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Phio Pharmaceuticals Corp (PHIO - NASDAQ)

sdRX-RNA is Now INTASYL

Based on our DCF model and a 15% discount rate, Phio Pharmaceuticals is valued at approximately $1.00 per share. Our model applies an 8% probability of ultimate approval and commercialization for RXI-109 and Samcyprone. The model includes contributions from the US, EU and rest of world.

Current Price (11/19/2019)	$0.14
Valuation	**$1.00**

OUTLOOK

Phio Pharmaceuticals has developed a unique composition of interference RNA that is able to self-deliver into the cellular cytoplasm. The compound, sd-rxRNA, combines features of RNAi and antisense, and is able to silence unwanted gene expression with a limited side effect profile.

The company has two Phase II dermal assets and one Phase I/II ocular asset which are expected to be partnered and provide development capital for earlier stage immuno-oncology (IO) programs.

Phio recently directed its primary research focus towards its preclinical IO program that is being developed to augment existing cell therapies. A favorable investment and regulatory environment are supportive of IO and should allow for rapid entry into the clinic. We expect to see three programs enter the clinic in 2020.

We attach a valuation to the Phase I/II and Phase II assets and expect to see regulatory approvals and subsequent commercialization over the 2022 to 2024 period as described in our analysis.

SUMMARY DATA

52-Week High	**0.53**
52-Week Low	**0.12**
One-Year Return (%)	**-77.6**
Beta	**1.83**
Average Daily Volume (sh)	**192,217**
Shares Outstanding (mil)	**36.4**
Market Capitalization ($mil)	**5.1**
Short Interest Ratio (days)	**2.26**
Institutional Ownership (%)	**13.8**
Insider Ownership (%)	**5.9**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2018 Estimate	**N/A**
P/E using 2019 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of USD)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	$0.0 A	$0.1 A	$0.1 A	$0.0 A	$0.1 A
2019	$0.0 A	$0.0 A	$0.0 A	$0.0 E	$0.0 E
2020					$0.0 E
2021					$0.0 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2018	-$0.90 A	-$0.46 A	-$0.34 A	-$0.09 A	-$1.80 A
2019	-$0.10 A	-$0.08 A	-$0.08 A	-$0.08 E	-$0.34 E
2020					-$0.23 E
2021					-$0.25 E

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WHAT'S NEW

Third Quarter 2019 Financial & Operational Update

Phio Pharmaceuticals Corp. (NASDAQ: PHIO) reported third quarter 2019 results and filed its Form 10-Q on November 12, 2019. Since the beginning of the year, the company has announced a several new collaborations with partners including Glycostem Therapeutics, Helmholtz Zentrum Munchen and Carisma Therapeutics. Research and development efforts have put the company is on track to launch up to three clinical trial programs in 2020. This includes PH-762 for adoptive cell therapy (ACT) and direct intra-tumoral injection targeting checkpoint inhibitors and PH-804 to activate T cells and natural killer (NK) cells. The company has also designated the proprietary name, INTASYL, for its self-delivering RNAi platform.

Total expenses in the third quarter of 2019 were $2.1 million, up 36% from the prior year quarter. This was composed of research and development expenditures of $1.0 million, rising 24% on higher consulting and professional service fees and general and administrative expenditures of $1.1 million, up 51% on higher payroll related expenses and legal fees. Net loss was ($2.1) milion or ($0.08) per share, reflecting 25.4 million average diluted shares outstanding.

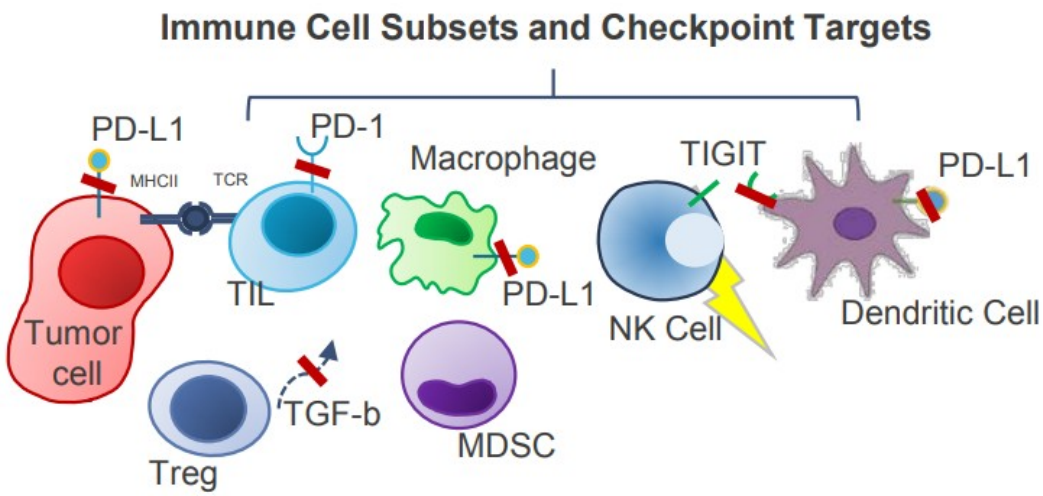
As of September 30, 2019, cash stood at $8.7 million and debt remained at zero. Cash burn was ($2.1) million for the quarter, up slightly from prior year levels. A small amount of cash was used in financing related to stock issuance costs. Phio management anticipates current cash levels will be sufficient to fund the company for at least the next 12 months. Following the third quarter earnings release, Phio announced a $1 million raise at $0.10 per share.

SITC Posters

Several posters were presented at the Society for Immunotherapy of Cancer (SITC) 2019 Annual Meeting in November, summarizing the work performed both internally and in collaboration with Iovance Biotherapeutics and the Karolinska Institutet. The posters addressed cellular therapies and novel single-agent immunotherapies in presentations given on November 8th and 9th. Poster titles were:

- Silencing PD-1 using self-delivering RNAi PH-762 to improve Iovance TIL effector function using Gen 2 manufacturing method
- Modulating BRD4 in T cells using self-delivery RNAi to improve adoptive cell therapy of cancer
- Local modulation of T cell PD-1 using self-delivering RNAi as a potential immunotherapeutic

Exhibit I – Reprogramming the Tumor Microenvironment[1]



[1] Source: Phio Corporate Presentation, September 2019

New Collaborations & Partnerships

On August 15, 2019, Phio announced a collaboration with Helmholtz Zentrum München, a German research organization focused on studying environmental health issues. The organization incubates promising development projects and promotes their further development in an effort to be an attractive partner for industry. This includes projects in drug discovery and immuno-oncology. The collaboration project between Phio and the research center will design new targets employing INTASYL in cancer immunotherapy. The project will be led by Professor Dr. Elfriede Nößner, an expert in the study of lymphoid and myeloid effector cells. Dr. Nößner believes that Phio's technology can be effective in inhibiting checkpoints in immune effector cells, such as T cells and NK cells.

The company announced an additional collaboration with Carisma Therapeutics on September 9th. Carisma is a Philadelphia-based chimeric antigen receptor macrophage (CAR-M)-focused biotechnology company. Carisma's technology uses macrophages, which are naturally drawn to solid tissues, to orient the CAR approach toward addressing solid tumors. Phio will work with Carisma to synergistically modify Carisma's CAR-Ms to silence key genes that may enhance the immune function of the cells. The combination of technolgies may enhance an immunostimulatory phenotype and promote tumor cell killing.

Pipeline Candidates

Phio's pipeline includes lead candidate PH-762 for melanoma and PH-804 for a variety of immuno-oncology targets as well as other compounds focused on checkpoint receptor inhibition, adoptive cell therapy (ACT) and tumor microenvironment. Cell differentiation is another program that is seeking to extend the life of modified immune cells to combat exhaustion.

Exhibit II – Phio INTASYL Immuno-Oncology Pipeline[2]

MECHANISM	INDICATION	DISCOVERY	PRECLINICAL	CLINICAL	COMMENT
PD-1 Inhibition – ACT (TILs)	Melanoma (+ others*)	PH-762			Entering clinic 1H 2020
PD-1 Inhibition – TME (IT Injection)	Melanoma (+ others*)	PH-762			Entering clinic 2H 2020
TIGIT Inhibition – ACT (T cells/NKs)	Various	PH-804			Entering clinic 2H 2020
TIGIT Inhibition – TME (IT Injection)	Various	PH-804			
PD-L1 Inhibition – ACT (T cells/NKs)	Various	PH-790			
PD-L1 Inhibition – TME (IT Injection)	Various	PH-790			
Additional Opportunities: T cell Exhaustion, Cell Metabolism, Innate Immunity	Various	Undisclosed			

IT = intra-tumoral

* Basket study including PD-1+ melanoma, triple negative breast cancer, ovarian cancer, head and neck squamous cell cancer

NASDAQ Compliance

On November 2, 2018 Phio received a letter from NASDAQ stating that the company was not in compliance with exchange rules which require a minimum bid price of $1.00. The exchange gave the company 180 days to achieve compliance and then another 180 days, extending the requirement target date to November 11, 2019. On November 2nd, 2019 the NASDAQ notified Phio that it remained out of compliance with minimum bid price requirements. The company expects that the NASDAQ will delist the company's shares after which the company will appeal. If the appeal is unsuccessful, the shares will likely trade on the OTC Bulletin Board or the OTCQX market. Phio is also seeking shareholder approval for a reverse share split in order to achieve the minimum bid price.

[2] Source: Phio Corporate Presentation, September 2019

Capital Raise

On November 17th Phio proposed a public offering of common stock that raised $1.0 million in gross proceeds. 10 million shares were issued at a price of $0.10. Phio was placed in a difficult position with respect to reaching a quorum for its annual shareholder meeting as it was not able to get a response for over 50% of outstanding shares. The identity of many of the company's holders were not available or disclosed by foreign institutions that held the shares deterring the proxy specialists from directly contacting them. This prevented a quorum from being reached and important items from receiving a vote. In order to meet the minimum required representation from shareholders to vote and allow for a reverse stock split, Phio announced a public offering and 10 million additional shares were issued. The company anticipates that the new shares will both be voted and allow for the quorum requirements to be met.

Milestones:

- Addition of partner Glycostem for NK IO treatment development – March 2019
- Elevation of Dr. Gerrit Dispersyn to CEO – March 2019
- Partnership/Sale of Dermatology and Ophthalmology Programs – TBD
- Preparation of IND for PH-762 – 2H:19
- Collaboration with Helmholtz Zentrum München – August 2019
- Collaboration with Carisma Therapeutics – September 2019
- New PD-L1 pipeline product, PH-790 – 3Q:19
- Presentation of INTASYL technology at SITC – October 2019
- Resignation of Chief Development Officer, John Barrett, Ph.D. – October 2019
- IND enabling study results for PH-762 – 4Q:19
- PH-762 (TILs – Melanoma) into clinic – 1H:20
- Announce new cell metabolism/differentiation product – 1H:20
- Announce new innate immunity pipeline product – 2H:20
- PH-762 (Intratumoral injection – Melanoma) into clinic – 2H:20
- PH-804 (ACT) into clinic – 2H:20

Summary

Phio continues to advance its pipeline towards the clinic and engage in additional collaborations. Phio has a multi-pronged approach to its immuno-oncology efforts, with three broad areas of research conducted in collaboration with partners. Immuno-oncology is an attractive area for development as the FDA frequently provides preferential consideration for candidates pursuing a cancer indication and there is broad demand for therapies in this pathology. Phio's sd-rxRNA platform, now designated INTASYL, has many favorable characteristics, including low cost, a high degree of safety, and the ability to enhance the IP of partner products among other benefits. Phio has indicated that they have sufficient cash to support activity until 3Q:20, a runway that may be extended with funds generated from asset sales or accessing funds under purchase agreements.

We think it is necessary for the company to develop a partnership with a peer that can both provide funding and validation of Phio's projects, which will also have the benefit of increasing investor interest in the company. While Phio has an impressive portfolio with clinical data supportive of safety and efficacy, financial support will be critical to their ultimate success. As it is too early to assign a valuation to the immuno-oncology platform, we continue to base our current valuation on the Phase II assets RXI-109 and Samcyprone. Due to the longer than expected marketing period for these programs and the lack of interest to date, we are applying a 50% discount to our previous valuation of these assets which we will adjust accordingly if a deal materializes. We remind investors that we attach a value to development programs when they enter the clinic and will assign a value to PH-762 and PH-804 at that time. Based on our discount for lack of marketability, our target price for Phio is $1.00 per share.

PROJECTED FINANCIALS

Phio Pharmaceuticals Corp. - Income Statement

Phio Pharmaceuticals Corp	2018	Q1 A	Q2 A	Q3 A	Q4 E	2019 E	2020 E	2021 E
Total Revenues	**$0.1**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
YOY Growth								
Research & Development	$4.3	$1.1	$1.1	$1.0	$1.3	$4.6	$6.0	$8.5
General & Administrative	$3.2	$1.1	$0.9	$1.1	$1.0	$4.1	$4.5	$4.7
Income from operations	($7.4)	($2.1)	($2.1)	($2.1)	($2.3)	($8.6)	($10.5)	($13.2)
Operating Margin	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Interest Income	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Other Income	$0.0	$0.0	$0.0	$0.0	$0.0	$0.1	$0.0	$0.0
Pre-Tax Income	($7.4)	($2.1)	($2.0)	($2.1)	($2.3)	($8.5)	($10.5)	($13.2)
Provision for Income Tax	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Net Income	**($7.4)**	**($2.1)**	**($2.0)**	**($2.1)**	**($2.3)**	**($8.5)**	**($10.5)**	**($13.2)**
Reported EPS	**($1.80)**	**($0.10)**	**($0.08)**	**($0.08)**	**($0.08)**	**($0.34)**	**($0.26)**	**($0.26)**
YOY Growth								
Basic Shares Outstanding	7.04	20.42	24.23	25.41	30.40	25.11	40.00	50.00

Source: Company Filing // Zacks Investment Research, Inc. Estimates

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HISTORICAL STOCK PRICE

Phio Pharmaceuticals Corp. – Share Price Chart



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