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Reviva Pharmaceuticals, Inc. (RVPH - NASDAQ)

Phase III Initiation Before Year End

Based on our DCF model and a 15% discount rate, Reviva is valued at approximately $16.00 per share. Our model applies a 50% probability of ultimate approval and commercialization for RP5063 for schizophrenia. The model includes contributions from the United States and rest of world.

Current Price (11/15/2021)	$3.68
Valuation	**$16.00**

Reviva is a research and development pharmaceutical company with two portfolio compounds targeting nine indications. The candidates address multiple related mental disorders, rare diseases & other categories of unmet need. Reviva's lead indication in schizophrenia with Brilaroxazine (RP5063) will begin a Phase III trial in 2021. Complementary Phase II work with RP5063 in bipolar disorder and depression may also begin.

Brilaroxazine is a novel, multimodal serotonin, dopamine & nicotinic receptors modulator with an improved efficacy & side effect profile compared with other antipsychotics. The drug class is established with over $10 billion in revenues. Unmet needs persist in the category, related to efficacy, side effects & discontinuation. Brilaroxazine's improved profile is expected to carve material share from the existing market and expand into untreated patients. Secondary candidate, RP1208, is in preclinical studies for depression and obesity.

We expect three Phase III trials for RP5063 starting in mid-2021, generating registrational data by 2024 assuming a sufficient capital raise. After agency review in the US and other jurisdictions, we anticipate approval to be granted by the FDA in 2025 followed by other territories. Our valuation assumes commercialization in the US and rest of world in 2025 and 2026 respectively.

OUTLOOK

SUMMARY DATA

52-Week High	**$15.10**
52-Week Low	**$3.29**
One-Year Return (%)	**-66.2**
Beta	**-0.10**
Average Daily Volume (sh)	**106,959**
Shares Outstanding (mil)	**14.0**
Market Capitalization (€mil)	**51.5**
Short Interest Ratio (days)	**3.22**
Institutional Ownership (%)	**24.7**
Insider Ownership (%)	**38.8**
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 2020 Estimate	**N/A**
P/E using 2021 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 US$)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2021	$0.0 A	$0.0 A	$0.0 A	$0.0 E	$0.0 E
2022					$0.0 E
2023					$0.0 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2020	-$0.27 A	-$0.31 A	-$0.24 A	-$0.16 A	-$1.24 A
2021	-$0.10 A	-$0.12 A	-$0.12 A	-$0.26 E	-$0.65 E
2022					-$0.76 E
2023					-$0.73 E

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WHAT'S NEW

Third Quarter 2021 Financial and Operational Results

On November 15, 2021, Reviva Pharmaceutical Holdings, Inc. (NASDAQ: RVPH) announced third quarter 2021 financial and operational results and filed its Form 10-Q with the SEC for the period ending September 30, 2021. Reviva is on the cusp of launching its Phase III Brilaroxazine trial for acute schizophrenia which is expected to start before year end.

Recent highlights include:

- Report of positive Phase II clinical trial results for acute schizophrenia - April 2021
- Engagement of clinical research organization (CRO) for schizophrenia trial - 3Q:21
- Close of $30 million public offering - June 2021
- Addition of company to Russell Microcap Index - June 2021

Reviva generated no revenues in the third quarter 2021 and expended ($2.5) million in operational costs producing a net loss of ($2.3) million or ($0.12) on a per share basis.

For the quarter ending September 30, 2021 and versus the same ending September 30, 2020:[1]

- Research & development expense was $1.4 million vs. $1,000, primarily attributed to higher drug development costs, salary expenditures and increased consulting costs;
- General & administrative expenses totaled $1.1 million, increasing 106% from $511,000, primarily on account of a $214,000 increase in salaries and a $344,000 rise in insurance cost due to higher premiums;
- Gain on remeasurement of warrant liabilities was $200,000, absent in the comparable period;
- No interest expense was recognized vs $146,000 on liquidation of debt;
- Net loss was ($2.3) million vs ($659,000), or ($0.12) and ($0.24) per share, respectively.

At the end of the reporting period, Reviva held $33.5 million in cash on its balance sheet, buoyed by the $34.5 million capital raise completed in June 2021. Cash burn was ($6.8) million year-to-date. Management expects this amount to sustain the firm into 4Q:22.

Capital Raise

On May 26, Reviva announced a $30 million capital raise, which included an overallotment of $4.5 million. The capital raise closed on June 1, 2021 selling 9.2 million equity shares and prefunded warrants, which included the full exercise of the overallotment option. The offering price was $3.75 per share and the effort raised a gross $34.5 million in proceeds. After subtracting underwriter costs of $3.0 million, net proceeds of $31.5 million remained to fund corporate operations. The transaction included 6.9 million warrants, granted at a rate of 0.75 warrant per equity share or prefunded warrant. Exercise price for the warrants is $4.125 with a five year duration, expiring on June 1, 2026. The funds from the capital raise will be used to continue the clinical development of Brilaroxazine (RP5063) for the treatment of acute and maintenance schizophrenia, for working capital and other general corporate purposes.

Phase III Trial Details

With the close of the financing in June 2021, Reviva is waiting for its Phase III protocol to be affirmed by the FDA, to finalize trial locations and obtain Institutional Review Board (IRB) approval at each of the sites. The contract research organization (CRO) has been selected and once the protocol is cleared, we expect the trial to start shortly after. There are now three sites identified that have received IRB approval and Reviva expects a total of 35 sites to be active around the globe. Sufficient amounts of Brilaroxazine are available to start and complete the trial.

[1] Note: comparisons use prior year data as provided in the 10-Q.

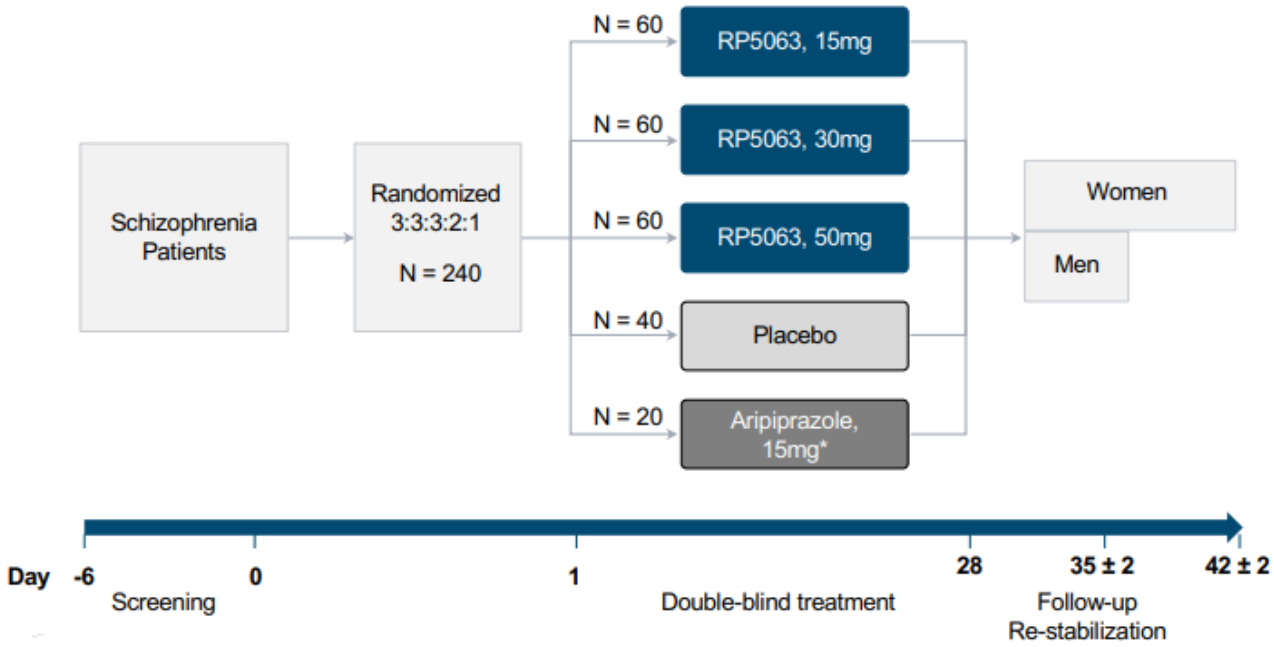
As we elaborated in our initiation, two Phase III trials will be launched including a four week efficacy study and a one year safety study in schizophrenia. Based on the construction of the study, which could be impacted by exogenous events, we see the trial lasting 16 – 18 months with results available in 2023.

Full Details of Phase II Trial in Acute Schizophrenia

On April 26, Reviva issued a press release describing full details of its Phase II trial of Brilaroxazine in acute schizophrenia. Among highlights from the study results, the trial met safety and efficacy endpoints, met primary endpoint of reduction in PANSS[2], achieved well-rounded effects by reducing both positive and negative symptoms and improving social functioning and cognition, and, perhaps most importantly, presented no metabolic and endocrine side effects[3] and no increase in suicidal ideation compared to placebo.

The trial was a randomized, double-blind, placebo-controlled, multicenter Phase II trial to assess safety and efficacy of Brilaroxazine in acute exacerbation of schizophrenia or schizoaffective disorder. The trial enrolled 234 subjects. Total PANSS was reduced by 20 points from baseline, statistically significant when compared to placebo.

Exhibit I – Phase II Schizophrenia Trial Design[4]



Milestones

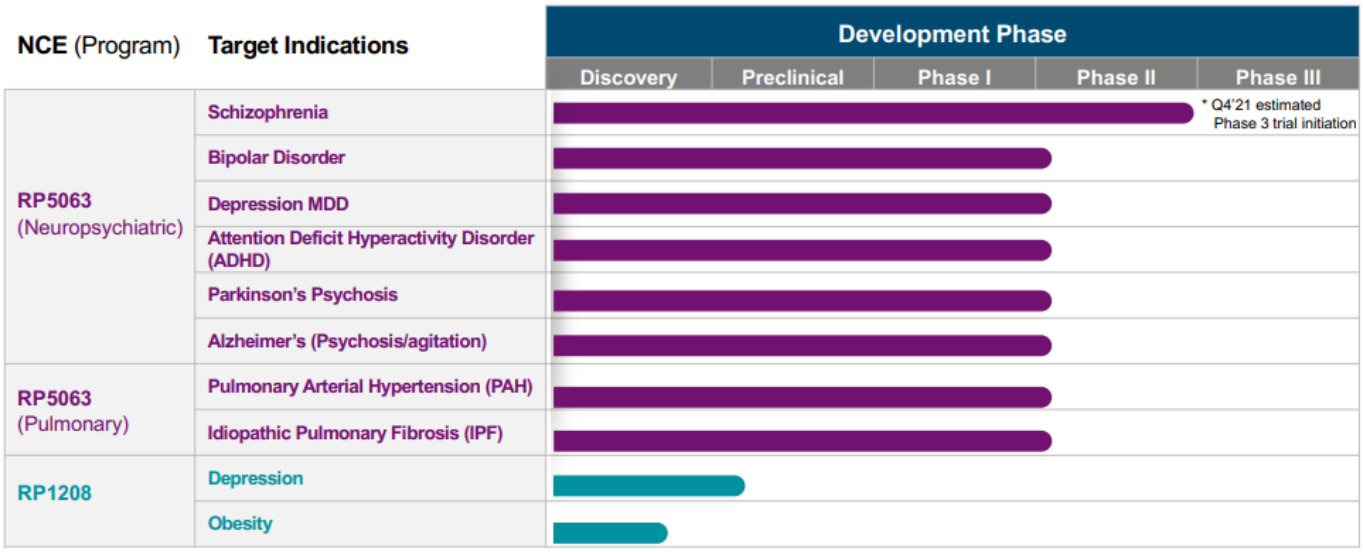
Reviva has a number of upcoming milestones that relate to the launch of its Phase III trial in schizophrenia. Preparation for Phase II trials for Brilaroxazine in additional indications is underway with regulatory work expected in the next quarters and launch next year. See below for additional detail on recent and upcoming achievements:

- **Completion of $34.5 million public offering – June 2021**
- **Phase III trial design finalization with FDA – 4Q:21**
- **Launch of Phase III RP5063 trial in acute and maintenance schizophrenia – 4Q:21**
- **Regulatory submissions for Pulmonary Arterial Hypertension (PAH) and Idiopathic Pulmonary Fibrosis (IPF) – 1Q:22**
- **Launch of PAH and IPF Phase II trials – 2022**
- **Phase III schizophrenia topline data – 1Q:23**

[2] Positive and Negative Syndrome Scale (PANSS)
[3] Metabolic and endocrine side effects include weight gain, elevated blood sugar, increase in lipids, hypothyroidism, and hyperprolactinemia
[4] Source: Reviva Pharmaceuticals July 2021 Corporate Presentation.

Company Pipeline

Exhibit II – Reviva Pipeline[5]



Valuation

We adjust our valuation to reflect the issuance of new shares, prefunded warrants and warrants in the May public offering. We also increase our estimates for research and development expenses. These changes to our discounted cash flow model generate an updated target price of $16 per share.

Summary

Reviva provides a financial update in its third quarter report and is on the cusp of launching its Phase III trial in schizophrenia. Reviva generated no revenues in the third quarter 2021 and expended ($2.5) million in operational costs producing a net loss of ($2.3) million or ($0.12) on a per share basis. At the end of the reporting period, Reviva held $33.5 million in cash on its balance sheet, buoyed by the $34.5 million capital raise completed in June 2021. Cash burn was ($6.8) million year-to-date. Management expects cash levels to sustain the firm into 4Q:22.

Reviva is waiting on a response from the FDA regarding its protocol for the Phase III trial in acute schizophrenia prior to launching the effort in the next few weeks. Upcoming milestones for 2021 also include regulatory submissions to the FDA for Phase II studies in pulmonary arterial hypertension and idiopathic pulmonary fibrosis. In parallel, management is pursuing partnerships to support pipeline development and non-dilutive financing opportunities.

Our retrospective analysis of Brilaroxazine's safety and efficacy in comparison with 32 other antipsychotics places Reviva's candidate in a favorable position showing above average efficacy and lower side effects compared with blockbuster antipsychotics. As many patients discontinue their medication due to side effects, remaining on treatment is key to ensuring a benefit. RP5063 may address an unmet need for patients with schizophrenia and other mental disorders, providing a safer, more tolerable and more effective treatment than what is now available. We adjust our valuation to reflect the updated share balance and assign a valuation of $16.00 per share.

[5] Source: Reviva Pharmaceuticals July 2021 Corporate Presentation.

PROJECTED FINANCIALS

Reviva Pharmaceutical. - Income Statement[6]

Reviva Pharmaceuticals	2020 A	Q1 A	Q2 A	Q3 A	Q4 E	2021 E	2022 E	2023 E
Total Revenues ($US ,000)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth								
Research & Development	$295	$391	$374	$1,423	$3,820	$6,009	$10,500	$9,250
General & Administrative	$2,140	$1,481	$1,416	$1,053	$988	$4,938	$4,202	$5,850
Income from operations	($2,435)	($1,872)	($1,790)	($2,477)	($4,808)	($10,947)	($14,702)	($15,100)
Operating Margin								
Other Income (Expense)	($1,348)	$924	$186	$200	($101)	$1,208	($422)	($441)
Pre-Tax Income	($3,783)	($949)	($1,605)	($2,277)	($4,909)	($9,739)	($15,124)	($15,541)
Provision for Income Tax	$1	$1	$4	$0	$0	$5	$0	
Tax Rate	*0.0%*					*0.0%*	*0.0%*	
Net Income	**($3,783)**	**($949)**	**($1,608)**	**($2,277)**	**($4,909)**	**($9,744)**	**($15,124)**	**($15,541)**
Net Margin	*# DIV/0!*	*# DIV/0!*	*# DIV/0!*	*# DIV/0!*	*# DIV/0!*	*# DIV/0!*	*# DIV/0!*	*# DIV/0!*
Reported EPS	**($1.24)**	**($0.10)**	**($0.12)**	**($0.12)**	**($0.26)**	**($0.65)**	**($0.76)**	**($0.73)**
YOY Growth	*304%*	*-62.0%*	*-59.4%*	*-48.2%*	*56.7%*	*-47%*	*16%*	*-0.03287335*
Basic Shares Outstanding	3,062	9,232	12,875	18,456	19,100	14,916	20,000	21,250

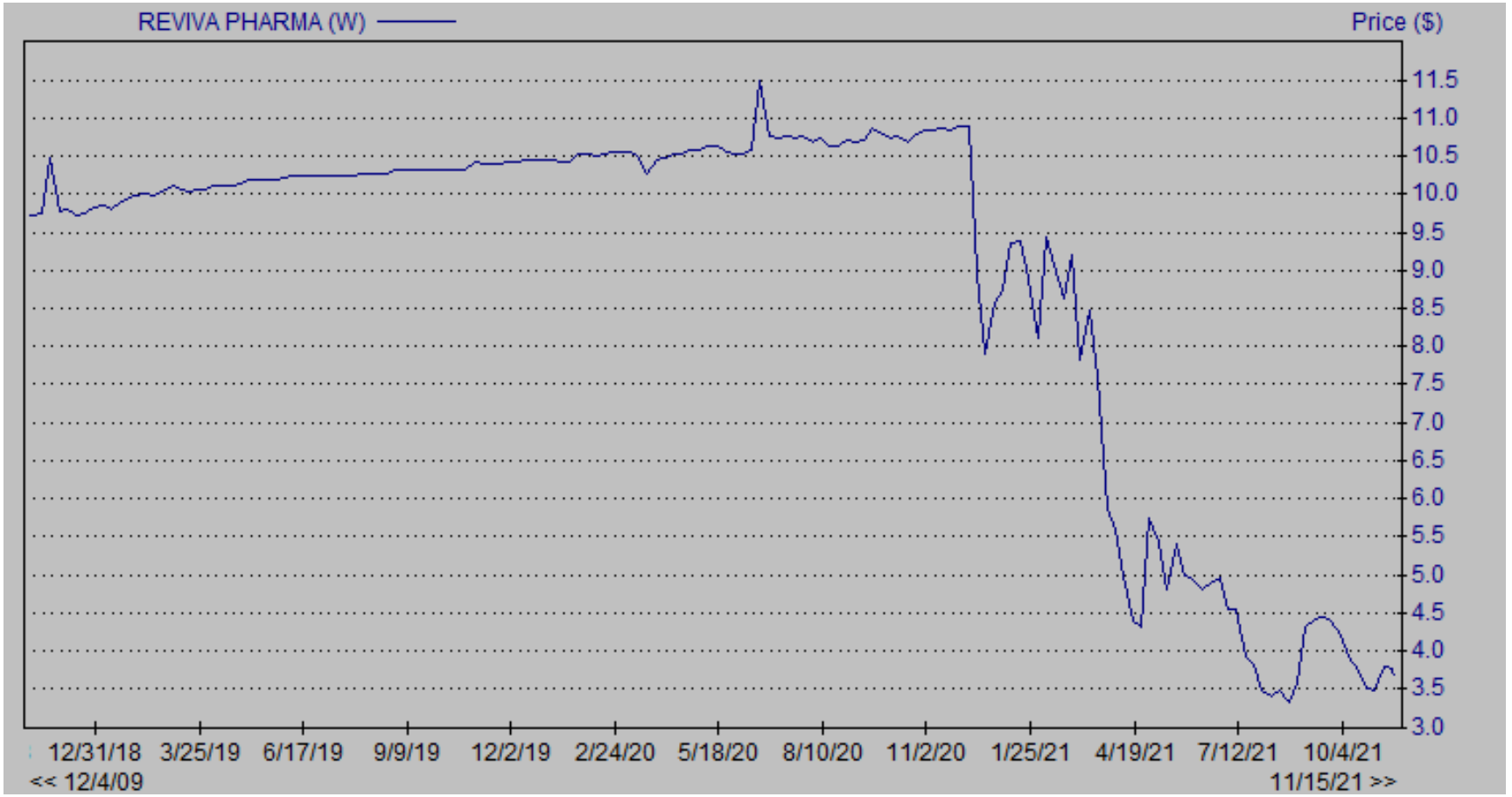
Source: Company Filing // Zacks Investment Research, Inc. Estimates

[6] Historical financial statement information presents data as originally reported.

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HISTORICAL STOCK PRICE

Reviva Pharmaceutical Holdings, Inc. – Share Price Chart[7]



[7] Source: Zacks Research System

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