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Reviva Pharmaceuticals, Inc. (RVPH: NASDAQ)

RVPH: Psoriasis IND Expected

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 (5/16/2023)	$7.74
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	**$0.53**
One-Year Return (%)	**337**
Beta	**0.1**
Average Daily Volume (sh)	**147,453**
Shares Outstanding (mil)	**20.6**
Market Capitalization ($mil)	**159.4**
Short Interest Ratio (days)	**8.4**
Institutional Ownership (%)	**6.4**
Insider Ownership (%)	**24.2**
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 E	$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	-$0.29 E	-$0.28 E	-$0.19 E	-$1.03 E
2024					-$0.82 E
2025					-$0.76 E

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WHAT'S NEW

1Q:23 Financial and Operational Results

On May 15, 2023, Reviva Pharmaceutical Holdings, Inc. (NASDAQ: RVPH) reported 1Q:23 financial and operational results and filed its Form 10-Q with the SEC. Since our previous update just over a month ago, Reviva has presented and participated in scientific and investor conferences, held a key opinion leader (KOL) event with a CNS consulting expert and announced its intent to file an investigational new drug (IND) application for brilaroxazine in psoriasis. Looking ahead, management has guided towards a mid-2023 topline announcement for the RECOVER Phase III study in schizophrenia which is now over 60% enrolled. Reviva is also developing protocols for two Phase IIa trials in ADHD and PAH that are slated to launch following receipt of non-dilutive funding.

Highlights for 2023:

- Completion of multiple parallel studies in support of schizophrenia program – March 2023
- Poster presentation at Society of Biological Psychiatry convention – April 2023
- >60% enrollment reached – May 2023

Reviva generated no revenues in 1Q:23 and expended ($6.7) million in operational endeavors, producing a net loss of ($6.6) million or ($0.30) on a per share basis.

For the quarter ending March 31, 2023 and versus the same prior year period:

- Research & development expense totaled $5.2 million, down 10% from $5.8 million, primarily attributed to a decrease in Phase III clinical trial expenses and lower drug development costs. A decline in preclinical expenditures also contributed to the change. These contractions were partially offset by increases in spend related to safety and toxicology studies, salary raises, greater stock-based compensation and payroll taxes and higher consulting expenses;
- General & administrative expenses totaled $1.5 million, falling 7% from $1.6 million on account of lower health and commercial insurance, legal expenses and payroll related expenses. These were partially offset by higher consultant and professional expense and board compensation;
- Gain on remeasurement of warrant liabilities of $11,000 resulted from a decrease in the value of the share price during the measurement period;
- Net interest income was $139,000 which increased over prior year levels due to higher interest rates;
- Provision for taxes was $3,000 related to taxable subsidiary revenue operations;
- Net loss was ($6.6) million vs ($7.4) million, or ($0.30) and ($0.40) per share, respectively.

At the end of March 2023, Reviva held $11.3 million in cash on its balance sheet. Management expects this amount to sustain the firm until 3Q:23. 1Q:23 cash burn was ($8.0) million and cash contributions from financing were $0.7 million sourced from debt issued to fund director and officer liability insurance and warrant exercise. We expect to see continued warrant exercise as Reviva share price sustains prices above 52-week highs. Proceeds from warrant exercise will contribute additional cash to Reviva's coffers.

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, 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.

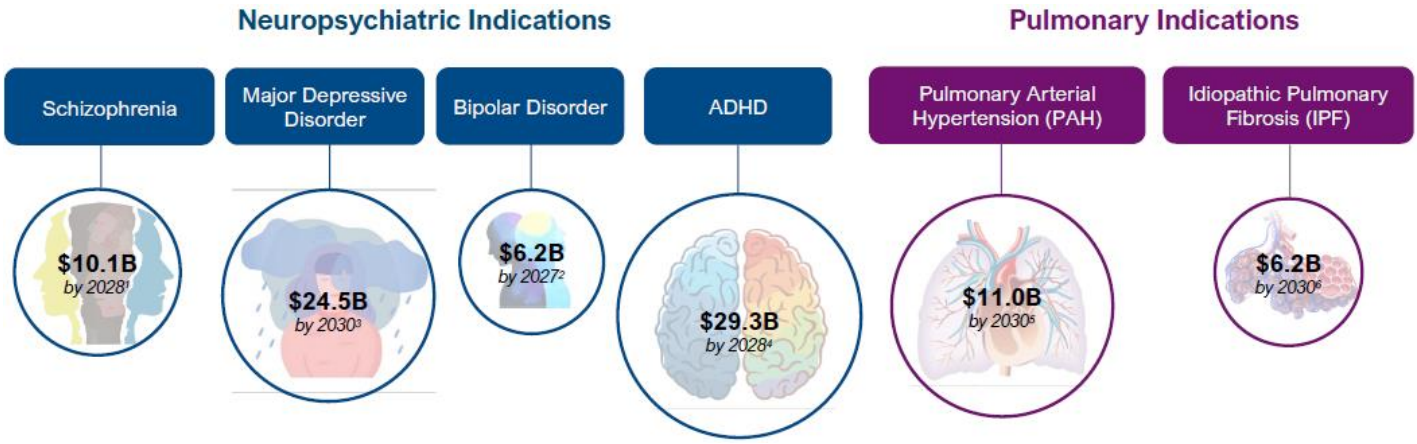
While antipsychotics have improved with new generations, there are still shortcomings, such as metabolic, endocrine, neuroleptic and autonomic side effects that have not been fully resolved. Dr. Ereshefsky's presentation continued with a technical discussion of brilaroxazine's performance in animal models 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]



Conference Attendance

Annual Scientific Convention of the Society of Biological Psychiatry
Reviva CEO Laxminarayan Bhat presented a poster entitled Brilaroxazine (RP5063), a novel serotonin-dopamine stabilizer, displays antipsychotic efficacy in rodents at the 78th Annual Scientific Convention of the Society of Biological Psychiatry. The conference was held in San Diego with the presentation given the evening of April 29, 2023.

The poster concluded that brilaroxazine demonstrated significant antipsychotic effects on pharmacologic-induced behaviors associated with psychosis and schizophrenia in three standard translational surrogate rodent models. The data supports the proposed mechanism of action which modulates the dopamine and 5-HT pathways and neuroinflammation in animal models.

Data from the poster was accepted for publication in Medical Research Archives as detailed in a May 1st press release. The preclinical findings were further supported in the Reviva's previously conducted Phase II REFRESH trial

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

in schizophrenia. Brilaroxazine's ability to favorably impact neuroinflammation, as shown in the preclinical models, is supportive of an additional element of effectiveness not present in approved antipsychotics.

Other Scientific Conferences
As outlined in a recent communication, Reviva will participate in several upcoming scientific conferences. Dr. Bhat will present materials at the International Societies for Investigative Dermatology (ISID) Meeting, American Society for Pharmacology and Experimental Therapeutics (ASPET) and the American Thoracic Society (ATS). Topics will range from preclinical study results to pharmacokinetics, with each addressing brilaroxazine. At ATS, Dr. Bhat will discuss efficacy of brilaroxazine in an animal model of idiopathic pulmonary fibrosis. Presentation dates range from May 12th to May 24th and span the globe from Tokyo, Japan to Washington, DC.

Investor Conference
On May 18th, Dr. Bhat will participate in an investor conference hosted by Lytham Partners that will be conducted virtually. Reviva's CEO will join a panel entitled "Phase 3 Drugs to Watch" and be available for 1:1 meetings with investors. Details of the event are available in the associated press release.

IND Filing for Brilaroxazine in Psoriasis

Reviva intends to file an investigational new drug (IND) application with the FDA for brilaroxazine in psoriasis 2024. 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.

Dr. Bhat Interview

Exhibit II – Dr. Bhat Discusses Brilaroxazine Product Profile[2]



[2] Screenshot from March 2023 Interview with Dr. Bhat.

Interviews with Reviva's CEO, Dr. Laxminarayan Bhat:

- Reviva: Next Generation Blockbuster
- Reviva's Clinical and Regulatory Timelines
- Reviva: More Than Schizophrenia
- Reviva's Brilaroxazine Addresses Antipsychotics' Biggest Hurdles
- Fireside Chat: Reviva's RP1208 & Thoughts on Peers

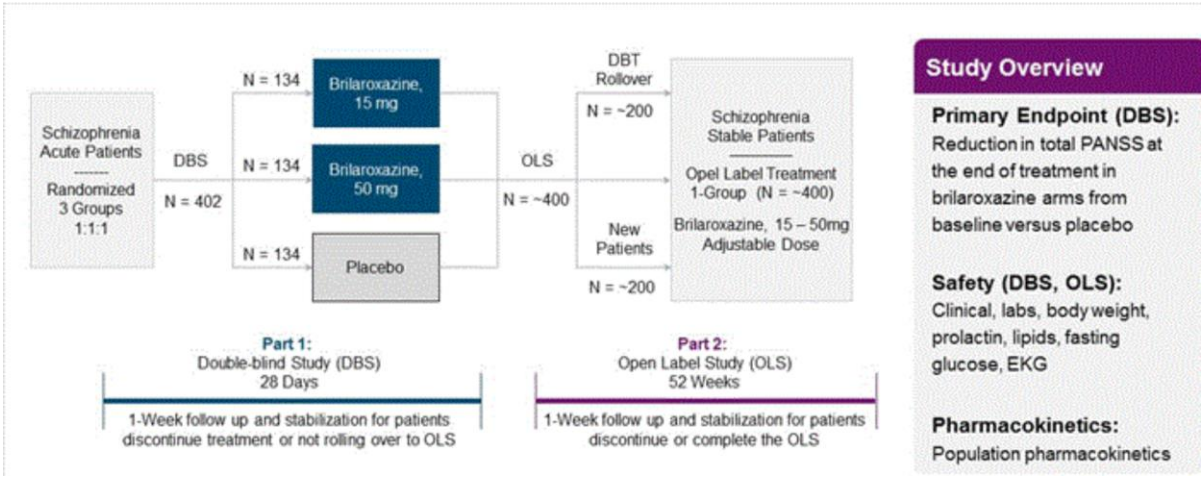
RP1208 Composition of Matter Patent

Reviva holds two compounds in its portfolio of assets: lead candidate brilaroxazine and secondary candidate RP1208. The latter of these is a triple reuptake inhibitor in preclinical development for depression and obesity. Both of these assets are fully owned by Reviva and the claim on their intellectual property was recently strengthened with the grant of a composition of matter patent in Canada. The patent (CA2858837C) protects the composition of novel phenylcycloalkylmethylamine derivatives (PDs) and methods of preparing them. The invention also provides methods of using PDs for the pharmacological treatment of obesity, depression and obesity related comorbid indications.

RECOVER Phase III Trial

As of mid-May 2023, Reviva had enrolled more than 60% of the targeted 400 patients in its Phase III, RECOVER (NCT05184335), trial. Subjects have been enrolled in the United States, Europe and Asia. Top-line data is expected around mid-year 2023. As illustrated in the following exhibit, the trial is designed as a four-week efficacy study followed by a one-year safety extension.

Exhibit III - RECOVER Trial Design[3]



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 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, 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 target patient population.

[3] Reviva 2021 10-K

Parallel Registrational Studies

Reviva has been completing several parallel registrational studies for its Phase III brilaroxazine study in schizophrenia. This includes the clinical absolute bioavailability, metabolism and excretion study, the non-clinical study of interactions with drug transporters as well as the pharmacokinetic, metabolism and excretion studies in mouse and dog models.

A drug-drug interaction (DDI) study has also been completed, which is especially important in schizophrenia patients. Antipsychotic medications are the primary class of drugs used to treat schizophrenia, which work by blocking dopamine receptor activity in the brain. However, not all antipsychotic medications work equally well for all patients and some individuals may experience significant side effects. As a result, healthcare providers may need to prescribe a combination of different antipsychotics or other medications, such as mood stabilizers or antidepressants, to achieve the best results for their patients resulting in multiple drug regimens.

Reviva announced positive safety data from its DDI study investigating the potential effect of CYP3A4 enzyme on brilaroxazine in healthy subjects. Management believes the data reinforce brilaroxazine's potential advantage over other treatments for patients taking multiple drugs who are at higher risk of experiencing adverse drug interactions or discontinuation of their medications due to those interactions. Following FDA guidelines, the DDI clinical study was designed to evaluate the drug interaction effect of a strong CYP3A4 inhibitor or inducer when co-administered with brilaroxazine. The CYP3A4 inhibitor, itraconazole, slightly increased brilaroxazine C_{max}, AUC_{last} and AUC_{inf} by 6%, 16% and 13%, respectively, in 11 healthy volunteers. Similarly, a strong CYP3A4 inducer, phenytoin, decreased the drug's C_{max}, AUC_{last} and AUC_{inf} by 33%, 56% and 53%, respectively in 16 healthy volunteers. The DDI study found no clinically significant interaction when combined with a CYP3A4 inhibitor.

Individuals with schizophrenia may have other medical conditions in addition to their mental health condition and as a result, they may need to take medications for other disorders. Some common medical conditions that may occur alongside schizophrenia include high blood pressure, diabetes and obesity.

This is important because some medications used to treat schizophrenia can cause side effects or have interactions with other drugs. This requires the use of yet other therapies to manage these issues. For example, some antipsychotic medications can cause weight gain or increase the risk of developing diabetes and those taking antipsychotics may need other drugs to manage these coincident disorders.

It is critical for providers to consider the potential interactions between medications when treating schizophrenia, as well as monitor for any side effects or adverse reactions. To provide the necessary data to support these decisions, sponsors must run DDI studies. According to Reviva's research approximately 50% of prescribed drugs and over 25% of antipsychotics currently on the market are known to cause drug interactions with CYP3A4 inhibitors. Brilaroxazine, specifically, is metabolized by CYP3A4 and CYP2D6. In an unpublished study which will be submitted to the FDA in the NDA, brilaroxazine produced an increase in the area under the curve (AUC)[4] in the pharmacokinetic analysis of 15% with a CYP3A4 inhibitor and a 54% AUC decrease with a CYP3A4 inducer. This compares favorably with other commonly prescribed antipsychotics.

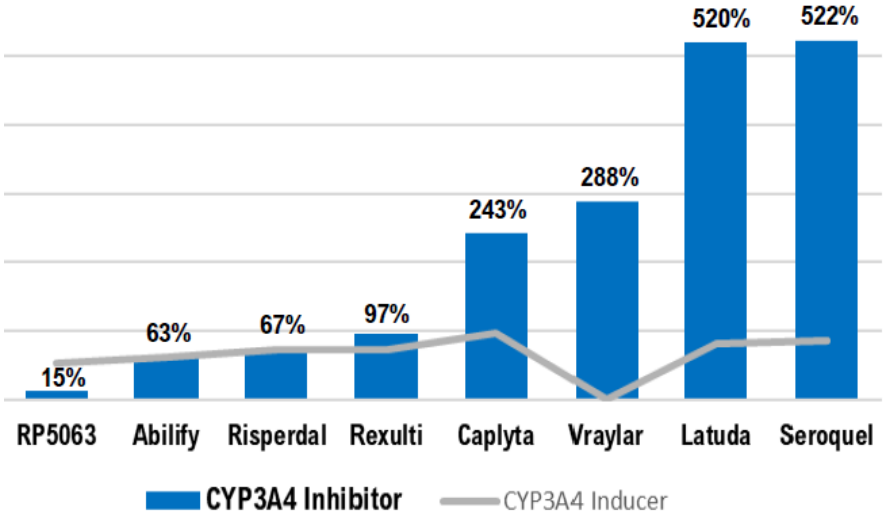
[4] AUC represents the total amount of drug in the bloodstream over a given period of time after a single dose or multiple doses of the drug.

Exhibit IV – Drug-Drug Interaction Comparison of Leading Antipsychotics with Brilaroxazine[5]

	Antipsychotic	AUC Increase with CYP3A4 Inhibitor	AUC Decrease with CYP3A4 Inducer
1	**Brilaroxazine[1] RP5063**	**15%**	**54%**
2	Abilify[2]	63%	61%
3	Rexulti[3]	97%	73%
4	Vraylar[4]	288%	Not evaluated
5	Seroquel[5]	522%	87%
6	Risperdal[6]	67%	72%
7	Zyprexa[7]	Not evaluated (CYP1A2)*[8]	Not evaluated (CYP1A2)
8	Latuda[9]	520%	82%
9	Caplyta[10]	243%	98%

CYP3A4 is a key enzyme responsible for metabolizing a wide range of drugs in the liver. CYP3A4 inhibitors are drugs or compounds that inhibit the activity of this enzyme, which can lead to slower metabolism and clearance of other drugs that are substrates for CYP3A4. As a result, the AUC of these drugs may increase when taken together with a CYP3A4 inhibitor. A minimal change in AUC increase is preferred as it allows for blood plasma levels of the drug to be closer to targeted levels. CYP3A4 inducers are drugs or compounds that increase the activity of this enzyme, which can lead to faster metabolism and clearance of other drugs that are substrates for CYP3A4. As a result, the AUC of these drugs may decrease when taken together with a CYP3A4 inducer. Minimizing the decrease in AUC is desired as it attenuates the reduction in drug levels in plasma from therapeutically efficacious levels.

Exhibit V – Change in Plasma Drug Concentration (AUC)[6]



Itraconazole

In addition to its use as an antifungal medication, itraconazole is sometimes used as a CYP3A4 inhibitor to enhance the effects of other medications. It has been used to increase the blood levels of certain chemotherapy drugs, which can improve their effectiveness against cancer. It is also used in DDI studies to evaluate its effects on other medications. Itraconazole is a potent inhibitor of the cytochrome P450 enzyme CYP3A4, which is involved in the metabolism of many drugs. As a result, itraconazole can affect the metabolism and elimination of other medications that are also metabolized by CYP3A4.

[5] Source: Reviva Corporate Presentation February 2023.
[6] Source: Reviva Corporate Presentation February 2023.

When itraconazole is co-administered with drugs that are metabolized by CYP3A4, it can increase the blood levels of those drugs by inhibiting their metabolism. This can cause an increased risk of side effects and toxicities associated with those drugs. Therefore, it's important to monitor patients closely when itraconazole is used in combination with other medications that are metabolized by CYP3A4.

Phenytoin
Phenytoin is a medication that is primarily used to treat seizures and epilepsy. It is also known to induce the activity of several cytochrome P450 enzymes, including CYP3A4. As a CYP3A4 inducer, phenytoin can increase the metabolism and elimination of other medications that are also metabolized by CYP3A4. This can result in lower blood levels of those drugs, potentially reducing their effectiveness.

Phenytoin is a useful tool in DDI studies as it can induce the cytochrome P450 enzyme system. By evaluating its effects on other medications, researchers can better understand how different drugs interact with each other and how to optimize patient drug therapy.

Examples of medications that may experience reduced effectiveness by the CYP3A4-inducing effects of phenytoin:

- Oral contraceptives: increased risk of pregnancy;
- Anticoagulants: increase metabolism, which reduces blood levels of medications such as warfarin;
- Antidepressants: causes lower blood levels of medications such as fluoxetine;
- Antipsychotics: causes lower blood levels of medicines such as clozapine.

CYP3A4 (Cytochrome P450 3A4)
CYP3A4 (cytochrome P450 3A4) is a member of the cytochrome P450 family of enzymes that is primarily found in the liver, but can also be found in other tissues such as the intestine. CYP3A4 plays an important role in the metabolism and elimination of a many drugs, toxins, and endogenous substances, including steroids and bile acids.

CYP3A4 metabolizes drugs via oxidation, a process that facilitates their elimination from the body. However, the activity of CYP3A4 can also be influenced by various factors such as genetics, age, diet, and other medications. Certain drugs can inhibit or induce the activity of CYP3A4, which can affect the metabolism and elimination of other drugs that are also metabolized by CYP3A4.

Because CYP3A4 is involved in the metabolism of many drugs, it is one of the most important drug-metabolizing enzymes in the human body. Understanding the effects of CYP3A4 on drug metabolism is crucial in determining appropriate dosages, preventing drug interactions and avoiding adverse drug reactions.

Milestones

Preparation for Phase II trials for brilaroxazine in additional indications is underway with regulatory work expected in 2H:23 followed by launch, pending funding. We provide additional detail on recent and anticipated achievements 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
- Second Phase III confirmatory trial – 4Q:23
- Pursue strategic partnerships to support pipeline development – 2023
- Brilaroxazine NDA submission – Late 2024/Early 2025

Company Pipeline

Exhibit VI – Reviva Pipeline[7]



Summary

Reviva is in the last stages of its RECOVER trial and should post topine data around the mid-year. 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 begin before year end.

Based on Reviva's guidance, cash of $11.3 million is sufficient to fund operations into the third quarter. 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. We maintain our valuation of $16.00 per share.

[7] Source: Reviva Pharmaceuticals 2022 10-K.

PROJECTED FINANCIALS

Reviva Pharmaceutical Holdings Inc. - Income Statement[8]

Reviva Pharmaceuticals	2022 A	Q1 A	Q2 E	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	$5,450	$4,910	$4,200	$19,795	$19,250	$20,125
General & Administrative	$5,359	$1,501	$1,100	$1,305	$1,495	$5,401	$5,710	$6,100
Income from operations	($24,307)	($6,736)	($6,550)	($6,215)	($5,695)	($25,196)	($24,960)	($26,225)
Other Income (Expense)	($12)	$136	$120	$98	$75	$429	($410)	($409)
Pre-Tax Income	($24,319)	($6,600)	($6,430)	($6,117)	($5,620)	($24,767)	($25,370)	($26,634)
Provision for Income Tax	$21	$3	$5	$5	$5	$18	$0	$0
Net Income	**($24,339)**	**($6,603)**	**($6,435)**	**($6,122)**	**($5,625)**	**($24,785)**	**($25,370)**	**($26,634)**
Reported EPS	**($1.25)**	**($0.30)**	**($0.29)**	**($0.28)**	**($0.19)**	**($1.03)**	**($0.82)**	**($0.76)**
YOY Growth	*116%*					*-17%*	*-21%*	*-7%*
Basic Shares Outstanding	19,516	21,834	21,980	22,200	30,050	24,016	31,100	35,000

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

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

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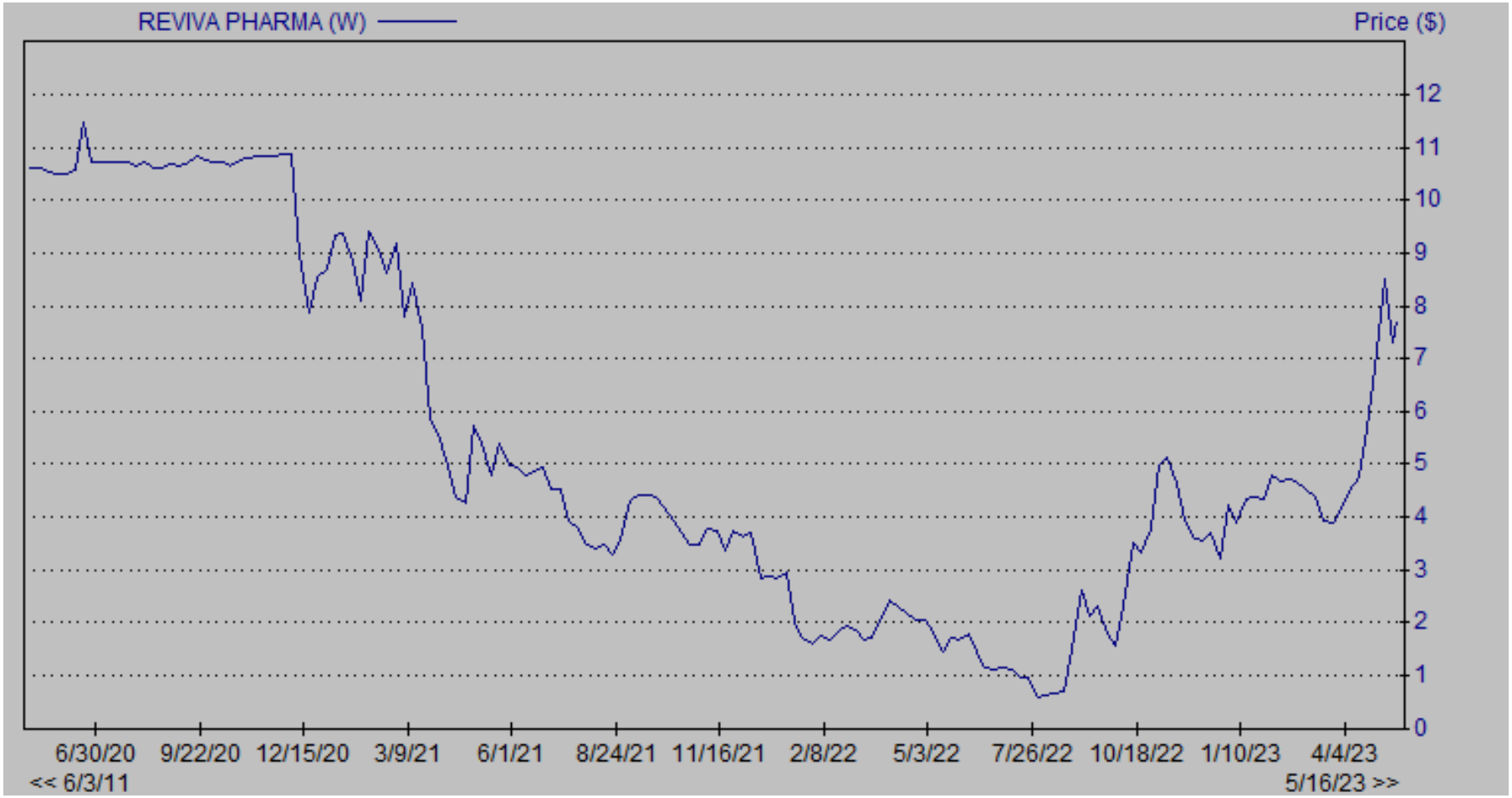
HISTORICAL STOCK PRICE

Reviva Pharmaceutical Holdings, Inc. – Share Price Chart[9]



[9] Source: Zacks Research System

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