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Reviva Pharmaceuticals, Inc. (RVPH: NASDAQ)

RVPH: RECOVER Enrollment Complete

Our valuation relies on a DCF model employing a 15% discount rate and applies a 50% probability of approval and commercialization for RP5063 in schizophrenia. The model includes contributions from the United States and rest of world.

Current Price (8/17/2023)	$4.02
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 need persists in the category, related to efficacy, side effects & drug regimen compliance. 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	**$9.25**
52-Week Low	**$0.71**
One-Year Return (%)	**451**
Beta	**0.1**
Average Daily Volume (sh)	**198,232**
Shares Outstanding (mil)	**24.0**
Market Capitalization ($mil)	**96.5**
Short Interest Ratio (days)	**6.4**
Institutional Ownership (%)	**6.1**
Insider Ownership (%)	**21.9**
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 2023 Estimate	**N/A**
P/E using 2024 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)
2022	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2023	$0.0 A	$0.0 A	$0.0 E	$0.0 E	$0.0 E
2024					$0.0 E
2025					$0.0 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2022	-$0.40 A	-$0.29 A	-$0.18 A	-$0.40 A	-$1.25 A
2023	-$0.30 A	-$0.55 A	-$0.28 E	-$0.19 E	-$1.28 E
2024					-$0.82 E
2025					-$0.76 E

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WHAT'S NEW

2Q:23 Financial and Operational Results

On August 15, 2023, Reviva Pharmaceutical Holdings, Inc. (NASDAQ: RVPH) reported 2Q:23 financial and operational results and filed its Form 10-Q with the SEC. Since our previous update in May, Reviva has presented at scientific and investor conferences and was added to the Russell Microcap Index. In an August 17th press release, Reviva announced that it had completed enrollment for its Phase III RECOVER study for brilaroxazine in schizophrenia and that it expects to report topline data in October.

Looking ahead, management expects to complete a capital raise to support the confirmatory Phase III study evaluating brilaroxazine in schizophrenic patients and to several Phase II candidates. These programs seek to address Major Depressive Disorder (MDD), Attention-deficit/hyperactivity disorder (ADHD) and psoriasis.

Highlights for 2023:

- Completion of multiple parallel studies in support of schizophrenia program – March
- Added to Russell Microcap index - June
- RECOVER full enrollment reached – August

Reviva generated no revenues in 2Q:23 and expended ($12.1) million in operational endeavors, producing a net loss of ($12.4) million or ($0.55) on a per share basis. For the quarter ending June 30, 2023 and versus the same prior year period:

- Research & development expense totaled $9.0 million, doubling from $4.5 million, primarily attributed to higher Phase III clinical trial expenses and drug development costs, and increases in stock-based compensation, safety and toxicology expense and salary costs. These increases were partially offset by lower manufacturing and testing expense, preclinical expenditures, and recruiting expenses;
- General & administrative expenses totaled $3.1 million, rising 200% from $1.0 million on account of greater stock-based compensation, legal expenses, recruiting expenses, consultant and professional expenses, and salary and board of director compensation. These were partially offset by a decrease in health and commercial insurance;
- Loss on remeasurement of warrant liabilities of ($456,000) resulted from an increase in the value of the share price during the measurement period;
- Net interest income was $90,000 which decreased over prior year levels due to lower cash balances;
- Provision for taxes was $6,000 related to taxable subsidiary revenue operations;
- Net loss was ($12.4) million vs ($5.3) million, or ($0.55) and ($0.29) per share, respectively.

At the end of June 2023, Reviva held $11.2 million in cash on its balance sheet. Management expects this amount to sustain the firm until the fourth quarter of this year. 2Q:23 cash burn was ($5.3) million and cash contributions from financing were $5.2 million representing proceeds from exercise of warrants.

Summary of Scientific and Investor Conferences

- Poster presentation at Society of Biological Psychiatry convention – April 29, 2023
- AGP's Virtual Healthcare Conference – May 23, 2023
- Benchmark Virtual Healthcare House Call Conference – May 23, 2023
- American Society for Pharmacology and Experimental Therapeutics poster presentation – May 2023
- International Societies for Investigative Dermatology (psoriasis) – May 2023
- Annual Scientific Convention of the Society of Biological Psychiatry – May 2023
- American Thoracic Society International Conference (IPF) – May 2023
- Maxim Group Virtual Healthcare Conference – June 2023
- H.C. Wainwright Neuropsychiatry Virtual Conference – June 2023

Schizophrenia Key Opinion Leader Event

On May 2nd, 2023, Reviva hosted a key opinion leader (KOL) event featuring Larry Ereshefsky PharmD, BCPP, FCCP. He is a retired professor of Psychiatry, Pharmacology and Psychiatry at The University of Texas and Chief Scientific Officer and owner of Follow the Molecule LLC. The event included an introduction by Reviva CEO Laxminarayan Bhat, PhD, a review of antipsychotics, the unmet need and translational aspects by Dr. Ereshefsky then a review of brilaroxazine by Dr. Bhat followed by a question-and-answer session.

Dr. Ereshefsky began with a review of the clinical features of schizophrenia, identifying both the positive and negative symptoms that appear in those suffering from the affliction. Due to the debilitating symptoms, patients are not able to fully function at work or in society. Costs related to the physical, psychological, emotional, social and financial aspects run at over an estimated $340 billion broken down into direct health care costs, direct non-health care costs and indirect costs. The largest financial impact is caregiving which makes up a third of the total.

Schizophrenia is a progressive illness that consists of positive symptoms, negative symptoms and cognitive deficits that worsen over time. Multiple neural circuits, receptors and transmitters are implicated in the progression of the disease. A new theme that has come into focus is that there is an immune and inflammatory process that contributes to psychiatric and neurologic disorders. While there are medications available, they do not work very well, have poor tolerability and negative side effects which leads to poor or non-compliance with drug regimens.

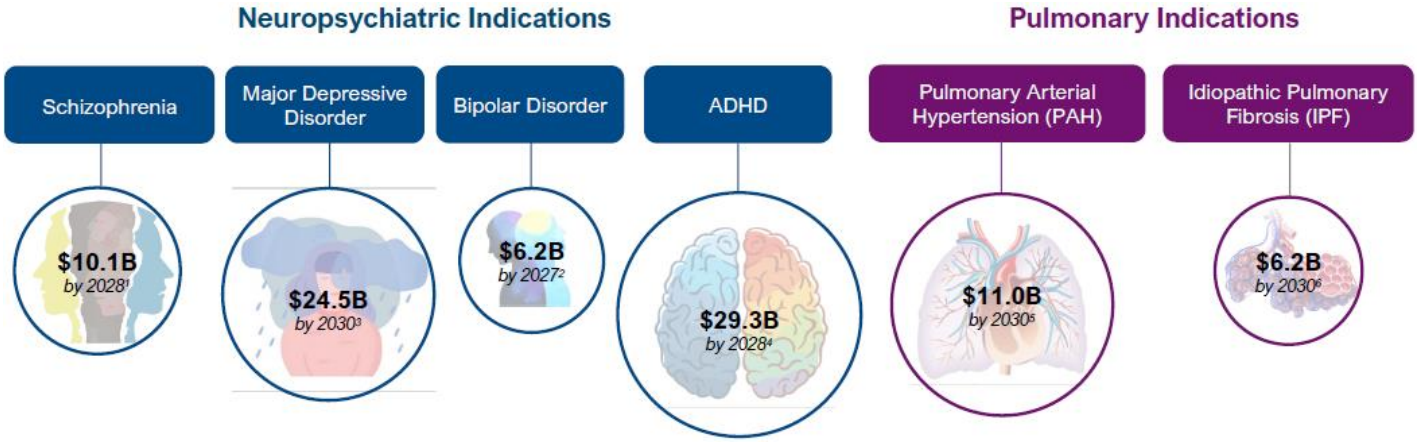
While antipsychotics have improved with new generations, there are still shortcomings, such as metabolic, endocrine, neuroleptic and autonomic side effects that have not been fully resolved. Dr. Ereshefsky's presentation continued with a technical discussion of brilaroxazine's performance in animal models and its functional activity in a number of dopamine, serotonin and nicotinic receptors in comparison with other approved antipsychotics. Brilaroxazine's mechanism of action suggests that it can temper the inflammatory response and provide another path to addressing the disease.

The presentation continued with a summary of some of the dimensions where brilaroxazine has a favorable profile compared to approved products.

- Reduction in inflammatory cytokines and chemokines in animal models;
- May have lower metabolic side effect profile (weight gain);
- Lower expected levels of drug-drug interaction;
- Less prevalence of extrapyramidal movement disorder;
- Lower sedation levels;
- Additional details provided in related presentation.

A replay of the event is available here.

Exhibit I – Market Opportunity for Brilaroxazine[1]



[1] Reviva Corporate Presentation, KOL Webinar, May 2023

IND Filing for Brilaroxazine in Psoriasis

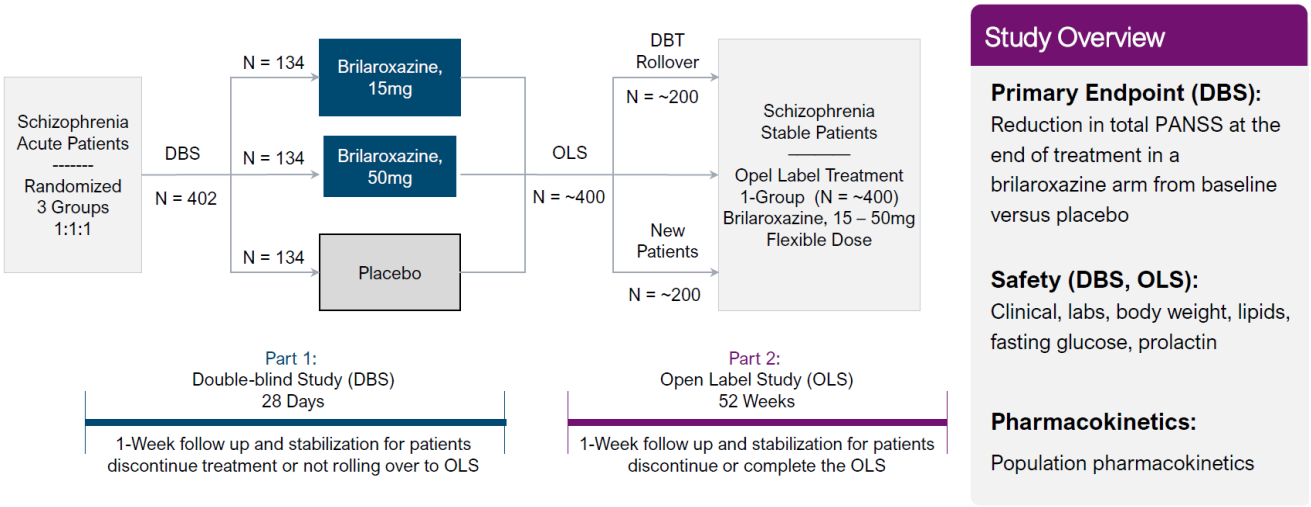
Reviva intends to file an investigational new drug (IND) application with the FDA for brilaroxazine in psoriasis next year. The basis for the filing relies on supportive preclinical data included in a recent poster that was presented in Tokyo, Japan at the ISID conference on May 12th. The poster demonstrates the therapeutic potential of brilaroxazine lipogel, a novel, proprietary lipogel formulation for the topical treatment of psoriasis. It also notes that mental illness is a common co-morbidity for psoriasis and inflammation.

The poster concluded that the brilaroxazine lipogel formulation provides an initial proof of concept for efficacy at the preclinical stage. This was based on results from the psoriasis area and severity index (PASI) score, Baker's score based on hematoxylin and eosin (H&E) skin staining and proinflammatory cytokines. The work in the study supports D and 5-HT receptors as viable psoriasis targets and offers a first look at changes indicating anti-inflammatory, anti-fibrotic, and anti-proliferative effects. Details and images of the analysis are found the poster link. A composition of matter patent has been filed for the associated brilaroxazine-lipogel formulation in the psoriasis indication.

RECOVER Phase III Trial

As of mid-August 2023, Reviva has fully enrolled its Phase III, RECOVER (NCT05184335), trial, ultimately enrolling 402 patients. Subjects have been enrolled in the United States (~60%), Europe (~10%) and Asia (~30%). As illustrated in the following exhibit, the trial was designed as a four-week efficacy study followed by a one-year safety extension.

Exhibit II - RECOVER Trial Design[2]



Brilaroxazine was administered at fixed doses of 15 mg or 50 mg once daily. The study assessed 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 are the 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, 15 mg was the best performing, with the 50 mg arm a close second in terms of efficacy.

Inclusion of the 50 mg dose arm will allow therapeutic insight, both in terms of efficacy and safety, of higher doses in the population 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 target patient population.

Top-line data is expected to be reported in October 2023 for the RECOVER trial. A one year open-label extension of the study is active and 50% enrolled. The extension is expected to be completed in the third quarter of 2024.

[2] Source: Reviva Pharmaceuticals July 2023 Corporate Presentation

Milestones

Preparation for Phase II trials for brilaroxazine in additional indications is underway with regulatory work expected in 2H:23 and clinical trial work dependent on funding. Following the release of what we hope are RECOVER's strong data, Reviva will be in a good position to raise additional funds for the second Phase III in schizophrenia and other Phase II trials that are listed in the pipeline. Reviva has prioritized additional work in major depressive disorder (MDD), attention deficit hyperactivity disorder (ADHD) and psoriasis. Since MDD and ADHD are both outpatient studies, Phase II work could be done relatively inexpensively. To move forward to proof of concept studies, psoriasis would need to receive an approved IND and conduct a Phase I. However, this would also be a relatively inexpensive endeavor as much of the safety work has been done for brilaroxazine and there would only need to be psoriasis-specific safety work completed with relatively low numbers of subjects. Each of these indications are exposed to very large markets with existing unmet needs. Brilaroxizine's multimodal mechanism modulates both dopamine and serotonin receptors and has indirect modulation of inflammatory cytokines which may provide anti-inflammatory features supporting expanded use. We provide additional detail on recent and anticipated milestones below:

- Phase III schizophrenia RECOVER topline data – mid-2023
- Submission of Phase II protocols for studies in PAH and ADHD – 2H:23
- Initiation of Phase II studies in ADHD and PAH – 2H:23
- Launch further Phase II studies in new indications – 2H:23
- RECOVER topline data – October 2023
- Second Phase III confirmatory trial – 4Q:23
- Pursue strategic partnerships to support pipeline development – 2023
- Completion of RECOVER trial open label extension – 3Q:24
- Brilaroxazine NDA submission – 2025

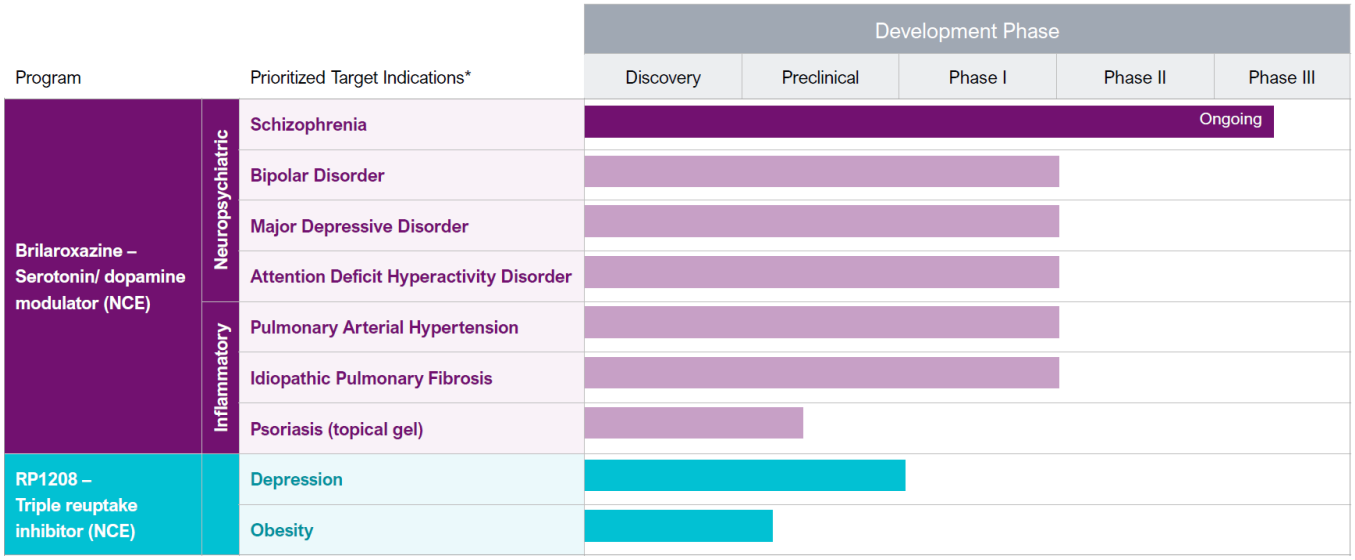
Exhibit III – Potential Indications for Brilaroxazine[3]

Neuropsychiatric Indications				Inflammatory Indications		
Schizophrenia	Major Depressive Disorder	Bipolar Disorder	ADHD	Psoriasis	Pulmonary Arterial Hypertension (PAH)	Idiopathic Pulmonary Fibrosis (IPF)
						
$10.1B *by 2028[1]*	**$24.5B** *by 2030[3]*	**$6.2B** *by 2027[2]*	**$29.3B** *by 2028[4]*	**$51.2B** *by 2030[5]*	**$11.0B** *by 2030[6]*	**$6.2B** *by 2030[7]*

[3] Source: Reviva Pharmaceuticals July 2023 Corporate Presentation

Company Pipeline

Exhibit IV – Reviva Pipeline[4]



Summary

Reviva has completed enrollment of its RECOVER trial and has guided towards an October report of topline data. Supporting trials, including the DDI and other critical studies, have been completed. Following a successful readout from RECOVER, we expect to see efforts to advance the second Phase III trial.

Based on Reviva's guidance, cash of $11.2 million is sufficient to fund operations into the fourth quarter; however, with data supporting safety and efficacy expected from the RECOVER topline report in Ocotober, we believe Reviva will be in a strong position to raise additional capital. We could also see additional funds contributed from warrant exercises due to the upward move in the stock that may extend this runway. 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 and a host of other indications lie in the wings awaiting resources to support their advance. We maintain our valuation of $16.00 per share.

[4] Source: Reviva Pharmaceuticals July 2023 Corporate Presentation

PROJECTED FINANCIALS

Reviva Pharmaceutical Holdings Inc. - Income Statement[5]

Reviva Pharmaceuticals	2022 A	Q1 A	Q2 A	Q3 E	Q4 E	2023 E	2024 E	2025 E
Total Revenues ($US ,000)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
Research & Development	$18,948	$5,235	$8,991	$4,910	$4,200	$23,336	$19,250	$20,125
General & Administrative	$5,359	$1,501	$3,079	$1,305	$1,495	$7,380	$5,710	$6,100
Income from operations	($24,307)	($6,736)	($12,071)	($6,215)	($5,695)	($30,716)	($24,960)	($26,225)
Other Income (Expense)	($12)	$136	($366)	$98	$75	($57)	($410)	($409)
Pre-Tax Income	($24,319)	($6,600)	($12,436)	($6,117)	($5,620)	($30,773)	($25,370)	($26,634)
Provision for Income Tax	$21	$3	$6	$5	$5	$19	$0	$0
Net Income	**($24,339)**	**($6,603)**	**($12,443)**	**($6,122)**	**($5,625)**	**($30,792)**	**($25,370)**	**($26,634)**
Reported EPS	**($1.25)**	**($0.30)**	**($0.55)**	**($0.28)**	**($0.19)**	**($1.28)**	**($0.82)**	**($0.76)**
YOY Growth	*116%*					*2%*	*-36%*	*-7%*
Basic Shares Outstanding	19,516	21,834	22,435	22,200	30,050	24,130	31,100	35,000

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

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

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HISTORICAL STOCK PRICE

Reviva Pharmaceutical Holdings, Inc. – Share Price Chart[6]



[6] Source: Zacks Research System

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