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John D. Vandermosten, CFA
312-265-9588 / jvandermosten@zacks.com

scr.zacks.com **10 S. Riverside Plaza, Suite 1600, Chicago, IL 60606**

Phio Pharmaceuticals Corp (PHIO - NASDAQ)

Intasyl Advantage vs. Gene Editing

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 (5/18/2020)	$2.29
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	**26.78**
52-Week Low	**1.60**
One-Year Return (%)	**-90.8**
Beta	**1.88**
Average Daily Volume (sh)	**387,660**
Shares Outstanding (mil)	**4.6**
Market Capitalization ($mil)	**10.5**
Short Interest Ratio (days)	**0.16**
Institutional Ownership (%)	**30.5**
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)
2019	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2020	$0.0 A	$0.0 E	$0.0 E	$0.0 E	$0.0 E
2021					$0.0 E
2022					$0.0 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2019	-$5.71 A	-$4.62 A	-$4.53 A	-$4.69 A	-$19.33 A
2020	-$1.33 A	-$0.73 E	-$0.57 E	-$0.67 E	-$2.93 E
2021					-$2.10 E
2022					-$1.49 E

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WHAT'S NEW

First Quarter 2020 Financial & Operational Update

Phio Pharmaceuticals Corp. (NASDAQ: PHIO) reported first quarter 2020 results and filed its Form 10-Q on May 12, 2020. Year to date, Phio has continued to generate valuable preclinical data supporting Intasyl's use in immuno-oncology and forge new or expanded collaborations with Helmholtz Zentrum München, Medigene, Karolinska Institutet and Carisma Therapeutics. In May, Phio announced participation in several upcoming events to present data to the scientific and investment community. The company was also able to raise additional capital in preparation for clinical trials later this year. Phio is dependent upon its partners for advancing PH-762 for adoptive cell therapy (ACT) and anticipates this candidate will enter the clinic by 2H:20. The company is also advancing its internal program for intra-tumoral injection for the same candidate.

No revenues were recognized for the first quarter, compared with $21,000 in 1Q:19. Total expenses for 1Q:20 were $2.4 million, 9% greater than prior year levels. This was composed of research and development expenditures of $1.2 million and general and administrative expenditures of $1.1 million. R&D expenses were up 12% reflecting increased headcount and the use of an outside contract research organization (CRO) to perform animal studies. G&A rose 6% on a rise in payroll expenses and transfer agent fees for the reverse stock split in January. Net loss was ($2.4) milion or ($1.33) per share on 1.77 million average diluted shares outstanding.

As of March 31, 2020, cash stood at $13.3 million and debt remained at zero. Cash burn was ($2.2) million for the quarter, similar to the amount in the comparable period. Cash from financing was a net $8.5 million reflecting the issuance of stock and warrants and the proceeds from warrant exercise. Following the end of the reporting period, Phio announced an additional capital raise of $4.0 million in gross proceeds. Phio management expects current cash reserves to sustain 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. New and existing partners continue to leverage the Intasyl platform to execute on their own cutting-edge technologies. Phio's leading efforts include ACT, intra-tumoral injection, chimeric antigen receptor macrophages (CAR-M) and the development of a combination therapy in immuno-oncology (IO). In March 2020, the company called upon 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 continuing preclinical evidence of Intasyl-enabled compounds effectively reducing tumor-microenvironment (TME) immunosuppression. 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 Intasyl compound completely inhibited tumor growth in contrast to the placebo-treated animals which 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

Posters

Phio presented a poster on May 12th at the American Society of Gene & Cell Therapy (ASGCT) 2020 Annual Meeting, which was held virtually. The poster highlighted the differences between gene editing and gene silencing to sponsors of adoptive cell therapy (ACT), making the case for using Intasyl to improve success in efforts to overcome resistance in the treatment of solid tumors.

The poster highlighted the differences between CRISPR Cas9 and RNAi, emphasizing Intasyl's chemical modifications that enable uptake of the siRNA. PH-762's ability to transiently silence 90% or more of PD1 expression in human T cells was compared to CRISPR Cas9's permanent 20% gene disruption of PD-1 in human TCR T cells and 50% protein silencing of PD-1 in CD19 CAR-T. The poster also noted the more advanced regulatory status of RNAi, with products already FDA approved for this class compared with the investigational product status of gene editing leaders.

The poster concluded that ACT developers can consider Intasyl and its many advantages when searching for ways to improve the effectiveness of their manufactured cells.

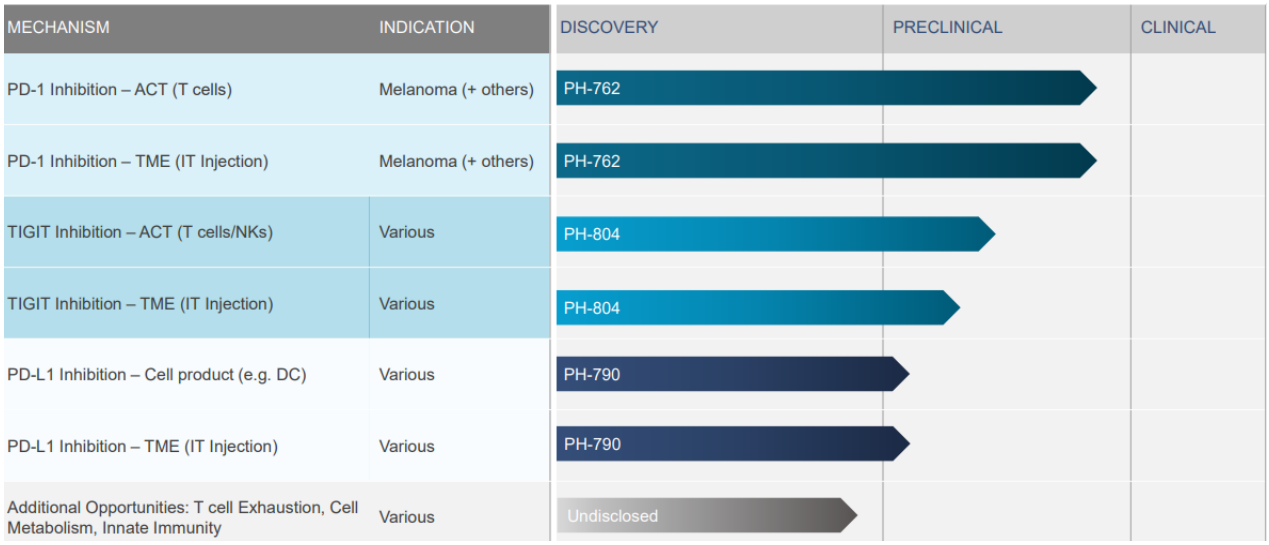
Other abstracts are expected to be shared at upcoming conferences, including the American Society of Clinical Oncology (ASCO) Virtual Scientific Program on May 29th and the American Association for Cancer Research (AACR) on June 22nd. We list the abstract titles for each of these conferences below.

- Intratumoral use of self-delivering RNAi to reprogram the tumor microenvironment and boost the antitumor response
- Intratumoral delivery of mPH-804 (TIGIT targeting INTASYL compound) inhibits tumor growth and confers an inflammatory tumor microenvironment

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]



[2] Source: Phio Corporate Presentation, January 2020

Capital Raise

Phio has closed three capital raises year to date, raising a gross $13.7 million which is expected to support planned operations for the next 12 months. The first capital raise provided $1.74 million, the second, $8.0 million and the third, $4.0 million. This should provide sufficient cash to enter the clinic in the second half of the year and fund operations for the next twelve months or more.

Milestones:

- Partnership/Sale of Dermatology and Ophthalmology Programs – TBD
- 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 should reduce costs and provide 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 domain. 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 provide both 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. We remind investors that we attach a value to development programs as they enter the clinic and will assign a value to PH-762 and PH-804 at that time. We maintain our target price of $9.00 per share.

PROJECTED FINANCIALS

Phio Pharmaceuticals Corp. - Income Statement

Phio Pharmaceuticals Corp	2019 A	Q1 A	Q2 E	Q3 E	Q4 E	2020 E	2021 E	2022 E
Total Revenues	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
YOY Growth								
Research & Development	$4.3	$1.2	$1.2	$1.5	$1.8	$5.7	$8.5	$8.5
General & Administrative	$4.7	$1.1	$1.0	$1.1	$1.3	$4.5	$4.7	$4.9
Income from operations	($9.0)	($2.4)	($2.2)	($2.6)	($3.1)	($10.3)	($13.2)	($13.4)
Operating Margin	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*100%*
Interest Income	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Other Income	$0.1	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($8.9)	($2.4)	($2.2)	($2.6)	($3.1)	($10.3)	($13.2)	($13.4)
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	**($8.9)**	**($2.4)**	**($2.2)**	**($2.6)**	**($3.1)**	**($10.3)**	**($13.2)**	**($13.4)**
Reported EPS	**($19.33)**	**($1.33)**	**($0.73)**	**($0.57)**	**($0.67)**	**($2.93)**	**($2.10)**	**($1.49)**
YOY Growth								
Basic Shares Outstanding	0.461	1.77	3.00	4.60	4.61	3.50	6.30	9.00

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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