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March 31, 2020
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Phio Pharmaceuticals Corp (PHIO - NASDAQ)

Collaborations Provide Several Options

Based on our DCF model and a 15% discount rate, Phio Pharmaceuticals is valued at approximately $9.00 per share which reflects the recent share issuance and reverse stock split and additional share issuance to support proof of concept work. 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 (3/30/2020)	$2.21
Valuation	**$9.00**

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 available 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 PH-762 enter the clinic in 2020.

We attach a valuation to the Phase I/II and Phase II assets that are held for sale and, with an appropriate probability of success, expect to see regulatory approvals and subsequent commercialization over the 2023 to 2025 period.

SUMMARY DATA

52-Week High	**28.87**
52-Week Low	**2.01**
One-Year Return (%)	**-91.1**
Beta	**1.87**
Average Daily Volume (sh)	**237,830**
Shares Outstanding (mil)	**2.87**
Market Capitalization ($mil)	**6.3**
Short Interest Ratio (days)	**0.11**
Institutional Ownership (%)	**12.1**
Insider Ownership (%)	**6.8**
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 2019 Estimate	**N/A**
P/E using 2020 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 A	$0.0 A
2020					$0.0 E
2021					$0.0 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2018	-$49.37 A	-$25.49 A	-$18.79 A	-$5.58 A	-$99.22 A
2019	-$5.71 A	-$4.62 A	-$4.53 A	-$4.69 A	-$19.33 A
2020					-$3.39 E
2021					-$2.10 E

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WHAT'S NEW

Full Year 2019 Financial & Operational Update

Phio Pharmaceuticals Corp. (NASDAQ: PHIO) reported full year 2019 results and filed its Form 10-K on March 26, 2020. The prior year saw substantial change with a new captain at the helm and numerous new and expanded collaborations with Glycostem Therapeutics, Helmholtz Zentrum München, Medigene, Karolinska Institutet and Carisma Therapeutics. Phio is dependent upon its partners for the timeline to enter the clinic for its T cell programs; and, based on the current status of PH-762, anticipates its Adoptive Cell Transfer (ACT) candidate entering the clinic by 2H:20. The company has also designated the proprietary name, INTASYL, for its self-delivering RNAi platform.

Revenues recognized for the year were $21,000 and related to the company's work as a sub-awardee for BioAxone's spinal cord injury product. Total expenses for 2019 were $9.0 million, 20% greater than the prior year. This was composed of research and development expenditures of $4.3 million and general and administrative expenditures of $4.7 million. R&D expenses were down slightly on lower legacy clinical trial fees while G&A rose 48% on expenses related to legal costs, recruting fees and proxy related fees from the company's special stockholders' meeting. Net loss was ($8.9) milion or ($19.33) per share, reflecting 461,000 average diluted shares outstanding.

As of December 31, 2019, cash stood at $7.0 million and debt remained at zero. Cash burn was ($8.7) million for the year, compared to ($7.5) million in 2018. Cash from financing was a modest $772,000 reflecting the issuance of stock and warrants and the proceeds from warrant exercise. Following the end of the reporting period, Phio announced two capital raises of $1.74 million and $8.0 million in gross proceeds. Phio management anticipates cash levels as of March 26, 2020 will be sufficient to fund the company for at least the next 12 months.

Collaborations

One of the bright spots for Phio has been the collaborations forged over the last year. We count five additional relationships or expansions with existing partners that seek to advance the Intasyl platform into immuno-oncology indications using a variety of approaches. Phio's leading efforts include ACT, intra-tumoral injection, chimeric antigen receptor macrophages (CAR-M) among other approaches to develop a combination therapy in immuno-oncology (IO). In March 2020, the company added Medigene's expertise to assist in the development of clinical candidates in conjunction with Helmholtz Zentrum München.

Exhibit I – Recent Partnerships and Partnership Expansions[1]

Partner	Focus	Date
Glycostem Therapeutics	Synergies of Intasyl & oNKord for cancer	Mar-19
Helmholtz Zentrum München	T cell & NK cell ACT for solid tumors	Aug-19
Carisma	Intasyl & CAR-Macrophages	Sep-19
Karolinska Institutet	Intasyl & T/NK cells + others	Nov-19
Medigene + HZM expansion	Intasyl & TCR to enhance IO efficacy	Mar-20

New Intasyl Data

On March 31st, Phio reported the accumulation of preclinical findings that demonstrate Intasyl-enabled compounds are effective to reduce immunosuppression in the tumor microenvironment (TME). Details of the findings will be presented at an upcoming scientific conference. A mouse version of PH-762 and PH-894 were injected intra-tumorally into a murine model of hepatocellular carcinoma and compared to a placebo arm. The animals treated with the Intasyl compound exhibited inhibited tumor growth while the placebo-treated animals experienced exponential tumor growth. The work showed that PH-762 and PH-894 can penetrate solid tumors and reduce tumor growth by activating the immune response in an animal model. PH-762 inhibits PD-1 receptor expression in T cells while PH-894 silences the expression of bromodomain-containing protein 4 (BRD4), which impacts cell differentiation. This compound has demonstrated an ability to improve T cell function and persistence by differentiating T cells into an effector memory phenotype.

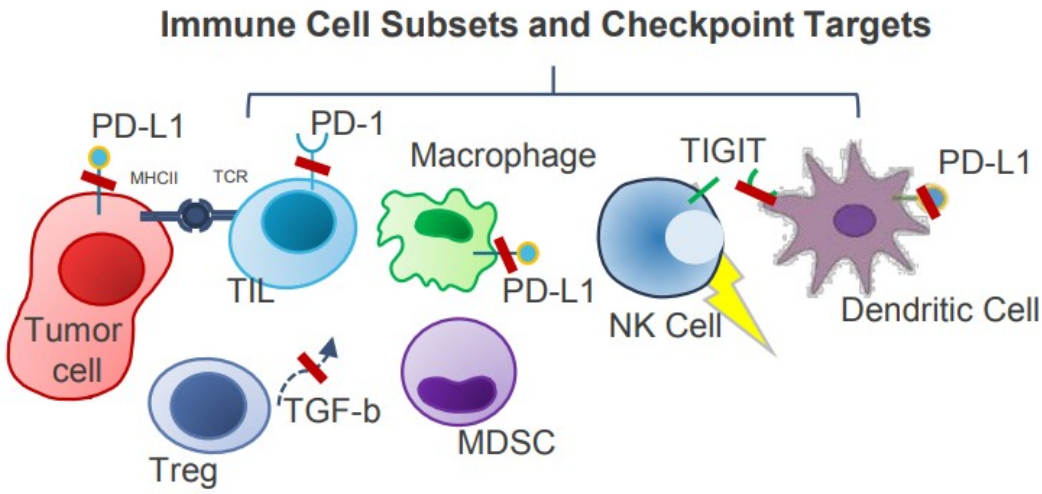
[1] Table created by the author

SITC Posters

Phio presented several posters at the Society for Immunotherapy of Cancer (SITC) 2019 Annual Meeting in November 2019, 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 II – Reprogramming the Tumor Microenvironment[2]



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 III – Phio INTASYL Immuno-Oncology Pipeline[3]

MECHANISM	INDICATION	DISCOVERY	PRECLINICAL	CLINICAL
PD-1 Inhibition – ACT (T cells)	Melanoma (+ others)	PH-762		
PD-1 Inhibition – TME (IT Injection)	Melanoma (+ others)	PH-762		
TIGIT Inhibition – ACT (T cells/NKs)	Various	PH-804		
TIGIT Inhibition – TME (IT Injection)	Various	PH-804		
PD-L1 Inhibition – Cell product (e.g. DC)	Various	PH-790		
PD-L1 Inhibition – TME (IT Injection)	Various	PH-790		
Additional Opportunities: T cell Exhaustion, Cell Metabolism, Innate Immunity	Various	Undisclosed		

[2] Source: Phio Corporate Presentation, September 2019
[3] Source: Phio Corporate Presentation, January 2020

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. Phio was successful in obtaining shareholder approval for a reverse share split which was effected in a ratio of 1:55 on January 14, 2020. Phio is now in compliance with NASDAQ rules.

Capital Raise

In February Phio closed two equity offerings raising gross proceeds of over $9.7 million. The first capital raise provided $1.74 million and the second $8.0 million. This should provide sufficient capital to enter the clinic in the second half of the year and provide sufficient funding to continue operations for the next twelve months or more.

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 – 1H: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 – November 2019
- Expansion of collaboration with Helmholtz Zentrum München & Medigene – March 2020
- IND enabling study results for PH-762 – 2020
- PH-762 (ACT – Melanoma with partner) into clinic – 2H:20
- PH-762 (IT – Melanoma) – 2021
- PH-804 (ACT – with partner) – 2021

Summary

Phio continues to advance its pipeline towards the clinic and engage in additional collaborations. There are many synergies among the targeted indications in preclinical work, which reduces costs and provides the greatest number of ultimate options for Intasyl development. 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 Intasyl platform 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 maintain sufficient cash to support activity for the next year, 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. A partnership 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 maintain a discount to our original 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 and an adjustment for the reverse stock split and issuance of new shares, our target price for Phio moves to $9.00 per share.

PROJECTED FINANCIALS

Phio Pharmaceuticals Corp. - Income Statement

Phio Pharmaceuticals Corp	2018	Q1 A	Q2 A	Q3 A	Q4 A	2019 A	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	$1.0	$4.3	$6.0	$8.5
General & Administrative	$3.2	$1.1	$0.9	$1.1	$1.6	$4.7	$4.5	$4.7
Income from operations	($7.4)	($2.1)	($2.1)	($2.1)	($2.7)	($9.0)	($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)	($2.7)	($8.9)	($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)**	**($2.7)**	**($8.9)**	**($10.5)**	**($13.2)**
Reported EPS	**($99.22)**	**($5.71)**	**($4.62)**	**($4.53)**	**($4.69)**	**($19.33)**	**($3.39)**	**($2.10)**
YOY Growth								
Basic Shares Outstanding	0.128	0.371	0.440	0.462	0.567	0.461	3.10	6.30

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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