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Phio Pharmaceuticals Corp (PHIO - NASDAQ)

Overcoming Immune Checkpoints

Based on our DCF model and a 15% discount rate, Phio Pharmaceuticals is valued at approximately $2.00 per share. Our model applies a 15% 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 (8/16/2019)	$0.34
Valuation	**$2.00**

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 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	**2.19**
52-Week Low	**0.27**
One-Year Return (%)	**-77.6**
Beta	**1.83**
Average Daily Volume (sh)	**192,217**
Shares Outstanding (mil)	**25.6**
Market Capitalization ($mil)	**8.7**
Short Interest Ratio (days)	**5.52**
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 E	$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 E	-$0.09 E	-$0.36 E
2020					-$0.35 E
2021					-$0.25 E

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WHAT'S NEW

Phio Pharmaceuticals Corp. (NASDAQ: PHIO) reported second quarter 2019 results and filed its Form 10-Q on August 12, 2019. Since the beginning of the year, the company has announced a new collaborations with Glycostem Therapeutics, the promotion of Dr. Gerrit Dispersyn to CEO and the appointment of Dr. John Barrett as CDO. Research efforts have placed Phio 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. Following the second quarter report, another collaboration was announced with Helmholtz Zentrum München to advance reseach in cancer immunotherapies.

Total expenses in the second quarter of 2019 were $2.1 million, up 5% from the prior year quarter. This was composed of research and development expenditures of $1.1 million, falling 3% on a reduction in licensing fees and general and administrative expenditures of $0.9 million, up 18% on higher legal fees. Net loss was ($2.0) milion or ($0.08) per share, reflecting 24.2 million average diluted shares outstanding.

As of June 30, 2019, cash stood at $10.8 million and debt remained at zero. Cash burn was ($1.9) million for the quarter, even with prior year levels. A small amount was contributed from financing activities representing the exercise of pre-funded warrants. Phio management anticipates current cash levels will be sufficient to fund the company until 2H:20.

Dermatology and Ophthalmology Assets

Phio continues to meet with potential acquirors and partners for RXI-109 and Samcyprone. The company is seeking a large dermatology player for the scarring indication and feedback has been limited. Potential buyers are seeking an advanced asset that can be approved within a short time period or a 505(b)(2) type of asset that is already understood by the regulatory agencies and RXI-109 for scarring is outside of this zone. We continue to see value here and anticipate that Phio will continue meeting with interested suitors until the environment shifts in their favor. Samcyprone can address an unmet need in warts and we think it can fill a niche in the retail space. The asset also can extend into other areas such as genital warts, precancerous lesions and has an orphan designation for skin cancer. No deals have yet been announced for this asset. Data for RXI-109 for retinal fibrosis and corneal scarring was the last to be fully available for review and could have the greatest near term value of the for-sale assets. In April, Regeneron and Alnylam announced a collaboration with $800 million in upfront cash to focus on disease targets expressed in the eye and central nervous system. This demonstrates that there is value recognized for RNAi in ophthalmology indications and we are hopeful that the value of Phio's asset will also be acknowledged. Despite the slow pace, we are optimistic that Phio will successfully monetize these partially developed assets.

Patent Issued

On May 28, 2019, the United States Patent and Trademark Office (USPTO) issued patent number 10,300,027 entitled "Effective sensitizing dose of a gelled immunomodulating topical composition." The patent employs diphenylcyclopropenone (DPCP), otherwise known as Samcyprone, for which Phio has completed a Phase II trial for the indication of common warts. DPCP is an immunomodulator and can provoke an immune response, which has been studied in the treatment of alopecia areata, warts and cutaneous metastases of malignant melanoma. With this patent, Phio has broadened its intellectual property protections in skin cancer and melanoma. Company strategy seeks to protect work the company has done with licensed compounds in other than lead indications. While DPCP is not an active target for Phio, the patent will protect potential advances the company may make in the future.

CEO Appointment and Management Changes

As of March 1st, Gerrit Dispersyn was appointed chief executive officer (CEO). Dr. Dispersyn joined the company in April 2017 as Chief Development Officer and was promoted to President and Chief Operating Officer in 2018. He takes the reins from Dr. Geert Cauwenbergh, who will remain as member of Phio's board of directors.

On April 10, Phio appointed Dr. John Barrett as Chief Development Officer. Dr. Barrett's background at Ziopharm Oncology for the past eight years provided experience in drug discovery and in developing cell-based immuno-oncology therapies.

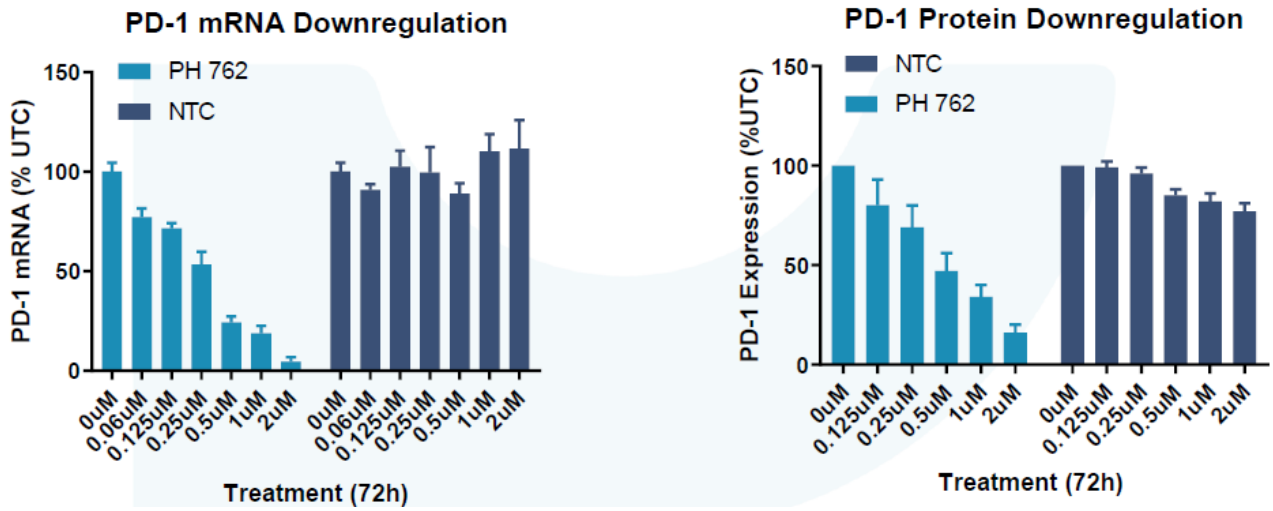
Programs & Partnerships

Phio maintains a relationship with the CCIT at Herlev Hospital to develop tumor-infiltrating lymphocytes (TILs) for cell therapies. Phio's sd-rxRNA is being used with TILs to modify their use in order to target immune checkpoints in cells from melanoma and other cancer patients. The use of sd-rxRNA with TILs has reduced the number of PD-1 receptors on the TILs' surface in a pilot study.

Phio is working with Iovance Biotherapeutics to develop and commercialize autologous cellular immunotherapies with tumor-directed TILs. Work with Iovance will combine sd-rxRNA with Iovance's autologous cell therapy approach in the treatment of cancer. In collaborative efforts, knock-down of PD-1 was associated with phenotypic changes suggesting TIL activation. Future efforts will evaluate the impact of sd-rxRNA on TIL activty.

The Medigene AG collaboration is combining sd-rxRNA with T cell receptors (TCR) to enhance the safety and efficiacy of their use in the treatment of cancer patients. Initial work with Medigene reduced PD-1 levels in T cells and the future goal is to expand to additional targets.

Exhibit I – Dose Response for PD-1 Silencing Using PH-762[1]



Combined efforts with Gustave Roussy employ sd-rxRNA in the tumor micro environment (TME). Intra-tumoral injection is applied to silence gene expression. Study results demonstrated an 80 – 85% reduction of the target gene expression in a melanoma mouse model.

[1] Exhibit compares the non-targeting control (NTC) with PH-762 at varying doses from 0 to 2 µM. The declining light blue bars illustrate the dose response in a reduction of PD-1 mRNA while the dark blue bars of the control are relatively steady.

Helmholtz Zentrum München Collaboration

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 sd-rxRNA 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.

Pipeline Candidates

The following exhibit illustrates Phio's pipeline, which includes undisclosed compounds in adoptive cell therapy (ACT) and tumor microenvironment. The lead asset is PH-762, which seeks to increase the expression of PD-1 in cell based therapies. Earlier stage programs are targeting the immune receptor TIGIT in solid tumors among other checkpoints. Cell differentiation is another program that is seeking to extend the life of modified immune cells so they will work longer.

Exhibit II – Phio Pipeline

MECHANISM	INDICATION	DISCOVERY	PRECLINICAL	CLINICAL	COMMENT
Checkpoint Inhibition in ACT (TILs)	Melanoma (+ others)	PH-762			Entering clinic 1H 2020
Checkpoint Inhibition in TME (Direct - IT)	Melanoma (+ others)	PH-762			Entering clinic 2H 2020
Checkpoint Inhibition in ACT (T cells/NKs)	Various	PH-804			Entering clinic 2H 2020
Checkpoint Inhibition in TME (Direct - IT)	Various	PH-804			
Checkpoint Inhibition in ACT (T cells/NKs)	Various	PD1/PD-L1 Axis			
Checkpoint Inhibition in TME (Direct - IT)	Various	PD1/PD-L1 Axis			
T cell exhaustion in ACT (T cells)	Various	Undisclosed			
Metabolism in ACT (T cells /NKs)	Various	Undisclosed			
Metabolism in TME (Tumor cells)	Various	Undisclosed			
Innate Immunity (NKs, DCs, Macrophages)	Various	Various			

NASDAQ Compliance

On November 2, 2018 Phio received a letter from NASDAQ stating that the company was not in compliance with exchange rules due to share price. The requirement calls for the minimum bid for shares to be $1.00, and falling below this level for thirty consecutive days violates the rule. The notification letter gave the company 180 days to achieve compliance, which is defined as 10 consecutive days of a minimum bid price of $1.00. The original compliance target date was May 14, 2019. In the 1Q:19 10-Q, Phio reported that the date was extended to November 11, 2019, providing an additional six months to achieve compliance. If the shares are delisted from the NASDAQ, Phio will likely trade on the OTC Bulletin Board or OTCQX market.

Milestones:

- Addition of partner Glycostem for NK IO treatment development – March 2019
- Elevation of Dr. Gerrit Dispersyn to CEO – March 2019
- Appointment of Dr. John Barrett to CDO – April 2019
- Partnership/Sale of Dermatology and Ophthalmology Programs – TBD
- Preparation of IND for PH-762 – 2H:19
- Collaboration with Helmholtz Zentrum München – August 2019
- New PD-1/PD-L1 product
- PH-762 (TILs – Melanoma) into clinic – 1H:20
- PH-762 (Intratumoral injection – Melanoma) into clinic – 2H:20
- PH-804 (ACT) into clinic – 2H:20

Summary

Phio remains in negotiations with potential buyers regarding the dermatology and ophthalmology assets. We are hopeful that execution on this sale will add to cash levels and be reflected in the valuation; however, progress has been slow.[2] 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 has many favorable characteristics, including low cost, a high degree of safety, and the ability to enhance the IP of partner products to name a few. Phio has indicated that they have sufficient cash to support activity until 2H:20, a runway that may be extended with funds generated from asset sales. We maintain our target price at $2.00 per share.

[2] We discuss the Samcyprone and PHIO-109 in a previous report found here.
https://s1.q4cdn.com/460208960/files/News/2018/Zacks_SCR_Research_08202018_PHIOI_Vandermosten.pdf

PROJECTED FINANCIALS

Phio Pharmaceuticals Corp. - Income Statement

Phio Pharmaceuticals Corp	2018	Q1 A	Q2 A	Q3 E	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	$4.5	$5.0	$8.0
General & Administrative	$3.2	$1.1	$0.9	$1.0	$1.0	$4.0	$4.0	$4.5
Income from operations	($7.4)	($2.1)	($2.1)	($2.0)	($2.3)	($8.5)	($9.0)	($12.5)
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)	($2.0)	($2.3)	($8.5)	($9.0)	($12.5)
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)**	**($2.0)**	**($2.3)**	**($8.5)**	**($9.0)**	**($12.5)**
Reported EPS	**($1.80)**	**($0.10)**	**($0.08)**	**($0.08)**	**($0.09)**	**($0.36)**	**($0.35)**	**($0.25)**
YOY Growth								
Basic Shares Outstanding	7.04	20.42	24.23	25.00	25.20	23.71	26.00	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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