accounts have been eliminated in consolidation.

Segments

The Company operates as one operating segment and all assets are located in the United States.

Reverse Stock Split

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**"). All share and per share amounts in the consolidated 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. Additionally, the Company made adjustments to the outstanding stock option and unvested restricted stock unit ("**RSU**") balances, and related per share amounts, at December 31, 2022 to reflect final revisions to those outstanding equity awards as a result of 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, and the valuation allowance on our deferred tax assets. On an ongoing basis the Company evaluates its estimates and bases its estimates on historical experience and other relevant assumptions that the Company believes are reasonable under the circumstances. Actual results could differ materially from these estimates.

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. There is no guarantee that debt, additional equity or other funding will be available to us on acceptable terms, or at all. If the Company fails to obtain additional funding when needed, the Company would be forced to scale back or terminate its 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, negative operating cash flows 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 consolidated 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 and/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 consolidated 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.

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 reputable financial institution that management believes is creditworthy, and 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.

The Company relies, and expects to continue to rely, on a small number of vendors to perform research activities and clinical trial activities that continue to progress its product candidates for its development programs. These programs could be adversely affected by a significant interruption in the related processes of these vendors.

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 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.

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. 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. Payments in excess of our collaboration expense will be recorded as revenue.

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 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 consolidated 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 consolidated 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.

The recognition and measurement of benefits related to the Company's tax positions requires significant judgment, as uncertainties often exist with respect to new laws, new interpretations of existing laws, and rulings by taxing authorities. The Company follows a more-likely-than not threshold for financial statement recognition and measurement of a tax position taken, or expected to be taken in a tax return. The guidance relates to, amongst other things, classification, accounting for interest and penalties associated with tax positions, and disclosure requirements. Any interest and penalties accrued related to uncertain tax positions are recorded as tax expense. Differences between actual results and the Company's assumptions or changes in the Company's assumptions in future periods are recorded in the period they become known.

Comprehensive Loss

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

Net Loss per Share

Basic net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding. Diluted net loss per share is computed by dividing the Company's net 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 November 2023, the FASB issued Accounting Standards Update ("**ASU**") 2023-07, "*Segment Reporting (Topic 280) – Improvements to Reporting Segment Disclosures"* ("**ASU 2023-07**"), which requires disclosure of incremental segment information on an annual and interim basis. In addition, ASU 2023-07 clarifies circumstances in which an entity can disclose multiple segment measures of profit or loss, provides new segment disclosure requirements for entities with a single reportable segment, and contains other disclosure requirements. The amendments in ASU 2023-07 are effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. The enhanced disclosures are required to be applied retrospectively to all prior periods presented in the financial statements. The Company is currently evaluating the impact of ASU 2023-07 on its consolidated financial statements and disclosures, but does not expect that it will have a material impact on its consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, "*Income Taxes (Topic 740) – Improvements to Income Tax Disclosures"* ("**ASU 2023-09**"), which requires disclosure of specific categories in the rate reconciliation table along with additional information for reconciling items that meet a quantitative threshold, disclosure of disaggregated income taxes paid and modifies other income tax-related disclosures. The amendments in ASU 2023-09 are effective for annual periods beginning after December 15, 2024 and allows for adoption on a prospective basis, with a retrospective option. Early adoption is permitted. The Company is currently evaluating the impact of ASU 2023-09, but does not expect that it will have a material impact on its consolidated financial statements.

2. Collaboration Agreement

*AgonOx, Inc. ("**AgonOx**")*

In February 2021, the Company entered into a clinical co-development collaboration agreement (the "**Clinical Co-Development 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 Co-Development 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" tumor infiltrating lymphocytes ("**DP TIL**") technology. Per the terms of the Clinical Co-Development Agreement, the Company agreed to reimburse AgonOx up to $4,000,000 in expenses incurred to conduct a Phase 1 clinical trial of PH-762 treated DP TIL in patients with advanced melanoma and other advanced solid tumors.

The Company will recognize its share of costs arising from research and development activities performed by AgonOx in the Company's consolidated 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 $1,115,000 and $130,000 of expense in connection with these efforts during the years ended December 31, 2023 and 2022, respectively.

There is approximately $2,757,000 of remaining costs not yet incurred under the Clinical Co-Development Agreement as of December 31, 2023.

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, the Company categorized its restricted cash of $50,000 as Level 2 hierarchy. Restricted cash consisted of certificates of deposit held by financial institutions as collateral for the Company's corporate credit cards. 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,	
	2023	**2022**
Computer equipment	$ 62	$ 116
Machinery & equipment	964	1,077
Furniture & fixtures	70	119
Leasehold improvements	46	46
Total gross fixed assets	1,142	1,358
Less: accumulated depreciation and amortization	(1,136)	(1,175)
Property and equipment, net	$ 6	$ 183

Depreciation and amortization expense for the years ended December 31, 2023 and 2022 was $56,000 and $71,000, respectively.

In November 2023, the Company decided not to renew the lease for its corporate headquarters and primary research facility in Marlborough, Massachusetts. Beginning in April of 2024, we expect to continue operations as a remote business with a small laboratory facility. Based on this evaluation, the Company determined that long-lived assets with a carrying amount of $126,000 were no longer recoverable and an impairment charge of $126,000 was recorded to write those assets down to their fair value. The Company did not record any impairment charges at December 31, 2022.

5. Accrued Expenses

Accrued expenses consist of the following, in thousands:

	December 31,	
	2023	2022
Compensation and benefits	$ 222	$ 408
Professional fees	126	97
Research and development costs	517	501
Other	77	19
Total accrued expenses	$ 942	$ 1,025

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 the Company's corporate headquarters represents all of its significant lease obligations. The amounts reported in the consolidated balance sheets for the operating lease 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,	
	2023	2022
Assets		
Right of use asset	$ 33	$ 161
Liabilities		
Lease liability, current	35	135
Lease liability, non-current	–	35
Total lease liability	$ 35	$ 170
Lease Term and Discount Rate		
Weighted average remaining lease term	0.25	1.25
Weighted average discount rate	4.70%	4.70%

Operating lease costs included in operating expense were $132,000 for the years ended December 31, 2023 and 2022, 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 the Company's consolidated statements of cash flows was $139,000 and $135,000 for the years ended December 31, 2023 and 2022, respectively.

Future lease payments for our non-cancellable operating lease and a reconciliation to the carrying amount of the operating lease liability presented in the consolidated balance sheet as of December 31, 2023 is as follows, in thousands:

2024	$ 35
Total lease payments	35
Less: Imputed interest	–
Total operating lease liability	$ 35

7. Commitments and Contingencies

Commitments

In February 2021, the Company entered into the Clinical Co-Development 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 Co-Development Agreement, the Company agreed to reimburse AgonOx up to $4,000,000 in expenses incurred to conduct a Phase 1 clinical trial of PH-762 treated DP TIL in patients with advanced melanoma and other advanced solid tumors. Refer to Note 2 for further details on the Clinical Co-Development Agreement with AgonOx.

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

In September 2011, the Company entered into an agreement with Advanced RNA Technologies, LLC ("**Advirna**"), pursuant to which Advirna assigned to the Company 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 of 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 Advirna agreement have been minimal.

The Company'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 Advirna agreement; or (ii) the abandonment of the last-to-be abandoned of such patents, unless earlier terminated in accordance with the provisions of the Advirna 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.

As part of its business, the Company may enter into licensing agreements with third parties that 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, 2023 and 2022, the Company did not trigger any milestone payments.

The Company's contractual license obligations that will require future cash payments as of December 31, 2023, which result from payments expected in connection with annual license fees, are as follows, in thousands:

Year Ending December 31,	
2024	$ 100
2025	100
2026	100
2027	100
2028	100
Thereafter	100
Total	$ 600

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

Litigation

From time to time, the Company 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, 2023.

8. 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 (the "**Board**") is authorized under the Company's Amended and Restated Certificate of Incorporation (as may be amended and/or restated from time to time, the "**Amended Certificate**"), 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 Board upon its issuance.

In November 2022, the Company sold one share of 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 not convertible into, or exchangeable for, shares of any other class or series of stock or other securities of the Company; 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; and was not entitled to receive dividends of any kind.

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 Certificate to effect a reverse stock split of the Company's common stock. The terms 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.

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 in its sole discretion or (ii) automatically and effective upon the approval by the Company's stockholders of an amendment to the Amended Certificate to effect a reverse stock split of the Company's common stock. The Series D Preferred Stock was redeemed in whole on January 4, 2023, upon the approval by the Company's stockholders of the Reverse Stock Split. Upon such redemption, the holder of the Series D Preferred Stock received consideration of $1,750 in cash.

At December 31, 2023, there were no shares of preferred stock issued or outstanding.

9. Stockholders' Equity

April 2023 Financing — In April 2023, the Company completed a registered direct offering and a concurrent private placement of a total of: 353,983 registered shares of the Company's common stock at a purchase price per share of $5.65, unregistered five and one-half year term Series A warrants to purchase up to 353,983 shares of common stock at an exercise price of $5.40 per share and unregistered eighteen month term Series B warrants to purchase up to 353,983 shares of common stock at an exercise price of $5.40 per share (collectively, the "**April 2023 Financing**"). In addition, the Company issued unregistered warrants to the placement agent, H.C. Wainwright & Co., LLC ("**HCW**"), in the April 2023 Financing to purchase a total of 26,549 shares of common stock at an exercise price of $7.0625 per share. Net proceeds to the Company from the April 2023 Financing were $1,538,000 after deducting placement agent fees and offering expenses.

In connection with the April 2023 Financing, the Company entered into warrant amendment agreements (the "**Warrant Amendment Agreements**") with the participating investors to amend the exercise price of certain existing warrants to purchase up to an aggregate of 191,619 shares of common stock that were previously issued in April 2018 through January 2021, such that each of the amended warrants have an exercise price of $5.40 per share. The Company received $24,000 as consideration in connection with the Warrant Amendment Agreements. The Company assessed the amendments to the exercise price of the warrants under the FASB ASC Topic 815, "*Derivatives and Hedging*" ("**ASC 815**") and determined that the amendment to the exercise price was completed in connection with and contingent on the close of the April 2023 Financing. The increase in fair value of $293,000 related to the Warrant Amendment Agreements was recognized as an equity issuance cost and recorded in additional paid in capital per ASC 815.

June 2023 Financing — In June 2023, the Company completed a registered direct offering and a concurrent private placement of a total of: 233,646 registered shares and 72,000 unregistered shares of the Company's common stock each at a purchase price per share of $4.28, unregistered pre-funded warrants to purchase up to an aggregate of 628,935 shares of common stock at a purchase price per share of $4.279 and with an exercise price of $0.001 per share, unregistered five and one-half year term Series A warrants to purchase up to an aggregate of 934,581 shares of common stock at an exercise price of $4.03 per share and unregistered eighteen month term Series B warrants to purchase up to an aggregate of 934,581 shares of common stock at an exercise price of $4.03 per share (collectively, the "**June 2023 Financing**"). In addition, the Company issued unregistered warrants to the placement agent, HCW, in the June 2023 Financing to purchase a total of 70,094 shares of common stock at an exercise price of $5.35 per share. Net proceeds to the Company from the June 2023 Financing were $3,510,000 after deducting placement agent fees and offering expenses.

December 2023 Financing – In December 2023, the Company entered into an inducement letter agreement (the "**Inducement Letter Agreement**") with certain holders of the Company's existing warrants to purchase up to an aggregate of 2,130,252 shares of the Company's common stock. The existing warrants were originally issued on dates between October 2018 and June 2023 with an exercise price of $5.40 or $4.03 per share. Pursuant to the Inducement Letter Agreement, these warrants were exercised for cash at a reduced exercise price of $1.33 per share in consideration of the Company's agreement to issue new five and one-half year term Series A warrants to purchase up to 2,270,320 shares of common stock at an exercise price of $1.08 per share and new eighteen month term Series B warrants to purchase up to 1,990,184 shares of common stock at an exercise price of $1.08 per share (collectively, the "**December 2023 Financing**"). In addition, the Company issued warrants to the placement agent, HCW, in the December 2023 Financing to purchase a total of 159,769 shares of common stock at an exercise price of $1.66 per share.

Pursuant to the terms of the Inducement Letter Agreement, in the event that the exercise of the existing warrants in the December 2023 Financing would have otherwise caused a holder to exceed the beneficial ownership limitations set forth in the existing warrant, the Company issued the number of shares that would not cause a holder to exceed such beneficial ownership limitation and agreed to hold such balance of shares of common stock in abeyance. Accordingly, at December 31, 2023, an aggregate of 826,370 shares of common stock were held in abeyance (the "**Abeyance Shares**") with such Abeyance Shares evidenced through the holder's existing warrants and which are deemed to be prepaid. The Abeyance Shares will be held until notice is received by the holder that the balance of the shares of common stock may be issued in compliance with such beneficial ownership limitations and may be exercised pursuant to a notice of exercise from the holder. Until such time, the Abeyance Shares are evidenced through the holder's existing warrants and have been included in the Company's table of outstanding warrants below.

Net proceeds to the Company from the December 2023 financing were $2,404,000 after deducting placement agent fees and offering expenses. The Company assessed the amendments to the exercise price of the warrants under the ASC 815 and determined that the amendment to the exercise price was completed in connection with and contingent on the close of the December 2023 Financing. The increase in fair value of $412,000 related to the modification of the terms of the warrants to induce exercise was recognized as an equity issuance cost and recorded in additional paid in capital per ASC 815.

Warrants

The Company first assessed the warrants in the April 2023 Financing, June 2023 Financing and December 2023 Financing under the FASB ASC Topic 480, "*Distinguishing Liabilities from Equity*" ("**ASC 480**") to determine whether they were within the scope of ASC 480. As there were no instances outside of the Company's control that could require cash settlement, the Company's warrants issued in the April 2023 Financing, June 2023 Financing and December 2023 Financing were determined to be outside the scope of ASC 480.

The Company then applied and followed the applicable accounting guidance in ASC 815. Financial instruments are accounted for as either derivative liabilities or equity instruments depending on the specific terms of the agreement. The warrants issued in the April 2023 Financing, June 2023 Financing and December 2023 Financing did 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 warrants issued in the April 2023 Financing, June 2023 Financing and December 2023 Financing were classified within stockholders' equity.

In addition to the December 2023 Financing, the Company issued 628,935 shares of common stock related to exercises from the pre-funded warrants issued in the June 2023 Financing for proceeds of $630. There were no warrants exercised during the year ended December 31, 2022.

The following table summarizes the Company's outstanding warrants, all of which are classified as equity instruments, at December 31, 2023:

	Number of Shares	Weighted-Average Exercise Price Per Share
Outstanding at December 31, 2022	545,401	$ 54.53
Issued	7,722,979	2.17
Exercised	(1,932,817)	0.90
Expired	(4,275)	624.62
Outstanding at December 31, 2023	6,331,288	$ 3.68

10. 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 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. In July 2023, the Company's stockholders approved an amendment to the 2020 Plan to increase the number of shares authorized for issuance thereunder to 231,140 shares of common stock.

As of December 31, 2023, there were 10,084 shares subject to outstanding stock options, 49,683 shares subject to unvested RSUs and 133,574 shares available for future grants.

Restricted Stock Units

RSUs are issued under the Company's 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 certain service requirements. RSUs granted by the Company to employees generally vest annually over 3 years after the grant date and over 1 year after the grant date for directors of the Board of Directors. 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 Company does not expect to repurchase shares to satisfy RSU vests. 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, 2023:

	Number of Shares	Weighted-Average Grant Date Fair Value Per Share
Unvested units at December 31, 2022	47,335	$ 15.03
Granted	43,500	5.24
Vested	(23,414)	14.99
Forfeited	(17,738)	9.88
Unvested units at December 31, 2023	49,683	$ 8.32

The weighted-average fair value of RSUs granted during the years ended December 31, 2023 and 2022 was $5.24 and $10.08, respectively.

Stock-based compensation expense related to RSUs was $298,000 and $401,000 for the years ended December 31, 2023 and 2022, respectively.

The aggregate fair value of awards that vested during the years ended December 31, 2023 and 2022 was $105,000 and $138,000, which represents the market value of the Company's common stock on the date that the RSUs vested.

As of December 31, 2023, the compensation expense for all unvested RSUs in the amount of approximately $212,000 will be recognized in the Company's results of operations over a weighted average period of 1.30 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. Stock options granted by the Company to employees generally vest annually over 4 years after the grant date and generally vest over 1 year after the grant date for members of the Board of Directors and expire within ten years of grant. 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 year ended December 31, 2022. For valuing options granted during the year ended December 31, 2023, the following assumptions were used:

	December 31, 2023
Risk-free interest rate	4.72%
Expected volatility	113.74%
Expected lives (in years)	5.25
Expected dividend yield	0%

The weighted average grant date fair value of options granted during the year ended December 31, 2023 was $1.14 per share.

The following table summarizes the Company's stock option activity for the year ended December 31, 2023:

	Total Number of Shares	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Balance at December 31, 2022	177	$ 35,231.40		
Granted	10,000	1.37		
Exercised	–	–		
Forfeited	–	–		
Expired	(93)	52,577.53		
Balance at December 31, 2023	10,084	$ 134.86	9.74 years	$ –
Exercisable at December 31, 2023	84	$ 16,026.76	2.78 years	$ –

Stock-based compensation expense related to stock options for the years ended December 31, 2023 and 2022 was $5,000 and $13,000, respectively.

As of December 31, 2023, the compensation expense for all unvested stock options in the amount of $6,000 will be recognized in the Company's results of operations over a weighted average period of 0.25 years.

There is no income tax benefit as the Company is currently operating at a loss and an actual income tax benefit may not be realized.

Employee Stock Purchase Plan

The Company has 684 shares authorized for issuance under the 2013 Employee Stock Purchase Plan ("**ESPP**"). The ESPP allows employees to contribute a percentage of their cash earnings, subject to certain maximum amounts, to be used to purchase shares of the Company's common stock on each of two semi-annual purchase dates at a purchase price equal to 90% of the market value per share on either (a) the date of grant of a purchase right under the ESPP or (b) the date on which such purchase right is deemed exercised, whichever is lower. As of December 31, 2023, 661 shares were reserved for future issuance under the ESPP. There was no activity under the ESPP for the years ended December 31, 2023 and 2022.

Compensation Expense Related to Equity Awards

The following table sets forth total stock-based compensation expense for the years ended December 31, 2023 and 2022, in thousands:

	December 31,	
	2023	2022
Research and development	$ 132	$ 154
General and administrative	171	260
Total stock-based compensation	$ 303	$ 414

11. Income Taxes

The provision for income taxes for the years ended December 31, 2023 and 2022 are as follows, in thousands:

	Years Ended December 31,	
	2023	2022
Current		
Federal	$ –	$ –
State	–	–
Total current	–	–
Deferred		
Federal	(1,831)	(1,733)
State	(718)	(553)
Total deferred	(2,549)	(2,286)
Valuation allowance	2,549	2,286
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,	
	2023	2022
Federal statutory rate	21.0%	21.0%
State income taxes, net of federal benefit	5.9	7.4
Non-deductible expenses	(0.5)	(0.8)
Income tax credits	2.1	3.2
Valuation allowance	(28.5)	(30.8)
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 consolidated 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. As a result of this evaluation, the Company has recorded a full valuation allowance against its deferred tax assets as the Company believes it is more likely than not that the benefit of all of its deferred tax assets will not be realized.

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

	Years Ending December 31,	
	2023	2022
Deferred tax assets:		
Net operating loss carryforwards	$ 774	$ 11,808
Tax credit carryforwards	295	1,227
Stock-based compensation	80	435
Capitalized research and development expenses	1,384	1,662
License fees	3	1,680
Lease liability	9	46
Other timing differences	13	120
Deferred tax assets	2,558	16,978
Deferred tax liabilities:		
Right of use asset	(9)	(43)
Deferred tax liability	(9)	(43)
Valuation allowance	(2,549)	(16,935)
Net deferred tax asset	$ –	$ –

Ownership changes may limit the amount of net operating loss ("**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 2023, the Company completed an assessment of the available NOL and tax credit carryforwards under Sections 382 and 383 of the Code since the last assessment completed in 2021 and concluded that the Company underwent an ownership change in 2023. As a result, NOL and tax credit carryforwards attributable to the pre-ownership change are subject to substantial annual limitations under Sections 382 and 383 of the Code. The Company adjusted its NOL and tax credit carryforwards to address the impact of the ownership change. For the year ended December 31, 2023, federal and state NOLs were reduced by $52,400,000 and $25,900,000, respectively, and federal and state research and development tax credit carryforwards were reduced by $918,000 and $517,000, respectively, as a result of the ownership change in 2023. 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.

At December 31, 2023, the Company had federal and state NOL carryforwards of approximately $2,900,000 and $2,475,000, respectively, 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, federal NOLs generated in tax years beginning after 2017 may be carried forward indefinitely, but are limited to offset up to 80% of future taxable income. As of December 31, 2023, all of our federal NOL carryforwards will carryforward indefinitely. The Company's available state NOL carryforwards will begin to expire in 2044, unless previously utilized.

At December 31, 2023, the Company also had federal and state research and development credits of approximately $227,000 and $87,000, respectively. The federal tax credit carryforwards will begin to expire in 2044 and the state tax credit carryforwards will begin to expire in 2039.

The Company has not recorded any uncertain tax positions as of December 31, 2023 or 2022. 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 consolidated financial statements as general and administrative expenses.

The Company files income tax returns in the United States and in multiple state jurisdictions. The Company is subject to tax examinations for federal and state purposes for tax years 2015 through 2023.

12. 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 the dilutive effect of potential common stock equivalents, except when the inclusion of such potential common stock equivalents would be anti-dilutive. Dilutive potential common stock equivalents primarily consist of stock options, RSUs and warrants. Therefore, basic and diluted net loss per share applicable to common stockholders were the same for all periods presented because the impact of these items is generally anti-dilutive during periods of net loss.

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,	
	2023	**2022**
Stock options	10,084	177
Unvested restricted stock units	49,683	47,335
Warrants[1]	5,504,918	545,401
Total	5,564,685	592,913

[1] The weighted average number of common shares outstanding as of December 31, 2023 includes the Abeyance Shares from the December 2023 Financing, the exercise of which was prepaid and requires no further consideration for the delivery of the shares of common stock. Therefore, these Abeyance Shares are not included in the table above.

13. Subsequent Events

In connection with the Inducement Letter Agreement, shares were held in abeyance in the event that the exercise of the existing warrants in the December 2023 Financing would have otherwise caused a holder to exceed the beneficial ownership limitations set forth in the existing warrant. These Abeyance Shares will be held until notice is received by the holder that the balance, or portion thereof, may be issued in compliance with the beneficial ownership limitations. Subsequent to the balance sheet date, 826,370 Abeyance Shares were released and issued.

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 Securities and Exchange Commission's 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, 2023. 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, 2023, 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 quarter ended December 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. *OTHER INFORMATION*

During the three months ended December 31, 2023, no director or officer of the Company adopted or terminated a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement, as each term is defined in Item 408(a) of Regulation S-K.

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 of Directors (the "**Board**") is currently set at five directors. Biographical and other information regarding our directors, whose terms expire at the 2024 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)	73	President, Chief Executive Officer and Chairman of the Board of Directors
Patricia A. Bradford (2022)	73	Director
Robert L. Ferrara (2019)	72	Director
Jonathan E. Freeman, Ph.D. (2017)	56	Director
Curtis A. Lockshin, Ph.D. (2013)	63	Director

Robert J. Bitterman has served as a member and the Chair of the Board since 2012 and as our President and Chief Executive Officer since February 2023. Mr. Bitterman served as the Interim Executive Chair of the Company from September 2022 to February 2023 until his appointment as 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 Chair 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 the 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.

Robert L. Ferrara has served as a member of the 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 the 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 University, St. Louis.

Curtis A. Lockshin, Ph.D. has served as a member of the 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 2004, Dr. Lockshin has served as a Director of the Ruth K. Broad Biomedical Research Foundation, a Duke University Support Corporation. 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 Securities Exchange Act of 1934, as amended (the "**Exchange Act**"). The Audit Committee of the Board (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 Exchange Act and the current Nasdaq independence standards, and 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, officers and directors. Our Code of Business Conduct and Ethics, as well as other corporate governance materials, is located on our website at *www.phiopharma.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 such amendment or waiver.

ITEM 11. *EXECUTIVE COMPENSATION*

The following describes the compensation earned by each of the executive officers identified below in the Summary Compensation Table, who are referred to collectively as our "named executive officers" or NEO. Our NEO with respect to the fiscal year that ended on December 31, 2023 is Robert J. Bitterman.

Summary Compensation Table

Name and principal position	Year	Salary ($)	Stock awards ($)[1]	Non-equity incentive plan compensation ($)[2]	All other compensation ($)[3]	Total ($)
Robert J. Bitterman [4]	2023	380,000	57,640	–	252	437,892
President and Chief Executive Officer	2022	77,885	31,464	–	31	109,380

(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. See Note 10 to our consolidated financial statements included elsewhere in this Annual Report for further information.

(2) Reflects the annual cash bonus earned for performance for each respective year under the Company's Incentive Bonus Program. Mr. Bitterman did not receive an annual cash bonus in 2023 or 2022.

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

(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. Upon his appointment to Interim Executive Chairman, Mr. Bitterman ceased receiving compensation in connection with his position as a director of the Company, including as Chairman of the Board. The amounts listed in fiscal year 2022 reflect the compensation paid to Mr. Bitterman as a member of our Board, totaling $46,112, and as our Interim Executive Chairman, totaling $63,268. Effective as of October 16, 2023, Mr. Bitterman voluntarily reduced his base salary by $100,000.

Outstanding Equity Awards at Fiscal Year-End

The following table shows information regarding outstanding equity awards as of December 31, 2023 for our NEO:

		Option Awards				Stock Awards			
Name	Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)	Equity Incentive Plan Awards: Number of Unearned Shares or Units of Stock That Have Not Vested (#)	Equity Incentive Plan Awards: Market Value of Unearned Shares or Units of Stock That Have Not Vested ($)[1]
Robert J. Bitterman [2]	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	–	–	–	–
	2/20/2023	–	–	–	–	11,000	8,360	–	–

(1) Value is based on the closing price of $0.76 of the Company's common stock on December 29, 2023.

(2) The equity awards granted to Mr. Bitterman on June 2, 2014, June 1, 2015, February 10, 2016, and February 1, 2017 vested in one installment on the first anniversary of the grant date. The equity award granted to Mr. Bitterman on February 20, 2023 will vest over two years commencing 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 Board (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. Our NEO received no annual incentive bonus payments in 2023 or 2022.

Equity Incentive

We maintain our Phio Pharmaceuticals Corp. 2020 Long Term Incentive Plan (the "**2020 Plan**") pursuant to which we currently grant RSU awards to eligible participants. Grants of restricted stock units under this plan to our NEO is 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 description of the employment agreement that is currently in effect for our NEO:

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. Effective as of October 16, 2023, Mr. Bitterman voluntarily reduced his base salary by $100,000.

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.

Pay versus Performance

As required by Section 953(a) of the Dodd-Frank Wall Street Reform and Consumer Protection Act and Item 402(v) of Regulation S-K, we are providing the following information about the relationship between the SEC-defined Compensation Actually Paid ("**CAP**") to our NEO and certain of our financial performance metrics during the fiscal years listed below. The SEC-defined CAP data set forth in the table below does not necessarily reflect amounts actually paid, earned or received by our NEO, and the metrics are not those that the Compensation Committee uses when setting executive compensation.

The following table sets forth additional compensation information of our principal executive officer ("**PEO**") along with total shareholder return and net income for our 2023 and 2022 fiscal years. The Company did not have any non-PEO NEO for fiscal years 2023 and 2022.

Year	Summary Compensation Table Total for PEO (1)	CAP to PEO (2)	Value of Initial Fixed $100 Investment Based On Total Shareholder Return (3)	Net Income (Loss) (Thousands)
2023	$437,892	$379,393	$6.33	$(10,826)
2022	$109,380	$94,715	$13.83	$(11,480)

(1) Mr. Bitterman has served as a member of the Company's Board since 2012, served as the Company's Interim Executive Chair from September 2022 to February 2023 and was appointed as our President and Chief Executive Officer in February 2023.

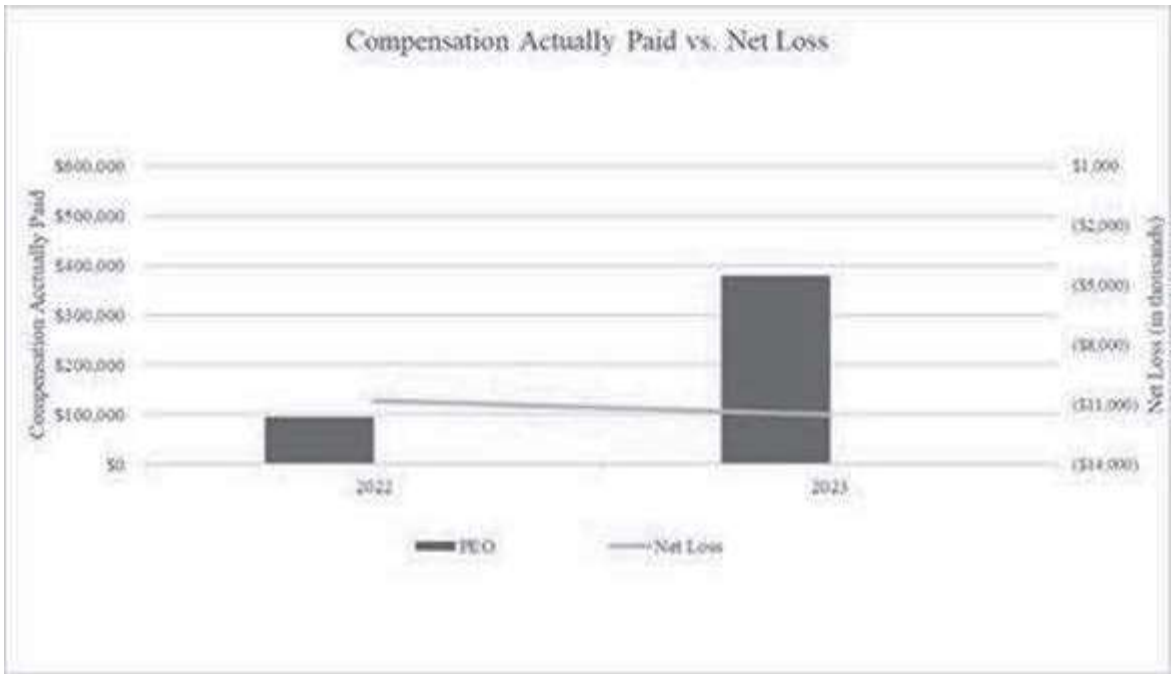
(2) CAP reflects the following exclusions and inclusions for the PEO in the table above:

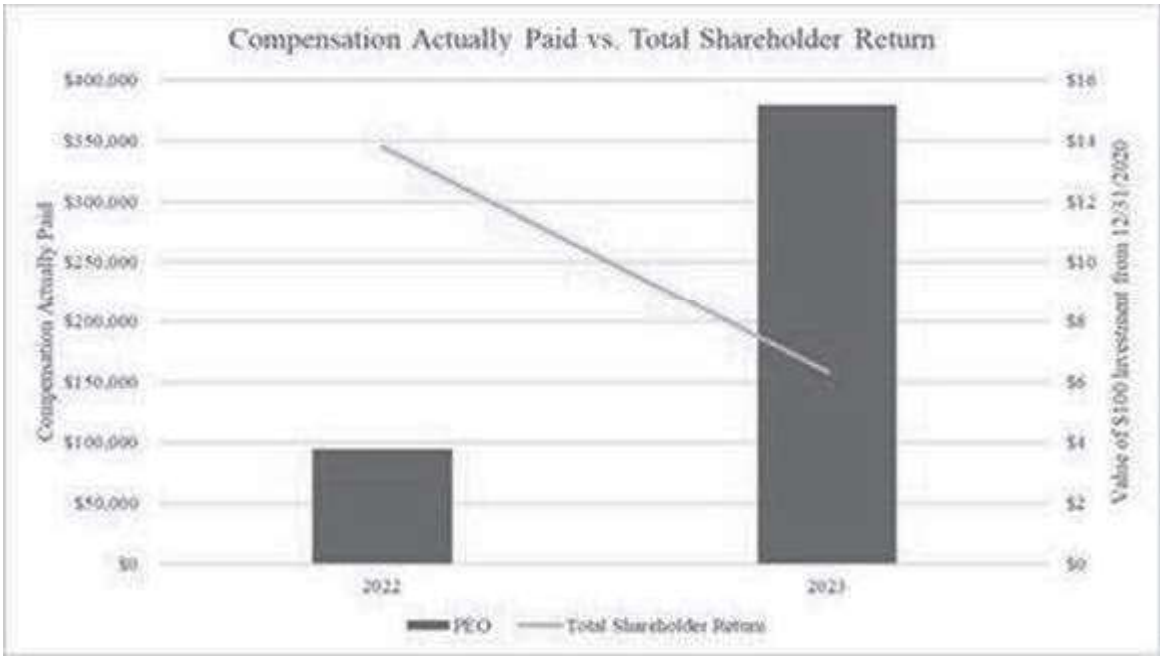
Year	Summary Compensation Table Total	Minus: Grant Date Fair Value of Stock Awards and Option Awards from Summary Compensation Table	Plus: Year-end Fair Value of Unvested Equity Awards Granted During Year	Plus: Year-Over-Year Difference of Year-End Fair Value of Unvested Awards Granted in Prior Years	Plus: Fair Value at Vest Date for Awards Granted and Vested During Year	Plus: Year-Over-Year Difference of Year-End Fair Value of Prior Years' Awards Vested During Year	Minus: Fair Value at Prior Year-end for Prior Years' Awards that Fail to Meet Vesting Conditions During Year	Compensation Actually Paid
2023	$437,892	$(57,640)	$8,360	–	–	$(9,219)	–	$379,393
2022	$109,380	$(31,464)	$18,590	–	–	$(1,791)	–	$94,715

(3) Total shareholder return as calculated based on a fixed investment of $100 measured from the market close on December 31, 2021 through and including the end of the fiscal year for each year reported in the table.

Relationship Between Pay and Performance

The following charts shown below illustrate the relationship of compensation actually paid to our PEO, as set forth in the table above, as compared to: our (1) total shareholder return and (2) net income (loss).





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 1,500 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 2023. 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, is set forth above in the Summary Compensation Table due to Mr. Bitterman's status as a NEO of the Company.

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)[1]	Total ($)
Patricia A. Bradford	50,000	7,860	57,860
Robert L. Ferrara	62,500	7,860	70,360
Jonathan E. Freeman, Ph.D.	35,000	7,860	42,860
Curtis A. Lockshin, Ph.D.	42,500	7,860	50,360

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

As of December 31, 2023, the aggregate number of shares underlying stock options and RSUs by our non-employee directors is as follows: Patricia A. Bradford — 1,500 RSUs, Robert L. Ferrara — 1,500 RSUs, Jonathan E. Freeman, Ph.D. — 1 option award and 1,500 RSUs, and Curtis A. Lockshin, Ph.D. — 4 option awards and 1,500 RSUs. Mr. Bitterman's outstanding equity awards are also included in the Outstanding Equity Awards at Fiscal Year-End table above due to his status a NEO during the fiscal year ended December 31, 2023.

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 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 March 15, 2024 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 March 15, 2024, or within 60 days of March 15, 2024, 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.

	Shares Beneficially Owned	
Name and Address of Beneficial Owner	**Number [1]**	**Percent of Class [2]**
Greater than 5% Holders		
Intracoastal Capital LLC[3]	509,622	9.99%
Directors and Named Executive Officers:		
Robert J. Bitterman [4]	13,498	*
Patricia A. Bradford	3,167	*
Robert Ferrara	4,001	*
Jonathan E. Freeman, Ph.D. [5]	3,201	*
Curtis A. Lockshin, Ph.D. [6]	3,204	*
All current directors and executive officers as a group (five persons)	27,071	*

* Indicates less than 1%.

(1) Represents shares of common stock held as of March 15, 2024 plus shares of common stock that may be acquired upon the exercise of options and warrants within 60 days of March 15, 2024.

(2) Based on 4,591,700 shares of common stock that were issued and outstanding as of March 15, 2024. Shares not outstanding but deemed beneficially owned by virtue of the right of a person to acquire them as of March 15, 2024, or within 60 days of March 15, 2024, 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 shares of common stock issuable upon the exercise of warrants held 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 509,622 shares of common stock issuable upon the exercise of certain warrants held by Intracoastal. Certain of the warrants held by Intracoastal contain a blocker provision under which the holder thereof does not have the right to exercise its warrants 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% or 9.99% of the Company's common stock. Based upon a Schedule 13G/A filed on February 6, 2024, Intracoastal and Messrs. Kopin and Asher would be deemed to have beneficial ownership of 1,177,723 shares of common stock in the absence of such blocker provisions. 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 4 stock options exercisable within 60 days of March 15, 2024.

(5) Includes 1 stock option exercisable within 60 days of March 15, 2024.

(6) Includes 4 stock options exercisable within 60 days of March 15, 2024.

Equity Compensation Plan Information

The following table sets forth certain information as of December 31, 2023 about the securities authorized for issuance under our equity compensation plans, which consist 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)]	59,767	$ 134.86	133,574
Equity compensation plans not approved by security holders	–	–	–
Total	59,767	$ 134.86	133,574

(1) Includes 10,084 outstanding options and 49,683 unvested RSUs under the 2020 Plan.

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

The 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.

During 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 and (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 SEC rules and 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 of the Board be independent and that members of our Audit Committee also satisfy independence criteria set forth in Rule 10A-3 under the Exchange Act. The 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*

Pre-Approval Policies and Procedures

Under the Sarbanes-Oxley Act of 2002, all audit and permissible non-audit services provided by our independent registered public accounting firm must be approved in advance by our Audit Committee to ensure that such services do not impair the independent registered public accounting firm's independence from us. Accordingly, the Audit Committee reviews and pre-approves all audit and non-audit services performed by our 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 independent registered public accounting firm's independence.

The following is a summary of the fees billed and expected to be billed to the Company by BDO USA, P.C. ("**BDO**"), our independent registered public accounting firm, for professional services rendered for the fiscal years ended December 31, 2023 and 2022. All fees incurred in fiscal years 2023 and 2022 for services rendered by BDO were approved in accordance with the pre-approval policies and procedures described above.

	2023	2022
Audit Fees	$ 443,162	$ 215,974
Audit-Related Fees	–	–
Tax Fees	–	–
All Other Fees	–	–
Total All Fees:	$ 443,162	$ 215,974

Audit Fees consist of fees for the audit of the Company's consolidated financial statements included in our annual reports on Form 10-K, the review of the Company's consolidated 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.

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.	Amendment No. 1 to the Registration Statement on Form S-1 (File No. 333-221173)	September 28, 2018
4.2	Form of Placement Agent Warrant.	Current Report on Form 8-K (File No. 001-36304)	November 19, 2019
4.3	Form of Warrant.	Current Report on Form 8-K (File No. 001-36304)	February 6, 2020
4.4	Form of Warrant.	Current Report on Form 8-K (File No. 001-36304)	February 13, 2020
4.5	Form of Underwriter Warrant.	Current Report on Form 8-K (File No. 001-36304)	February 13, 2020
4.6	Form of Warrant.	Current Report on Form 8-K (File No. 001-36304)	April 2, 2020
4.7	Form of Common Stock Warrant.	Current Report on Form 8-K (File No. 001-36304)	January 25, 2021
4.8	Form of Placement Agent Warrant.	Current Report on Form 8-K (File No. 001-36304)	February 17, 2021
4.9	Form of Series A Common Stock Warrant.	Current Report on Form 8-K (File No. 001-36304)	April 20, 2023
4.10	Form of Series B Common Stock Warrant.	Current Report on Form 8-K (File No. 001-36304)	April 20, 2023

4.11	Form of Existing Warrant Amendment.	Current Report on Form 8-K (File No. 001-36304)	April 20, 2023
4.12	Form of Series A Common Stock Warrant.	Current Report on Form 8-K (File No. 001-36304)	June 2, 2023
4.13	Form of Series B Common Stock Warrant.	Current Report on Form 8-K (File No. 001-36304)	June 2, 2023
4.14	Form of Series A/B Warrant.	Current Report on Form 8-K (File No. 001-36304)	December 8, 2023
4.15	Form of Placement Agent Warrant.	Current Report on Form 8-K (File No. 001-36304)	December 8, 2023
4.16	Description of Securities Registered Pursuant to Section 12(b) of the Securities Exchange Act of 1934.*		
10.1	Patent and Technology Assignment Agreement between RXi Pharmaceuticals Corporation (formerly RNCS, Inc.) and Advirna, LLC, effective as of September 24, 2011.	Registration Statement on Form S-1 (File No. 333-177498)	October 25, 2011
10.2	Clinical Co-development Agreement, dated February 26, 2021, by and between Phio Pharmaceuticals Corp. and AgonOx, Inc.+	Annual Report on Form 10-K (File No. 00136304)	March 22, 2023
10.3	Phio Pharmaceuticals Corp. 2020 Long Term Incentive Plan, as amended and restated.#	Quarterly Report on Form 10-Q (File No. 001-36304)	November 9, 2023
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	Form of Nonqualified Stock Option Award under the Company's 2020 Long Term Incentive Plan.#	Annual Report on Form 10-Q (File. 001-36304)	November 9, 2023
10.6	Phio Pharmaceuticals Corp. 2012 Long Term Incentive Plan.#	Quarterly Report on Form 10-Q (File No. 001-36304)	November 12, 2019
10.7	Form of Restricted Stock Unit Award under the Company's 2012 Long Term Incentive Plan, as amended.#	Amendment No. 2 to the Registration Statement on Form S-1 (File No. 333-177498)	December 29, 2011
10.8	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
10.9	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
10.10	RXi Pharmaceuticals Corporation Employee Stock Purchase Plan.#	Registration Statement on Form S-8 (File No. 333-277013)	August 24, 2018
10.11	Form of Indemnification Agreement.#	Amendment No. 3 to the Registration Statement on Form S-1 (File No. 333-177498)	January 23, 2012

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	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
10.14	First Amendment to Lease dated January 22, 2019.	Current Report on Form 8-K (File No. 001-36304)	January 28, 2019
10.15	Registration Rights Agreement, dated January 21, 2021, by and between the Company and the Purchasers signatory therein.	Current Report on Form 8-K (File No. 001-36304)	January 25, 2021
10.16	Form of Securities Purchase Agreement, dated April 18, 2023, by and between the Company and each of the Purchasers signatory thereto.	Current Report on Form 8-K (File No. 001-36304)	April 20, 2023
10.17	Form of Securities Purchase Agreement, dated May 31, 2023, by and between the Company and each of the Purchasers signatory thereto (Registered Direct Offering).	Current Report on Form 8-K (File No. 001-36304)	June 2, 2023
10.18	Form of Securities Purchase Agreement, dated May 31, 2023, by and between the Company and each of the Purchasers signatory thereto (PIPE Private Placement).	Current Report on Form 8-K (File No. 001-36304)	June 2, 2023
10.19	Form of Registration Rights Agreement, dated May 31, 2023, by and between the Company and each of the Purchasers signatory thereto.	Current Report on Form 8-K (File No. 001-36304)	June 2, 2023
10.20	Form of Inducement Letter Agreement, dated December 6, 2023, by and between Phio Pharmaceuticals Corp. and the Holders.	Current Report on Form 8-K (File No. 001-36304)	December 8, 2023
23.1	Consent of BDO USA, P.C., an Independent Registered Public Accounting Firm.*		

31.1	Sarbanes-Oxley Act Section 302 Certification of Principal Executive Officer and Principal Financial Officer.*
32.1	Sarbanes-Oxley Action Section 906 Certification of Principal Executive Officer and Principal Financial Officer.**
97.1	Phio Pharmaceuticals Corp. Incentive Compensation Recovery Policy.*
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).*

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* 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: April 1, 2024

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)	April 1, 2024
/s/ Caitlin Kontulis Caitlin Kontulis	Vice President of Finance and Administration and Secretary (Principal Accounting Officer)	April 1, 2024
/s/ Patricia Bradford Patricia Bradford	Director	April 1, 2024
/s/ Robert L. Ferrara Robert L. Ferrara	Director	April 1, 2024
/s/ Jonathan E. Freeman Jonathan E. Freeman, Ph.D.	Director	April 1, 2024
/s/ Curtis A. Lockshin Curtis A. Lockshin, Ph.D.	Director	April 1, 2024

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Board of Directors

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

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

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

Caitlin Kontulis
Vice President of Finance & Administration

Jennifer Phillips, Pharm.D.
Vice President of Regulatory & Corporate Affairs

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

Hogan Lovells US LLP

Philadelphia, PA

Auditors

BDO USA, LLP

Boston, MA

Corporate Headquarters

11 Apex Drive, Suite 300A, PMB 2006

Marlborough, MA 01752

508-767-3861

11 Apex Drive, Suite 300A, PMB 2006
Marlborough, MA 01752
Main: 508-767-3861
Fax: 508-767-3862
www.phiopharma.com