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Reviva Pharmaceuticals, Inc. (RVPH: NASDAQ)

RVPH: Raise & RECOVER Results Review

Our valuation relies on a DCF model employing a 15% discount rate which applies a 60% probability of approval and commercialization for RP5063 in schizophrenia. The model includes contributions from the United States and rest of world.

Current Price (11/17/2023)	$4.01
Valuation	**$18.00**

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) completed its 1st Phase III trial & will begin its 2nd in 1Q:24. 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 NDA submission to the FDA in 2025 followed by regulatory submission in other territories. Our valuation assumes commercialization in the US and rest of world in 2026 and 2027 respectively.

SUMMARY DATA

52-Week High	**$9.25**
52-Week Low	**$3.03**
One-Year Return (%)	**-6.6**
Beta	**0.0**
Average Daily Volume (sh)	**1,089,262**
Shares Outstanding (mil)	**24.0**
Market Capitalization ($mil)	**96.2**
Short Interest Ratio (days)	**1.0**
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 A	$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	-$0.44 A	-$0.19 E	-$1.43 E
2024					-$0.82 E
2025					-$0.76 E

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WHAT'S NEW

3Q:23 Financial and Operational Results

On November 14, 2023, Reviva Pharmaceutical Holdings, Inc. (NASDAQ: RVPH) reported 3Q:23 financial and operational results and filed its Form 10-Q with the SEC. The most important news since the previous quarterly update was the topline data for the Phase III RECOVER trial evaluating brilaroxazine in schizophrenia patients. It found meaningful reductions in all components of the PANSS score, a favorable side effect profile and compelling discontinuation rates. The results support plans for a second Phase III study, designated RECOVER-2, which is slated to start in early 2024. To fund the RECOVER-2 study, Reviva has announced a $30 million registered direct offering that is expected to close today, November 20.

Other activities during the third quarter and to date include Reviva's attendance at and participation in a variety of investor events and periodic status updates for the RECOVER trial.

Highlights for 2023:

- Multiple parallel studies in support of schizophrenia program completed – March
- Company added to Russell Microcap index - June
- RECOVER topline results reported – October
- $30 million capital raise - November

Reviva generated no revenues in 3Q:23 and expended ($10.7) million in operational activities, producing a net loss of ($10.5) million or ($0.44) on a per share basis. For the quarter ending September 30, 2023 and versus the same prior year period:

- Research & development expense totaled $8.7 million, almost three times the $2.3 million in the comparable period, primarily attributed to higher Phase III clinical trial expenses and drug development costs, and increases in stock-based compensation and salary;
- General & administrative expenses totaled $2.0 million, rising 58% from $1.3 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 other miscellaneous expenses;
- Gain on remeasurement of warrant liabilities of $139,000 resulted from a decrease in the value of the share price during the measurement period;
- Net interest income was $92,000 which increased over prior year levels due to higher interest rates and greater interest income;
- Provision for taxes was $12,000 related to taxable subsidiary revenue operations;
- Net loss was ($10.5) million vs ($3.5) million, or ($0.44) and ($0.18) per share, respectively.

At the end of September 2023, Reviva held $5.0 million in cash on its balance sheet. 3Q:23 cash burn was ($6.2) million and cash flows from financing was zero. Following the end of the quarter, Reviva announced a $30 million registered direct offering that should provide sufficient capital to support operations until the end of 2024. There is also a strong likelihood that the $5 exercise-price warrants associated with the deal may provide additional capital if the shares move back into the money.

RECOVER Topline Announcement

Following enrollment completion of the RECOVER trial on August 17th and evaluation of the last patient on September 25th, Reviva Pharmaceutical Holdings, Inc. (NASDAQ: RVPH) announced topline results. RECOVER was a global Phase III, randomized, double-blind, placebo-controlled, multicenter study designed to assess the safety and efficacy of brilaroxazine in patients with acute schizophrenia compared to placebo. It enrolled 412 subjects. Brilaroxazine was administered at fixed doses of 15 mg or 50 mg once daily for 28 days. The primary endpoint was a decrease in the Positive and Negative Syndrome Scale (PANSS) total score compared to placebo from baseline to Day 28. Key secondary endpoints include clinical global impression (CGI) severity, positive and negative symptoms, social functioning and cognition.

The trial met its primary endpoint, generating a 10.1-point reduction in PANSS score relative to placebo at four weeks for the 50 mg dose. The brilaroxazine arm generated a 23.9-point reduction whereas the placebo arm produced a 13.8-point reduction. Brilaroxazine also achieved statistically significant and clinically meaningful reductions in all major symptom domains and secondary endpoints at week 4 with the 50 mg dose vs. placebo. The 15 mg dose of brilaroxazine was numerically superior to placebo on the primary endpoint and most secondary endpoints, and reached statistical significance on two key secondary endpoints.

RECOVER will evolve into an open label extension (OLE) trial continuing with 100 of the subjects who have completed the four-week regimen. It will have a one-year duration. The outpatient OLE will evaluate the long-term safety and tolerability of brilaroxazine with a once daily 15, 30 and 50 mg flexible dose. The extension is expected to be complete by 4Q:24

Reviva held a webcast to review the data release which featured the CEO, Dr. Laxminarayan Bhat, and Reviva's consultant, Dr. Larry Ereshefsky. The slide deck review presented topline data, patient characteristics and analysis of each endpoint with score trend by week. It further summarized the safety and side effect profile of the candidate. The final data point for each of the endpoints is included in the following exhibit.

Exhibit I – Summary of RECOVER Primary and Secondary Endpoints[1,2]

	Brilaroxazine 50 mg vs. Placebo at week 4 Point Reduction / Improvement	*Cohen's d Effect Size*	*P Value*
PANSS Total Score	10.1	*0.6*	*< 0.001*
Positive Symptoms	2.8	*0.5*	*< 0.001*
Negative Symptoms	2.0	*0.4*	*0.003*
Negative Symptoms Marder Factor	2.1	*0.4*	*0.002*
PANSS Social Cognition	1.6	*0.5*	*< 0.001*
PANSS Excitement/Agitation	2.1	*0.5*	*< 0.001*
Personal and Social Performance	6.3	*0.5*	*< 0.001*
CGI-S score	≥1	*0.5*	*< 0.001*

Brilaroxazine was engineered based on the latest understanding in receptor efficacy and side effect relationships guided by the shortcomings and data generated by preceding therapies. Brilaroxazine possesses a high binding affinity for the $D_{2/3/4}$ and 5-$HT_{1A/2A/2B/7}$ receptors, moderate affinity for 5-HT_6 and nicotinic acetylcholine ($\alpha_4\beta_2$) receptors and the serotonin transporter, a partial agonist of $D_{2/3/4}$ and 5-$HT_{1A/2A}$ receptors and antagonist of 5-$HT_{2B/6/7}$ receptors. The agent has either very weak activity or no activity for off target 5-HT_{2C}, adrenergic $\alpha_{1,2}$ or muscarinic receptors. See our initiation for additional discussion of the drug design. This configuration sought to reduce the side effect profile of brilaroxazine compared with other antipsychotics. In the RECOVER Phase III study, the goal of the design was realized as brilaroxazine was generally well tolerated with treatment emergent adverse events (TEAEs) as listed below.

Exhibit II – RECOVER Subject Adverse Events[3]

	Placebo	Bril 15 mg	Bril 50 mg
Treatment Emergent Adverse Event Rate	30%	35%	36%
Serious TEAE Not Related to Drug	0	2	1
Serious TEAE Related to Drug	0	0	0

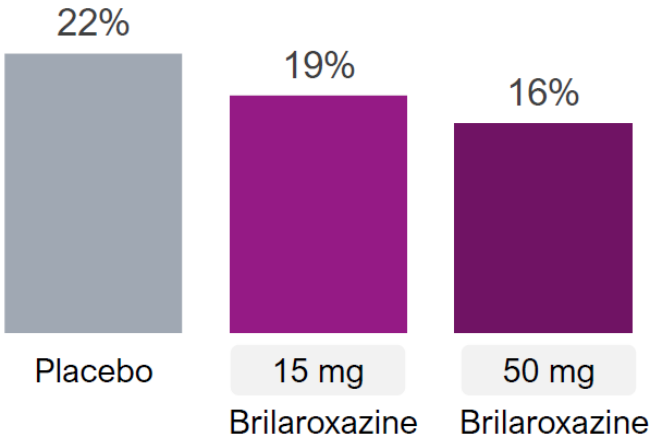
[1] Reviva RECOVER Topline Results Data Presentation, October 30, 2023.
[2] Cohen's d is a statistic used to measure the standardized difference between two group means. The statistic quantifies the difference between two group means relative to the standard deviation. This allows results to be compared across studies using different measures. It is calculated as the difference between the two group means, divided by the pooled standard deviation. d = (Mean 1 - Mean 2)/Pooled SD
The pooled standard deviation is calculated using a weighted average of the variances of the two groups. Cohen provided guidelines for interpreting the size of d: Small effect: d = 0.2; Medium effect: d = 0.5; Large effect: d = 0.8
[3] Compiled from data provided in company materials by Zacks analyst

The most common TEAEs above 5% were headache (<6%) and somnolence (<7.5%).

The trial further observed that there was no incidence of suicidal ideation and no significant change in bodyweight, blood glucose levels, lipid levels or endocrine hormones as compared to placebo. In particular, weight gain was measured at a 2.1% increase in the 15 mg arm, 5.9% in the 50 mg arm and 2.9% in placebo. While the 50 mg arm showed an increase in excess of placebo, Dr. Ereshefsky noted that enrolled subjects received meals as part of the treatment regime. This is in contrast to many acutely ill schizophrenia patients who do not receive proper nutrition.

Discontinuation of antipsychotic medication is one of the major problems with treating schizophrenia. This can lead to relapse and can lead to treatment resistance. Many patients stop taking their antipsychotics due to side effects such as sedation, weight gain, movement disorders, or lack of insight into their illness. Estimates range from 50-75% of patients discontinuing within 1-2 years. This hurdle accentuates the need for improved compliance and better adherence to medicine administration. **Reviva produced an attractive discontinuation rate** for the Phase II and Phase III studies, which was better than placebo in both. As shown below, discontinuation for the RECOVER trial was 22% for placebo, 19% for the 15 mg brilaroxazine dose and 16% for the 50 mg brilaroxazine dose. Discontinuation due to side effects was 4% in the placebo group, 1% for the 15 mg brilaroxazine group and 0% for the 50 mg brilaroxazine group.

Exhibit III – Discontinuation Rate[4]



In summary, the RECOVER clinical trial met its objectives:

- Achieved primary endpoint of clinically meaningful and statistically significant reduction in PANSS score;
- Demonstrated improvement in all major symptom domains;
- Drug was well-tolerated with side effects comparable to placebo;
- Discontinuation rate low and below that of placebo.

RECOVER-2

Reviva is planning to launch its confirmatory Phase III RECOVER-2 trial in 1Q:24. The trial will have a similar design to the RECOVER trial with a few notable differences. We expect that the second Phase III trial will be able to enroll at a faster pace than the first as much of the ground work has already been completed and the trial managers are experienced. The confirmatory trial will measure endpoints over a 6-week (in contrast to 4-week) period and RECOVER-2 will randomize 450 patients 1:1:1 with 30 mg (in place of 15 mg), 50 mg and placebo arms. Completion is expected in early 2025. This sets Reviva up to submit its new drug application (NDA) in 2H:25.

Capital Raise

Following the topline results from the RECOVER trial and the report of third quarter results, Reviva announced a $30 million registered direct offering that is backed by several healthcare focused institutional investors. The sale and issuance of 5,853,660 units, consisting of shares and warrants, is expected to close on November 20th. Unit price is $5.125 and warrant exercise price will be $5.00 with a duration of five years. HC Wainwright is acting as the placement agent.

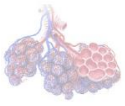
[4] Reviva RECOVER Topline Results Data Presentation, October 30, 2023.

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. 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 requires an approved IND and a Phase I. However, it would be a relatively inexpensive endeavor as much of the safety work has been done for brilaroxazine and only psoriasis-specific safety work would be required. 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.

- Phase III schizophrenia RECOVER topline data – October 2023
- Initiation of Phase III RECOVER-2 clinical trial – 1Q:24
- Completion of RECOVER trial open label extension – 4Q:24
- Completion of RECOVER-2 clinical trial – 1Q:25
- New Drug Application (NDA) submission to FDA – 2H:25

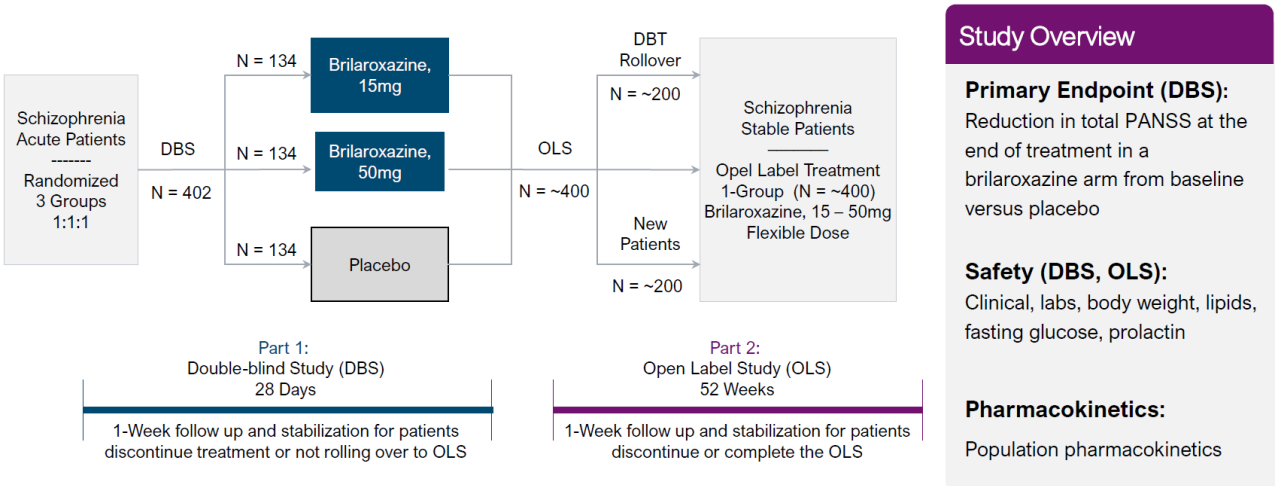
Exhibit IV – Market Opportunity for Brilaroxazine[5]

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]*

RECOVER Phase III Trial Background

Reviva fully enrolled its Phase III RECOVER (NCT05184335) trial in August. Subjects have been enrolled in the United States (60%), India (34%) and Bulgaria (6%). As illustrated in the following exhibit, the trial was designed as a four-week efficacy study followed by a one-year safety extension.

Exhibit V - RECOVER Trial Design[6]



Study Overview

Primary Endpoint (DBS):
Reduction in total PANSS at the end of treatment in a brilaroxazine arm from baseline versus placebo

Safety (DBS, OLS):
Clinical, labs, body weight, lipids, fasting glucose, prolactin

Pharmacokinetics:
Population pharmacokinetics

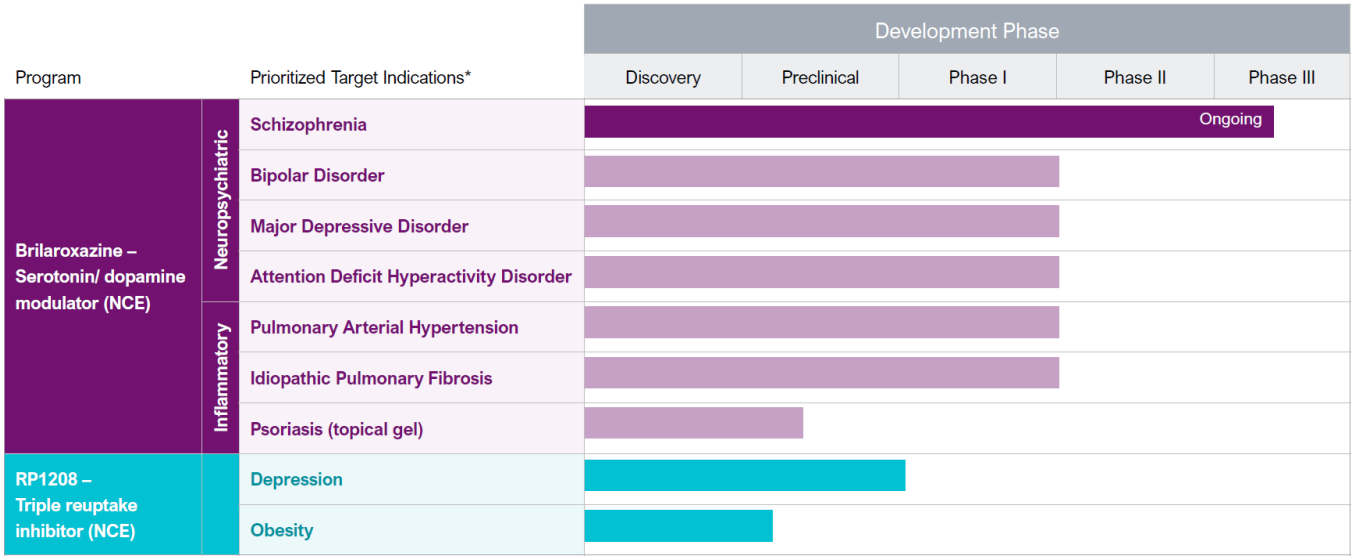
[5] Reviva Corporate Presentation, KOL Webinar, May 2023
[6] Source: Reviva Pharmaceuticals September 2023 Corporate Presentation

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 which is a significant advantage in supporting treatment adherence in the target patient population.

Company Pipeline

Exhibit VI – Reviva Pipeline[7]



Summary

Following the impressive RECOVER results, Reviva reported its third quarter financial standing and announced a $30 million capital raise. The company is in a strong position to produce results in its second Phase III trial designated RECOVER-2 which will evaluate brilaroxazine in schizophrenia patients. Trial design has been completed, funds have been raised and the study is expected to begin early next year. Familiarity with the process should allow for faster enrollment and a streamlined process. An OLE study is underway which will generate topline data late next year. Results from RECOVER confirm the findings of the Phase II with a greater level of statistical significance. Brilaroxazine represents a class-leading balance of efficacy and tolerability which was strongly evi-denced by the favorable discontinuation rates in the active arms. We maintain our valuation of $18.00 per share.

[7] Source: Reviva Pharmaceuticals September 2023 Corporate Presentation

PROJECTED FINANCIALS

Reviva Pharmaceutical Holdings Inc. - Income Statement[8]

Reviva Pharmaceuticals	2022 A	Q1 A	Q2 A	Q3 A	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	$8,717	$4,200	$27,144	$19,250	$20,125
General & Administrative	$5,359	$1,501	$3,079	$1,992	$1,495	$8,067	$5,710	$6,100
Income from operations	($24,307)	($6,736)	($12,071)	($10,709)	($5,695)	($35,210)	($24,960)	($26,225)
Other Income (Expense)	($12)	$136	($366)	$230	$75	$75	($410)	($409)
Pre-Tax Income	($24,319)	($6,600)	($12,436)	($10,479)	($5,620)	($35,135)	($25,370)	($26,634)
Provision for Income Tax	$21	$3	$6	$12	$5	$27	$0	$0
Net Income	**($24,339)**	**($6,603)**	**($12,443)**	**($10,491)**	**($5,625)**	**($35,161)**	**($25,370)**	**($26,634)**
Reported EPS	**($1.25)**	**($0.30)**	**($0.55)**	**($0.44)**	**($0.19)**	**($1.43)**	**($0.82)**	**($0.76)**
YOY Growth	*116%*					*15%*	*-43%*	*-7%*
Basic Shares Outstanding	19,516	21,834	22,435	24,034	30,050	24,588	31,100	35,000

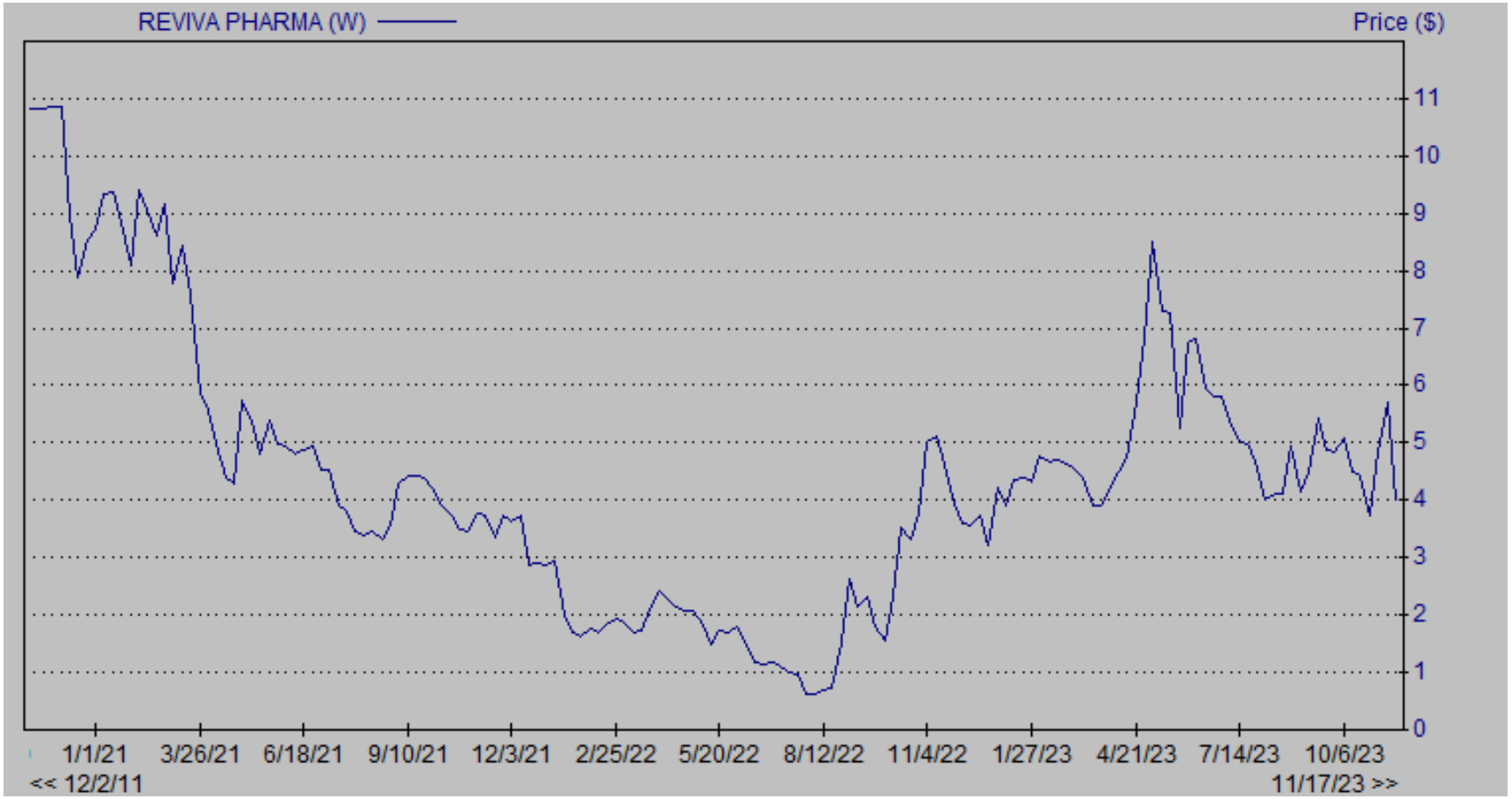
Source: Company Filing // Zacks Investment Research, Inc. Estimates

[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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