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May 22, 2025
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Reviva Pharmaceuticals, Inc. (RVPH: NASDAQ)

RVPH: 1Q:25 Results

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

Current Price (5/21/2025)	$0.99
Valuation	**$10.00**

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 completed its 1st Phase III trial & is set to begin its 2nd in 2025.

Brilaroxazine is a novel multimodal modulator of serotonin, dopamine and nicotinic receptors, demonstrating improved efficacy and a better side effect profile compared to 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 2026 followed by regulatory submission in other territories. Our valuation assumes commercialization in the US and rest of world following regulatory approval.

SUMMARY DATA

52-Week High	**$4.28**
52-Week Low	**$0.49**
One-Year Return (%)	**-24.4**
Beta	**0.1**
Average Daily Volume (sh)	**730,169**
Shares Outstanding (mil)	**46.7**
Market Capitalization ($mil)	**46.2**
Short Interest Ratio (days)	**3.7**
Institutional Ownership (%)	**20.9**
Insider Ownership (%)	**10.6**
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 2025 Estimate	**N/A**
P/E using 2026 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)
2024	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2025	$0.0 A	$0.0 E	$0.0 E	$0.0 E	$0.0 E
2026					$0.0 E
2027					$0.0 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2023	-$0.30 A	-$0.55 A	-$0.44 A	-$0.37 A	-$1.65 A
2024	-$0.13 A	-$0.13 E	-$0.13 E	-$0.14 E	-$0.57 E
2025					-$0.33 E
2026					-$0.16 E

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WHAT'S NEW

Reviva Pharmaceutical Holdings, Inc. (NASDAQ: RVPH) reported 1Q:25 results updating investors on the progress of the open-label extension (OLE) trial reporting it as complete and targeting release of the full data set before the end of the second quarter. The company also expects to begin the second registrational Phase III trial for brilaroxazine by mid-2025, which is dependent on raising capital.

Operational and Financial Results

On May 15th, 2025, Reviva reported 1Q:25 financial and operational results and filed its Form 10-Q with the SEC. Reviva generated no revenues in the quarter and generated an operational loss of ($6.5) million with expenses primarily related to the open-label extension (OLE) for RECOVER. For the quarter ending March 31st, 2025 and versus the same prior year period:

- Research & development expense totaled $4.1 million, down 29% from $5.7 million, with the change attributable to a decrease in external clinical research and development costs and fewer patient visits as the OLE trial winds down;
- General & administrative expenses totaled $2.4 million, rising 13% from $2.1 million on account of higher stock-based compensation and employee related expenses partially offset by lower directors' and officers' insurance expense, consultant and professional expenses;
- Other income of $111,000 compared to $496,000 with the difference almost entirely attributable to a lower gain on remeasurement of warrant liabilities. Net interest expense is a reversal from net interest income in the prior year due to lower cash balances generating less interest income and a lower magnitude of foreign currency loss related to the consolidation of the Indian subsidiary;
- Provision for taxes was $5,000 compared to $7,000 related to payment of state and foreign taxes;
- Net loss was ($6.4) million vs ($7.4) million, or ($0.13) and ($0.25) per share, respectively.

As of March 31st, 2025, Reviva held $5.3 million in cash on its balance sheet. 1Q:25 cash burn was ($8.2) million while cash flows from financing were negligible. We anticipate a capital raise in the near term.

Undiscovered Gem

Over the past 18 months, several multi-billion-dollar M&A transactions have targeted assets treating schizophrenia. At the time these deals were announced, only one asset had received FDA approval, while the two others remained under review. Notable transactions include Bristol-Myers Squibb's $14 billion acquisition of Karuna Therapeutics, AbbVie's $8.7 billion purchase of Cerevel Therapeutics and Johnson & Johnson's $14.6 billion acquisition of Intra-Cellular Therapies. These substantial investments highlight the significant opportunities associated with innovative therapies in the schizophrenia market, which exceeds $10 billion annually.[1] The late stage of the acquisitions trains the spotlight on Reviva Pharmaceuticals, which has a Phase III asset for schizophrenia ready to begin the second of two registrational trials.

Reviva's drug, brilaroxazine, has demonstrated a superior balance of safety and efficacy compared to other leading antipsychotics.[2] Despite near-term challenges associated with securing capital to fund the second Phase III trial, brilaroxazine offers a substantial improvement for patients, improving both positive and negative symptoms of the disorder and producing a clean safety profile and a low discontinuation rate that allows for meaningful therapy. Reviva's market capitalization of approximately $50 million severely discounts brilaroxazine's potential, suggesting substantial upside if RECOVER-2 can generate data in-line with the first Phase III trial.

[1] Source: Evaluate Ltd. 2024 Annual Worldwide Sales, Schizophrenia.
[2] See our April 15th, 2024 report that compares Brilaroxazine to other antipsychotics: RVPH: Update to Brilaroxazine Safety vs. Efficacy Comparison – Adding RECOVER Data.

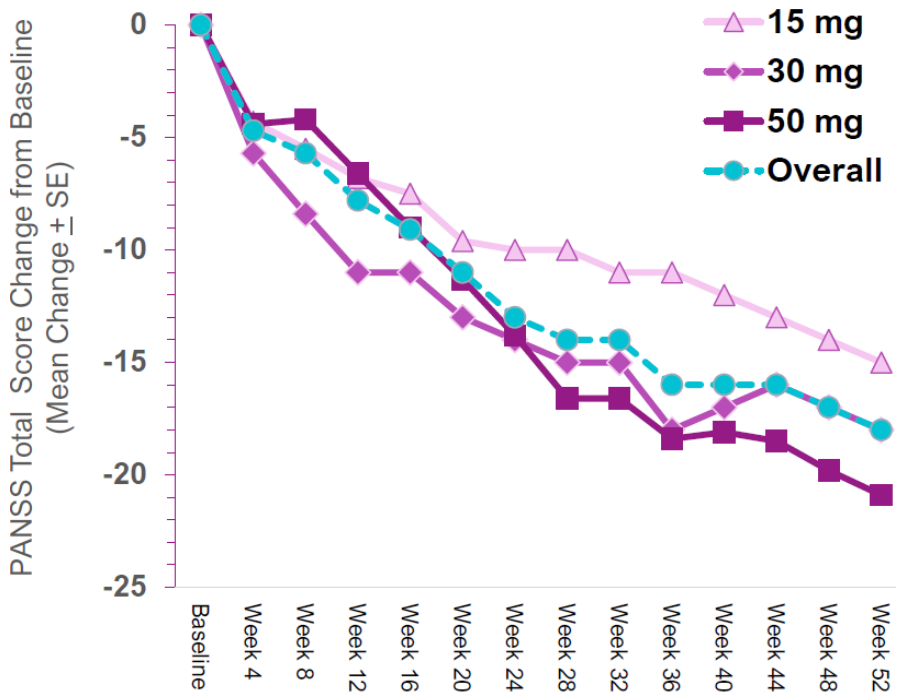
Open-Label Extension Initial Readout

Reviva Pharmaceutical Holdings, Inc. (NASDAQ: RVPH) reported preliminary results from its open-label extension (OLE) from the Phase III RECOVER trial. Brilaroxazine showed a favorable long-term safety profile and improved efficacy over the one-year observation period. The schizophrenia candidate produced discontinuation rates well below other antipsychotics. The update provided both pooled and individual safety and efficacy data.

OLE Background
Following the conclusion of the RECOVER study, patients were given the opportunity to continue on brilaroxazine to gather long term safety and tolerability in an OLE study. The OLE was designed to take place in parallel with RECOVER and evaluate the long-term safety of brilaroxazine. It was designed to evaluate at least 100 subjects for one year and can enroll patients that were part of the RECOVER trial. The study is listed under the identifier NCT05184335 on clinicaltrials.gov in an entry that is shared with the RECOVER trial. It evaluated flexible doses of brilaroxazine of 15, 30 or 50 mg. Data from the trial will be part of the new drug application (NDA) package that Reviva will submit to the FDA along with anticipated RECOVER-2 data.

OLE First Look
Preliminary results include efficacy results for 113 patients who completed a year of treatment. Safety results are for all 435 patients enrolled in the OLE, including those still actively part of the trial. Results showed dose dependent efficacy. Total Positive and Negative Syndrome Scale (PANSS)[3] scores changed by -15.2 (15 mg), -18.6 (30 mg) and -20.8 (50 mg) from baseline to final observation at one year. See exhibit below for an illustration of the data.

Exhibit I – Change in OLE PANSS Total Scores (N=113)



Source: Reviva Corporate Presentation, December 2024

The average change in PANSS score for all dosages was an 18.6-point decrease from 71.6 at baseline to 53.0 with a p value of less than 0.0001. Positive symptoms for the pooled data declined by 5.2 points ($p<0.0001$) and negative symptoms fell by 4.5 points ($p<0.0001$). If measured from the baseline determined at the start of the RECOVER trial, improvement in PANSS score of 30 points or more was achieved in 87% of patients, 40 points or more in 65% of patients and 50 points or more in 34% of patients. Note that the baseline PANSS score at the beginning of RECOVER was 99.

[3] The Positive and Negative Syndrome Scale (PANSS) is a widely used, clinician-administered rating scale designed to measure the severity of symptoms in individuals with schizophrenia. It was developed by Stanley Kay, Lewis Opler, and Abraham Fiszbein in 1987 and is considered a gold standard for evaluating the effectiveness of antipsychotic treatments in clinical trials and research.

Safety, Tolerability & Adherence
Treatment-related adverse events (TRAEs) were reported by 15.2% of participants, with most classified as mild (12.2%) and the remainder as moderate (3%). TRAEs were transient with the most common events being weight increase (3.2%) insomnia (1.8%) and somnolence (1.6%). Importantly, no drug-related serious adverse events (SAEs) were reported. No observations of movement disorders were recorded, such as tardive dyskinesia or acute dystonia which are associated with many first generation and some second-generation antipsychotics. The treatment discontinuation rate at one year was favorable at 35%, comparing positively to other approved antipsychotics. Based on a review of several resources[4,5,6,7], discontinuation rates for this class range anywhere from the mid-40% range to 70%. For Bristol Myers' recently approved KarXT, discontinuation was 53% after 52 weeks of treatment.

Exhibit II – Discontinuation and Adherence in the OLE (N=113)

Discontinuation Category	Percentage
Overall rate	35%
Withdrawal of consent-related	22%
Lost to Follow-Up-related	7%
TRAE-related	1.6%

Source: SIRS Poster Presentation, March 2025

OLE Poster Presented at Schizophrenia International Research Society (SIRS)
On March 30th, 2025, Reviva's CEO Dr. Laxminarayan Bhat, presented additional data regarding the OLE trial. The poster was entitled Brilaroxazine Phase 3 RECOVER 52-Week Open-Label Evaluation (OLE) of Efficacy and Safety over 12 Months in Stable Schizophrenia Participants. It was presented at the Schizophrenia International Research Society (SIRS) annual conference in Chicago.

Conclusions in the poster emphasize the confirmation of the safety and efficacy that was presented in the Phase III RECOVER trial including a dose dependent response and broad-spectrum efficacy as measured by both the positive and negative components of the PANSS score. Patients tolerated brilaroxazine well, with few treatment-related adverse events (TRAEs) and strict adherence to therapy.

Exhibit III – Safety and Tolerability in the OLE

Category	Details
TRAEs reported	15.2% reported at least one TRAE
Severity of TRAEs	Mild (12.2%), Moderate (3%), Transient in nature
Common TRAEs (>1%)	Weight increase (3.2%), Insomnia (1.8%), Somnolence (1.6%)
Movement Disorder Scales	No clinically meaningful changes observed
Serious Adverse Events (SAEs)	No drug-related SAEs; 3 SAEs reported, none brilaroxazine-related

Source: SIRS Poster Presentation, March 2025

Along with its first quarter report, Reviva announced that it had completed the OLE portion of the RECOVER Phase III study. 446 patients have completed the study, 156 patients have completed one year of treatment and 301 pa-

[4] Liberman, J.A., *et al*. Effectiveness of Antipsychotic Drugs in Patients with Chronic Schizophrenia. New England Journal of Medicine. September 2005.
[5] Zhang, C., *et al*. Rates and predictors of one-year antipsychotic treatment discontinuation in first-episode schizophrenia: Results from an open-label, randomized, "real world" clinical trial. Psychiatry Research. March 2019.
[6] Bertolini, F., *et al.* Comparing Long-Acting Antipsychotic Discontinuation Rates Under Ordinary Clinical Circumstances: A Survival Analysis from an Observational, Pragmatic Study. Springer. March 2021.
[7] Seung-Ho, J., *et al*. Factors Affecting Treatment Discontinuation and Treatment Outcome in Patients with Schizophrenia in Korea: 10-Year Follow-Up Study. Psychiatry Investigation. November 2010.

tients have completed six months of treatment as of late May 2025. Data from the OLE trial will be presented at the 2025 American Society of Clinical Psychopharmacology (ASCP) annual meeting on Wednesday May 28, 2025, in Scottsdale, Arizona.

RECOVER-2

Reviva is planning to launch its confirmatory Phase III RECOVER-2 trial in 2025. The trial will employ a similar design to the RECOVER trial with a few notable differences. Once it starts, 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 4-week period and will randomize 450 patients 1:1:1 with 30 mg (in place of 15 mg), 50 mg and placebo arms.

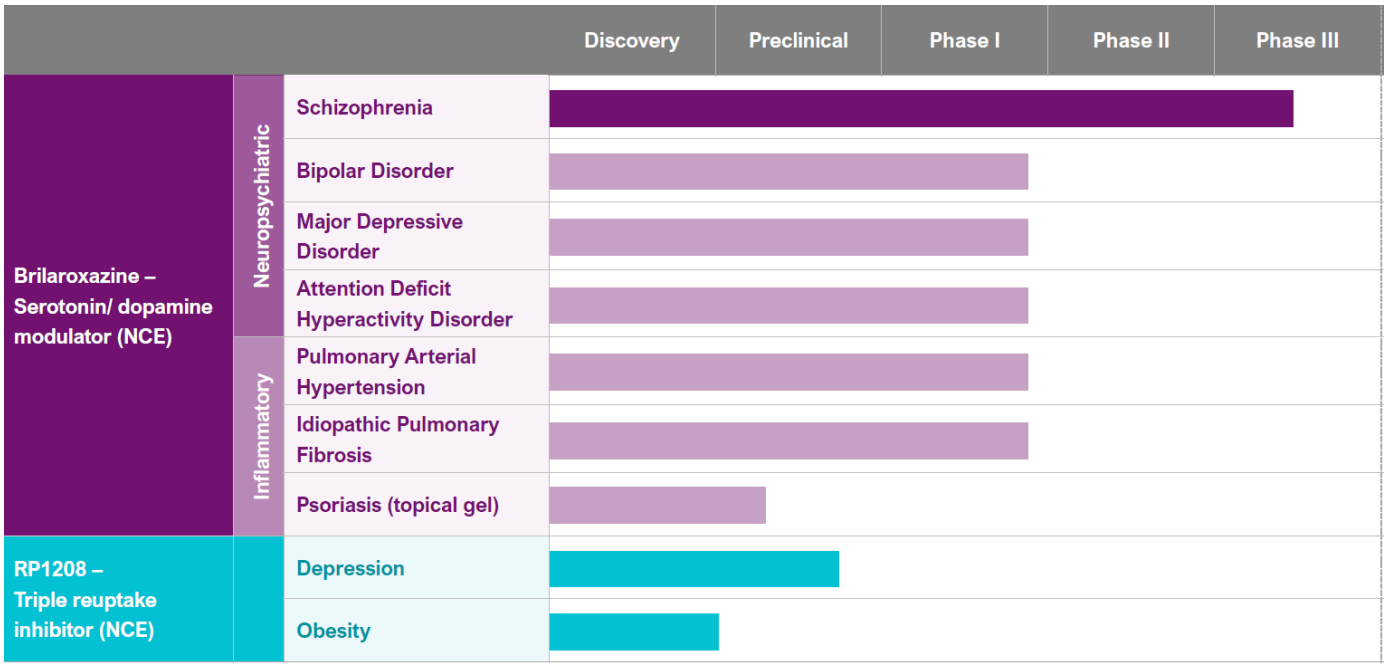
Last April, a press release announced that Reviva had come to an agreement with the FDA regarding the content desired in a new drug application (NDA). The agency wants to see two positive Phase III studies showing efficacy at week four that are accompanied by safety data of at least 12 months. The FDA will require a long-term randomized withdrawal study post-approval to support maintenance of effect.

Milestones

- Poster presentation at the Schizophrenia International Research Society (SIRS) Congress – March 2025
- Citizens Life Sciences Conference in NYC (replay available) – May 2025
- Virtual AGP Healthcare Company Showcase (replay available) – May 2025
- Late-breaking poster presentation at ASCP meeting – May 2025
- Full data release for OLE study – 2Q:25
- Key Opinion Leader Event – June 2025
- Initiation of Phase III RECOVER-2 clinical trial – 2025
- Topline data announcement for RECOVER-2 – 2026
- Brilaroxazine NDA submission to FDA for schizophrenia – 4Q:26

Company Pipeline

Exhibit IV – Reviva Pipeline



Source: Reviva July 2024 Corporate Presentation

Valuation

We adjust our valuation to $10 per share to reflect a delay in our original timeline for the start of the RECOVER-2 trial and to reflect additional shares required as part of a capital raise. We strongly believe that with the proper funding, brilaroxazine has tremendous value on par with other schizophrenia assets that have been acquired. It demonstrates a better efficacy and side effect profile compared with other treatments in the indication. Despite this, we do face the reality of dilutive funding and reflect the change in our assumptions in the valuation.

Summary

Reviva reported first quarter 2025 financial results following a poster presentation at SIRS and is preparing for a capital raise so it can complete its regulatory requirements for brilaroxazine to obtain approval. In support of its capital raise, CEO Laxminarayan Bhat has been attending investor conferences and sharing Reviva's buy thesis as well as presenting at medical meetings. The company is expected to initiate the second of two Phase III studies for brilaroxazine on the heels of strong confirmatory data generated in the OLE study.

The M&A market has produced three significant CNS transactions over the last 18 months, valuing schizophrenia assets in the multi billion dollar range. Although the market has been slow to recognize brilaroxazine's potential, we remain confident in its substantial value since it has demonstrated superior efficacy and produced a favorable safety profile. In the most recent OLE update at the SIRS conference, PANSS scores showed continued improvement over 52 weeks, extending results recorded in the RECOVER trial. Low discontinuation rates were a positive fundamental with only 35% of patients stopping their therapy at the one-year mark. Established biopharmas are willing to pay billions for new schizophrenia drugs such as Caplyta, KarXT and emraclidine, showing that the rewards are substantial if brilaroxazine can confirm its performance. With one Phase III completed and the second soon to start, we anticipate a faster pace for RECOVER-2. We adjust our target price of $10 per share to reflect timing for brilaroxazine's development, regulatory process and commercialization and update our estimate for shares outstanding.

PROJECTED FINANCIALS

Reviva Pharmaceutical Holdings Inc. - Income Statement[8]

Reviva Pharmaceuticals	2024 A	Q1 A	Q2 E	Q3 E	Q4 E	2025 E	2026 E	2027 E
Total Revenues ($US ,000)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
Research & Development	$22,907	$4,114	$4,000	$8,000	$9,000	$25,114	$15,000	$7,000
General & Administrative	$7,892	$2,425	$2,400	$1,800	$1,800	$8,425	$10,600	$6,100
Income from operations	($30,799)	($6,538)	($6,400)	($9,800)	($10,800)	($33,538)	($25,600)	($13,100)
Other Income (Expense)	$900	$111	$60	$100	$120	$391	($408)	($407)
Pre-Tax Income	($29,899)	($6,428)	($6,340)	($9,700)	($10,680)	($33,148)	($26,008)	($13,507)
Provision for Income Tax	$20	$5	$5	$5	$5	$20		
Net Income	**($29,919)**	**($6,433)**	**($6,345)**	**($9,705)**	**($10,685)**	**($33,168)**	**($26,008)**	**($13,507)**
Reported EPS	**($0.90)**	**($0.13)**	**($0.13)**	**($0.13)**	**($0.14)**	**($0.53)**	**($0.33)**	**($0.16)**
YOY Growth	*-45%*					*-42%*	*-38%*	*-51%*
Basic Shares Outstanding	33,147	48,644	50,000	76,000	78,000	63,161	80,000	85,000

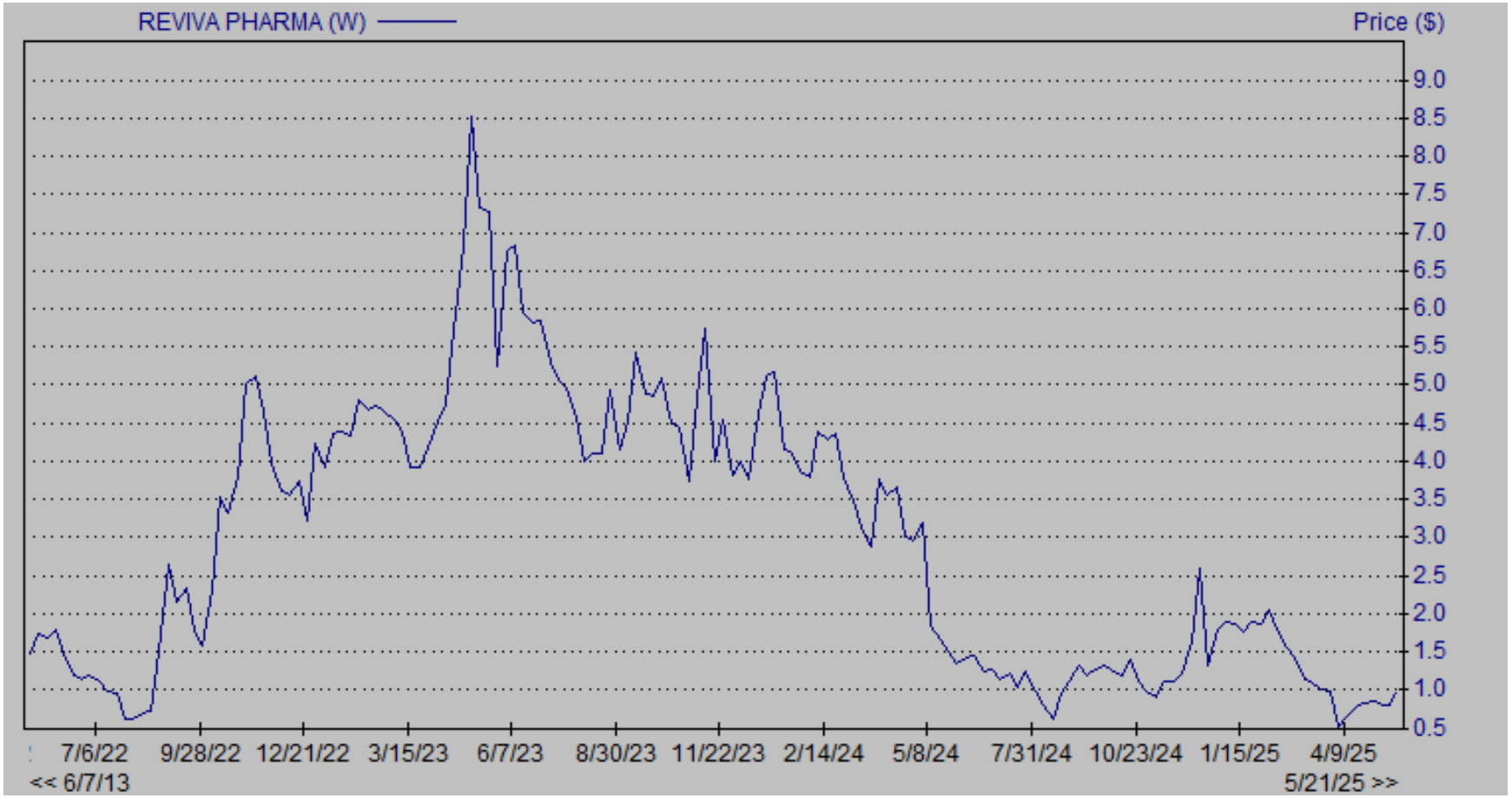
Source: Company Filing // Zacks Investment Research, Inc. Estimates

[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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