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Reviva Pharmaceuticals, Inc. (RVPH: NASDAQ)

Enthusiasm Abounds with Brilaroxazine

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 (11/16/2022)	$4.33
Valuation	**$16.00**

OUTLOOK

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) began a Phase III trial in 2022. Complementary Phase II work with RP5063 in ADHD and PAH 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.

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.

SUMMARY DATA

52-Week High	**$6.10**
52-Week Low	**$0.53**
One-Year Return (%)	**16.0**
Beta	**0.2**
Average Daily Volume (sh)	**1,616,296**
Shares Outstanding (mil)	**20.4**
Market Capitalization ($mil)	**88.3**
Short Interest Ratio (days)	**1.3**
Institutional Ownership (%)	**4.5**
Insider Ownership (%)	**26.9**
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 2022 Estimate	**N/A**
P/E using 2023 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)
2021	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2022	$0.0 A	$0.0 A	$0.0 A	$0.0 E	$0.0 E
2023					$0.0 E
2024					$0.0 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2021	-$0.10 A	-$0.12 A	-$0.12 A	-$0.19 A	-$0.58 A
2022	-$0.40 A	-$0.29 A	-$0.18 A	-$0.27 E	-$1.17 E
2023					-$0.73 E
2024					-$0.54 E

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WHAT'S NEW

Third Quarter 2022 Financial and Operational Results

On November 14, 2022, Reviva Pharmaceutical Holdings, Inc. (NASDAQ: RVPH) reported third quarter 2022 financial and operational results and filed its Form 10-Q with the SEC. Reviva conducted a capital raise, benefitted from a dramatic increase in share price and participated in several investor conferences since our second quarter report. In late October the company provided an update on the RECOVER trial noting that enrollment had exceeded 30% of target with subjects now added in Europe. Further enrollment is expected to begin at sites in India before year end and management reiterates an expected topline announcement in mid-2023. Reviva is also developing protocols for two Phase IIa trials in ADHD and PAH that will launch upon receipt of non-dilutive funding.

Highlights for 2022:

- Receipt of "May Proceed" letter from the FDA for Brilaroxazine - January 2022
- First patients dosed in Phase III RECOVER trial - February 2022
- KOL webinar on Brilaroxazine for schizophrenia hosted – May 2022
- Presentation at multiple investor conferences – May/June 2022
- Dr. Bhat participates in RedChip Interview – September 2022
- Annual shareholder meeting – November 2022
- 30% enrollment reached – October 2022

Reviva generated no revenues in 3Q:22 and expended ($3.6) million in operational costs, producing a net loss of ($3.5) million or ($0.18) on a per share basis.

For the quarter ending September 30, 2022 and versus the same period a year prior:

- Research & development expense totaled $2.3 million, up 62% from $1.4 million, primarily attributed to greater Phase 3 clinical trial activity, higher drug development costs, an increase in preclinical and other clinical expenses, and increases in salary;
- General & administrative expenses totaled $1.3 million, rising 19% from $1.1 million, primarily attributable to an increase in consultant and professional fees;
- Gain on remeasurement of warrant liabilities was zero versus $200,000;
- Interest income was $49,500 which increased over prior year levels due to higher interest rates;
- Net loss was ($3.5) million vs ($2.3) million, or ($0.18) and ($0.12) per share, respectively.

At the end of the reporting period, Reviva held $23.2 million in cash on its balance sheet. Management expects this amount to sustain the firm through at least the end of next year. 3Q:22 cash burn was ($4.0) million and cash contributions from financing were $7.8 million which was attributable to the September equity offering. Proceeds from this raise and other non-dilutive financing may enable Phase IIa studies this year in bipolar disorder, MDD, and ADHD. We expect that some of the lower priced warrants may be exercised on the substantial increase in share price over the last few months, which should contribute additional cash to Reviva's coffers.

Registered Direct Offering

In early September, Reviva announced that it had entered into a private placement for the sale of 3.4 million shares of stock or prefunded warrants at a price of $2.53/unit. The transaction raised a gross $8.5 million. 3.4 million warrants were issued to each unitholder with an exercise price of $2.40 and a duration of five years. Proceeds from the transaction will be used to advance development of brilaroxazine and other pipeline assets.

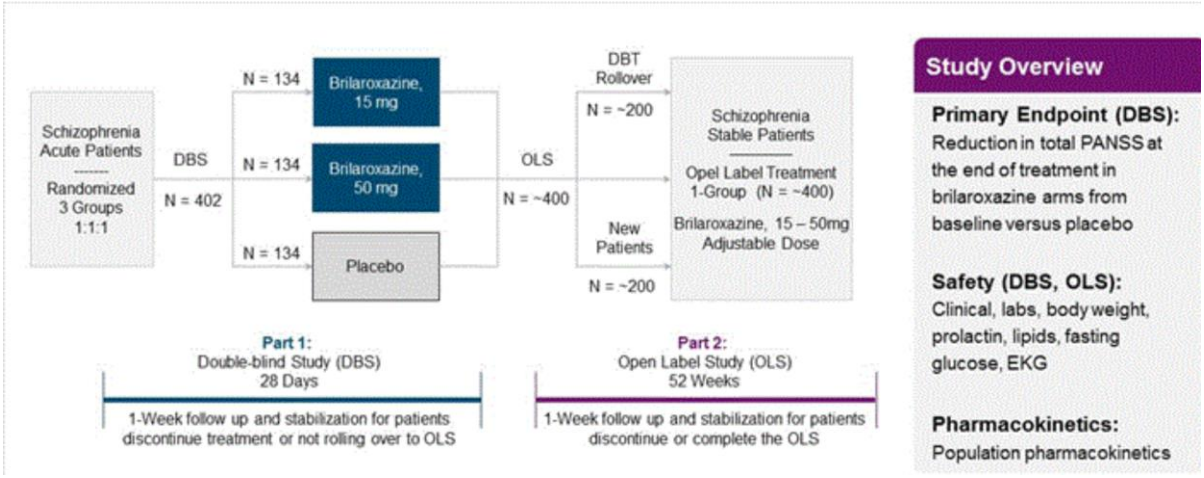
RECOVER Phase III Trial

Reviva announced on January 10, 2022 the receipt of a May Proceed letter from the FDA allowing the start of the pivotal Phase III clinical trials for brilaroxazine in schizophrenia. Reviva's Phase III trial, designated RECOVER (NCT05184335). is now underway and consists of a four-week efficacy study followed by a one-year safety exten-

sion. The trial will target enrollment of 400 subjects, which as of November 2022 was over 30% enrolled and progressing ahead of schedule. We expect the trial to last 16 – 18 months with results available mid-2023.

Brilaroxazine will be administered at fixed doses of 15 mg or 50 mg once daily. The study will assess both dose levels over 28 days in the double-blind phase in acute schizophrenia for a total of three arms, randomized 1:1:1, including placebo. In the 52-week open-label extension in stable schizophrenia, subjects will be dosed at 15 mg, 30 mg or 50 mg. Primary outcome measures will be change in total Positive and Negative Syndrome Scale (PANSS) scores from baseline over the 28-day evaluation period. Secondary outcome measures include antipsychotic efficacy using a variety of scales and subscales. In the Phase II REFRESH study, 15mg was the best performing, with the 50mg arm a close second in terms of efficacy.

Exhibit I - RECOVER Trial Design[1]



Inclusion of the 50 mg dose arm will allow therapeutic insight, both in terms of efficacy and safety, in higher doses in a population almost double the size, and will give Reviva an additional opportunity to meet primary endpoints. The open-label cohort will comprise both subjects who participated in the double-blind phase and new (*de novo*) subjects. With a 52-week open-label extension following the 28-day double-blind phase, the trial is expected in total to last 56 weeks. As demonstrated in earlier studies, Brilaroxazine represents class-leading tolerability in terms of side-effects, a significant deterrent to treatment adherence in the patient population suffering from schizophrenia.

Trial Progess
Reviva anticipates several of upcoming milestones that relate to the launch of its Phase III trial in schizophrenia. In July, Reviva announced that 20% of the targeted 400 patients in the schizophrenia trial had been enrolled, 15 sites had been opened and further enrolment was set to begin in Europe and India. By late October, another update was provided publicizing over 30% enrollment in the RECOVER trial and enrollment around the globe. No treatment-related serious adverse events or major safety and tolerability concerns have been observed.

Milestones

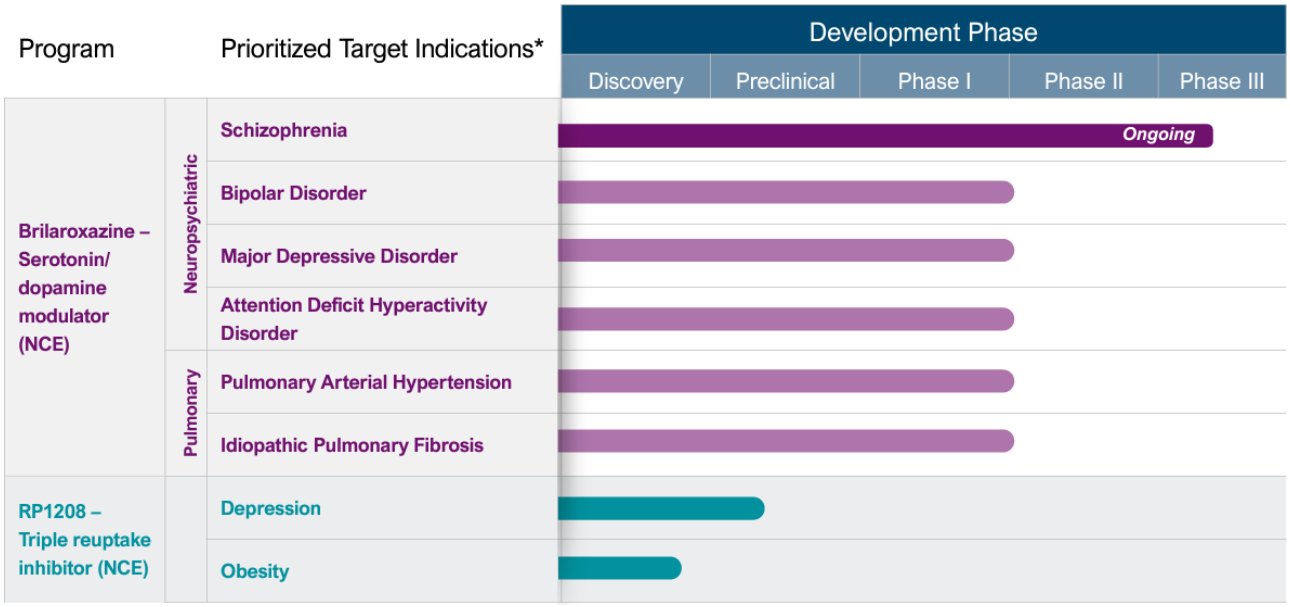
Preparation for Phase II trials for Brilaroxazine in additional indications is underway with regulatory work expected in the next quarters followed by launch, pending funding. We provide additional detail on recent and anticipated achievements below:

- Developing Phase II protocols for studies in PAH and ADHD – 2022/2023
- RECOVER sites in India open – 4Q:22
- Estimated last patient enrolled in RECOVER – March 2023
- Estimated last patient last visit in RECOVER – April 2023
- Phase III schizophrenia RECOVER topline data – mid-2023
- Launch further studies in new indications – 2023
- Pursue strategic partnerships to support pipeline development - 2023

[1] Reviva 2021 10-K

Company Pipeline

Exhibit II – Reviva Pipeline[2]



Summary

Reviva announced third quarter results and filed its Form 10-Q with the SEC. 2022 has seen the launch of the Phase III RECOVER trial for RP5063 in acute exacerbation of schizophrenia. The first patients were enrolled in February 2022, 30% enrollment was achieved in October and topline data is expected in mid-2023.

With the start of the pivotal trial, spending has accelerated with operational costs of $3.6 million in the quarter and cash burn of ($4.0) million. Reviva should have sufficient cash to make it through to the end of RECOVER and then some. We could also see additional funds contributed from warrant exercise due to the sharp upward move in the stock. Non-dilutive funding from partnerships and grants are also being considered. Reviva's lead candidate, Brilaroxazine, represents class-leading tolerability in an indication where side effects deter treatment adherence. We maintain our valuation of $16.00 per share.

[2] Source: Reviva Pharmaceuticals October 2022 Corporate Presentation.

PROJECTED FINANCIALS

Reviva Pharmaceutical Holdings Inc. - Income Statement[3]

Reviva Pharmaceuticals	2021 A	Q1 A	Q2 A	Q3 A	Q4 E	2022 E	2023 E	2024 E
Total Revenues ($US ,000)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth								
Research & Development	$4,852	$5,830	$4,514	$2,306	$4,200	$16,850	$9,250	$7,000
General & Administrative	$5,253	$1,620	$1,005	$1,257	$1,425	$5,307	$5,850	$6,100
Income from operations	($10,105)	($7,450)	($5,519)	($3,563)	($5,625)	($22,158)	($15,100)	($13,100)
Operating Margin								
Other Income (Expense)	$1,589	$89	$186	$50	$0	($422)	($441)	($410)
Pre-Tax Income	($8,516)	($7,361)	($5,334)	($3,513)	($5,625)	($22,580)	($15,541)	($13,510)
Provision for Income Tax	$6	$4	$7	$2	$0	$12		
Tax Rate	*0.0%*					*0.0%*		
Net Income	**($8,522)**	**($7,365)**	**($5,341)**	**($3,515)**	**($5,625)**	**($22,592)**	**($15,541)**	**($13,510)**
Net Margin	*# DIV/0!*	*# DIV/0!*	*# DIV/0!*	*# DIV/0!*	*# DIV/0!*	*# DIV/0!*	*# DIV/0!*	*# DIV/0!*
Reported EPS	**($0.58)**	**($0.40)**	**($0.29)**	**($0.18)**	**($0.27)**	**($1.17)**	**($0.73)**	**($0.54)**
YOY Growth	*-53%*	*287.9%*	*131.5%*	*47.9%*	*38.0%*	*103%*	*-0.37520117*	*-0.26108359*
Basic Shares Outstanding	14,791	18,467	18,467	19,270	21,000	19,301	21,250	25,000

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

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

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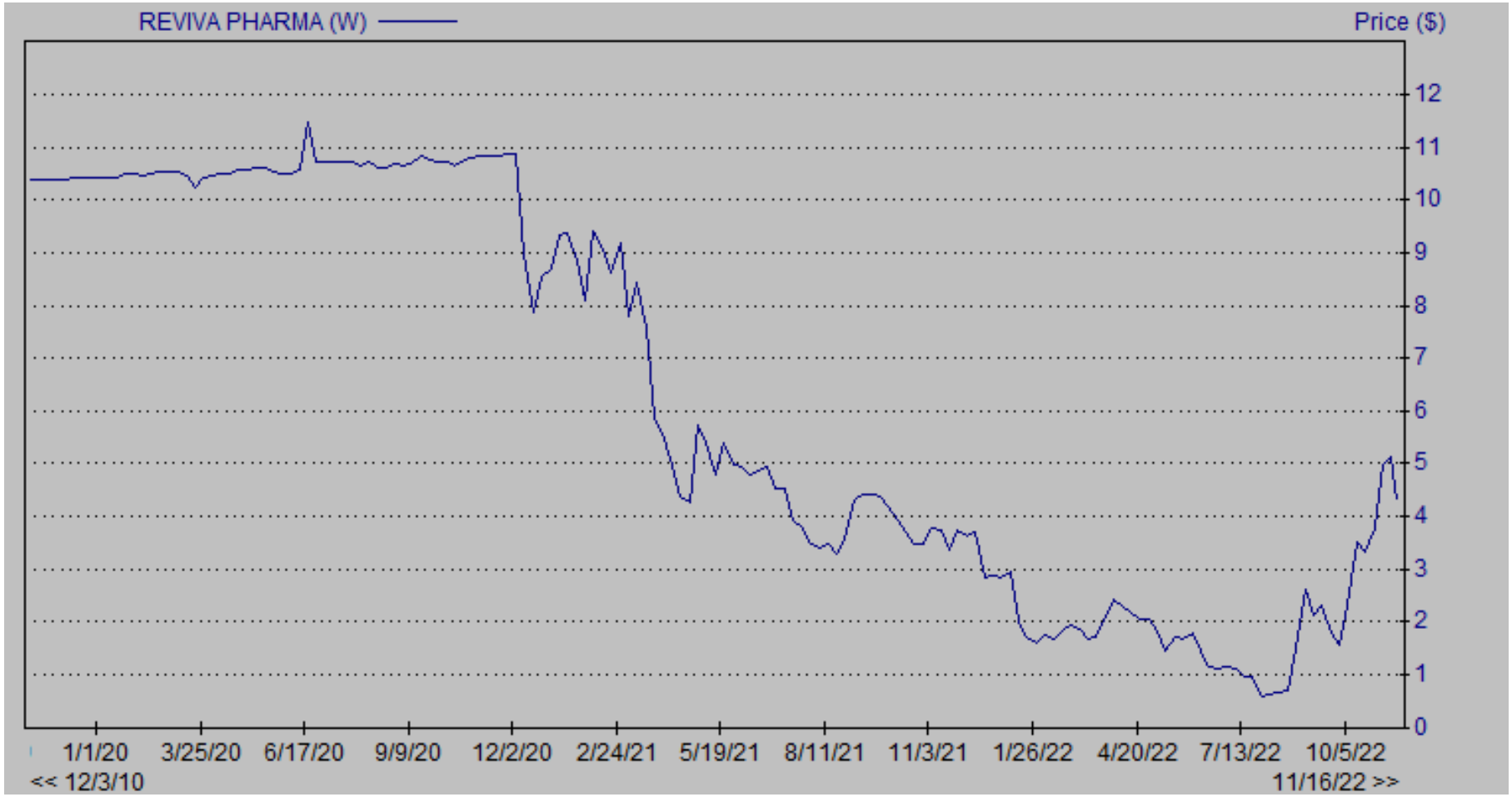
HISTORICAL STOCK PRICE

Reviva Pharmaceutical Holdings, Inc. – Share Price Chart[4]



[4] Source: Zacks Research System

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