

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

FORM 8-K

CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(d)

OF THE SECURITIES EXCHANGE ACT OF 1934

Date of report (Date of earliest event reported): March 26, 2020

PHIO PHARMACEUTICALS CORP.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation or organization)

001-36304
(Commission
File Number)

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

257 Simarano Drive, Suite 101
Marlborough, Massachusetts 01752

(Address of Principal Executive Offices) (Zip Code)

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class of securities:	Trading Symbol(s):	Name of exchange on which registered:
Common Stock, par value \$0.0001	PHIO	The Nasdaq Capital Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

Item 2.02. Results of Operations and Financial Condition.

On March 26, 2020, Phio Pharmaceuticals Corp. reported its results of operations for the year ended December 31, 2019. A copy of the press released is furnished as Exhibit 99.1 to this Current Report on Form 8-K (the "Report").

The information in this Item 2.02 and attached as Exhibit 99.1 to this Report will not be treated as "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section. This information will not be incorporated by reference into any filing under the Securities Act of 1933, as amended, or into another filing under the Exchange Act, unless that filing expressly incorporates this information by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued by the Company on March 26, 2020.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

PHIO PHARMACEUTICALS CORP.

Date: March 26, 2020

By: /s/ Gerrit Dispersyn
Gerrit Dispersyn
President and Chief Executive Officer



Phio Pharmaceuticals Reports Year End 2019 Financial Results and Provides Business Update

Marlborough, Mass., March 26, 2020 -- Phio Pharmaceuticals Corp. (Nasdaq: PHIO), a biotechnology company developing the next generation of immuno-oncology therapeutics based on its proprietary self-delivering RNAi (INTASYL™) therapeutic platform, today reported its financial results for the full year ended December 31, 2019 and provided a business update.

“Our progress in 2019, along with the bolstering of our balance sheet, now positions us to further unlock the value of our immuno-oncology programs based on our self-delivering RNAi (INTASYL™) therapeutic platform,” said Dr. Gerrit Dispersyn, President and CEO of Phio. “With new data from animal studies becoming available, we look forward to continuing our R&D momentum in 2020, including the transition towards the clinical development stage of our lead candidate PH-762. We also continue to leverage our RNAi platform to establish research collaborations with leading companies and academic institutions. We recently announced a new collaboration and option agreement with Medigene AG, further building on our previously announced research collaboration with the Helmholtz Zentrum München to design and develop novel candidates in adoptive cell therapy.”

Year in Review and Recent Corporate Updates

Pipeline

- Phio has developed a product platform based on our INTASYL™ technology that allows easy, precise, rapid and selective non-genetically modified programming of cells. It can be used to improve immune cells used in adoptive cell transfer (ACT therapy) and to reduce immunosuppression in the tumor microenvironment (TME). The use of INTASYL™ to improve ACT can be done *ex vivo*, during cell manufacturing. The direct therapeutic use of INTASYL™ compounds towards the TME can be done *in vivo* by local delivery to the tumor in the patient. Both applications of our INTASYL™ technology result in improved immunotherapy.
- Lead product candidate PH-762 is designed to elicit checkpoint blockade by inhibiting PD-1 receptor expression in T cells. Recent data developed in-house and with our collaborators, has shown that PH-762 can elicit PD-1 checkpoint blockade by silencing PD-1 receptor expression resulting in enhanced T cell activation and tumor cytotoxicity, and shows the potential of PH-762 in both ACT and TME applications. The Company expects that PH-762 can be ready to enter the clinic with a partner in ACT therapy in the second half of 2020, and for direct therapeutic use towards the TME through intra-tumoral injection in 2021.
- The Company's next pipeline product, PH-804, is designed to silence the expression of the immune exhaustion target TIGIT by NK cells and T cells resulting in them becoming "weaponized." Phio has shown that reduction of TIGIT by PH-804 leads to an increase in the cytotoxic capacity of NK cells. In addition, in recent *in vivo* studies by the Company it was shown that intra-tumoral injections of a mouse version of PH-804 reduced the tumor growth in colorectal carcinoma tumor bearing mice. The Company is developing PH-804 with the aim to enter the clinic with a partner in ACT therapy in 2021.

R&D Collaborations

- Entered into a new collaboration and option agreement with Medigene AG ("Medigene") in relation to the previously announced research collaboration with the Helmholtz Zentrum München for the design and development of new targets based on Phio's INTASYL™ platform for use in cancer immunotherapies.
- Expanded on a collaboration with the Karolinska Institutet to further develop self-delivering RNAi immunotherapies for treating solid tumors and build on the exciting results with several compounds in both T cells and NK cells developed under the previous agreement.
- Entered into a research collaboration with the Helmholtz Zentrum München for the design and development of new targets based on Phio's INTASYL™ platform for use in cancer immunotherapies.
- Entered into a research collaboration with Carisma Therapeutics to evaluate the potential of Phio's technology to enhance the immune function of Carisma's chimeric antigen receptor macrophages (CAR-M) as a novel adoptive cell therapy for use in cancer treatment.
- Entered into a research collaboration with Glycostem Therapeutics BV to explore the potential synergies of using our INTASYL™ in combination with Glycostem's proprietary Natural Killer-cell (NK-cell) generation technology (oNKord®). The goal of the collaboration is to develop cellular immunotherapies for cancer treatment with enhanced efficacy and/or safety, resulting in further improvement of Glycostem's cellular immunotherapies for the treatment of cancer patients.

Conference Presentations and Poster Exhibits

- Presented a corporate update at the Biotech Showcase 2020™ in January 2020. The presentation highlighted the Company's *in vivo* study result with PH-804. The *in vivo* studies showed that intra-tumoral injections of a mouse version of PH-804 reduced the tumor growth in colorectal carcinoma tumor bearing mice. This was shown to be correlated with the silencing of TIGIT messenger RNA expression and an increase in cytotoxic effector cells in the tumor micro-environment.
- Presented three posters at the Society for Immunotherapy of Cancer (SITC) 2019 Annual Meeting. The presentation highlighted the Company's proprietary INTASYL™ technology for "weaponizing" T cells against cancer reflecting internal work and the Company's collaborations with Iovance Biotherapeutics and the Karolinska Institutet.
- Presented a poster "Feasibility and efficacy using self-delivering RNAi against TGFB1 to reduce TME immunosuppression" at the American Association for Cancer Research (AACR) Annual Meeting 2019.

Organizational

- Appointed Gerrit Dispersyn, Dr. Med. Sc. as the Company's President and Chief Executive Officer.

Financial Results

Cash Position

At December 31, 2019, the Company had cash of \$6.9 million as compared with \$14.9 million at December 31, 2018. This does not include the \$9.74 million in gross proceeds the Company raised through two equity offerings completed in February 2020. The Company expects its cash will be sufficient to fund currently planned operations for at least the next 12 months.

Research and Development Expenses

Research and development expenses were approximately \$4.3 million for the years ended December 31, 2019 and 2018, respectively. Research and development expenses were consistent year over year primarily as a result of a reduction in the Company's legacy clinical trial-related expenses which ended in 2018; offset by increased use of third-party CROs to support preclinical immuno-oncology research efforts in 2019.

General and Administrative Expenses

General and administrative expenses were \$4.7 million for the year ended December 31, 2019, compared to \$3.2 million for the year ended December 31, 2018. The increase was primarily due to legal professional fees, recruiting fees related to employee hiring activities and increased proxy-related fees as a result of the Company's annual and special stockholder meetings held in 2019.

Net Loss

Net loss was \$8.9 million or \$19.33 per share for the year ended December 31, 2019, compared with \$7.4 million or \$57.46 per share for the year ended December 31, 2018. The increase was primarily attributable to an increase in operating expenses, discussed above.

About Phio Pharmaceuticals Corp.

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

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. 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, those identified in our Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q under the caption "Risk Factors" and in other filings the Company periodically makes with the SEC. Readers are urged to review these risk factors and to not act in reliance on any forward-looking statements, as actual results may differ from those contemplated by our forward-looking statements. Phio does not undertake to update forward-looking statements to reflect a change in its views, events or circumstances that occur after the date of this release.

Contact Phio Pharmaceuticals Corp.

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Investor Contact

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

	For the Three Months Ended December 31, 2019	For the Three Months Ended December 31, 2018	For the Year Ended December 31, 2019	For the Year Ended December 31, 2018
Revenues	\$ —	\$ —	\$ 21	\$ 138
Operating expenses:				
Research and development	1,023	944	4,300	4,326
General and administrative	1,646	790	4,708	3,176
Total operating expenses	<u>2,669</u>	<u>1,734</u>	<u>9,008</u>	<u>7,502</u>
Operating loss	(2,669)	(1,734)	(8,987)	(7,364)
Total other income, net	9	7	79	4
Loss before income taxes	(2,660)	(1,727)	(8,908)	(7,360)
Provision for income taxes	—	—	—	—
Net loss	<u>\$ (2,660)</u>	<u>\$ (1,727)</u>	<u>\$ (8,908)</u>	<u>\$ (7,360)</u>
Net loss per share: Basic and diluted	<u>\$ (4.69)</u>	<u>\$ (5.56)</u>	<u>\$ (19.33)</u>	<u>\$ (57.46)</u>
Weighted average shares: Basic and diluted	<u>567,334</u>	<u>310,542</u>	<u>460,809</u>	<u>128,085</u>

PHIO PHARMACEUTICALS CORP.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Amounts in thousands)

	December 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash	\$ 6,934	\$ 14,879
Restricted cash	50	50
Prepaid expenses and other current assets	316	221
Total current assets	7,300	15,150
Right of use asset	511	–
Property and equipment, net	210	172
Other assets	18	–
Total assets	<u>\$ 8,039</u>	<u>\$ 15,322</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 809	\$ 550
Accrued expenses	964	1,194
Lease liability	107	–
Total current liabilities	1,880	1,744
Lease liability, net of current portion	411	–
Total liabilities	2,291	1,744
Total stockholders' equity	5,748	13,578
Total liabilities and stockholders' equity	<u>\$ 8,039</u>	<u>\$ 15,322</u>