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Reviva Pharmaceuticals, Inc. (RVPH: NASDAQ)

RVPH: M&A Deals Highlight Brilaroxazine Value

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 (4/4/2025)	$0.53
Valuation	**$12.00**

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 & 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	**$0.49**
One-Year Return (%)	**-85.4**
Beta	**-0.1**
Average Daily Volume (sh)	**1,465,581**
Shares Outstanding (mil)	**46.7**
Market Capitalization ($mil)	**24.8**
Short Interest Ratio (days)	**2.6**
Institutional Ownership (%)	**29.5**
Insider Ownership (%)	**14.3**
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 2024 Estimate	**N/A**
P/E using 2025 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)
2023	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2024	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2025					$0.0 E
2026					$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	-$0.25 A	-$0.26 A	-$0.25 A	-$0.17 A	-$0.90 A
2025					-$0.71 E
2026					-$0.26 E

WHAT'S NEW

Materially Undervalued

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 $25 million severely discounts brilaroxazine's potential, suggesting substantial upside if RECOVER-2 can generate data in-line with the first Phase III trial.

Operational and Financial Results

On March 31st, 2025, Reviva Pharmaceutical Holdings, Inc. (NASDAQ: RVPH) reported 2024 financial and operational results and filed its Form 10-K with the SEC. Reviva provided updates on its open-label extension (OLE) trial and expects to report the full data set from the OLE in 2Q:25. Initiation of the RECOVER-2 study is slated for mid-year, depending on the availability of financing. We see a capital raise or a strategic partnership as a possibility in the near term to support further development. The preparation work for RECOVER-2 has been completed and we anticipate a rapid enrollment once started. Below, we summarize 2024's operational and financial achievements.

Reviva generated no revenues in 2024 and expended $30.8 million on operational activities including activity primarily related to the open-label extension (OLE) for RECOVER, producing a net loss of ($29.9) million or ($0.90) on a per share basis. For the year ending December 31st, 2024 and versus the same prior year period:[3]

- Research & development expense totaled $22.9 million, down 27% from $31.4 million, primarily attributable to the absence of Phase III clinical trial expenses related to the RECOVER trial which was active in 2023. 2024 expenses are related to the active outpatient OLE trial. Other factors contributing to the decline include lower wage and payroll costs, lower share-based compensation, reduced external research and development expenses and decreased non-clinical manufacturing related costs;
- General & administrative expenses totaled $7.9 million, falling 2% from $8.1 million on account of lower stock-based compensation and employee related expenses, less directors' and officers' insurance expense, partially offset by higher consultant and professional expenses and greater legal expenses;
- Other income of $900,000 compared to $260,000 with the difference attributable to a gain on remeasurement of warrant liabilities and reduced interest expense partially offset by reduced interest income;
- Provision for taxes was $20,000 compared to $17,000 related to payment of state and foreign taxes;
- Net loss was ($29.9) million vs ($39.3) million, or ($0.90) and ($1.65) per share, respectively.

As of December 31st, 2024, Reviva held $13.5 million in cash on its balance sheet. 2024 cash burn was ($35.5) million while cash flows from financing were $23.7 million related to the August underwriting agreement and December public offering.

[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.
[3] We use restated data for our comparisons.

Open-Label Extension Initial Readout

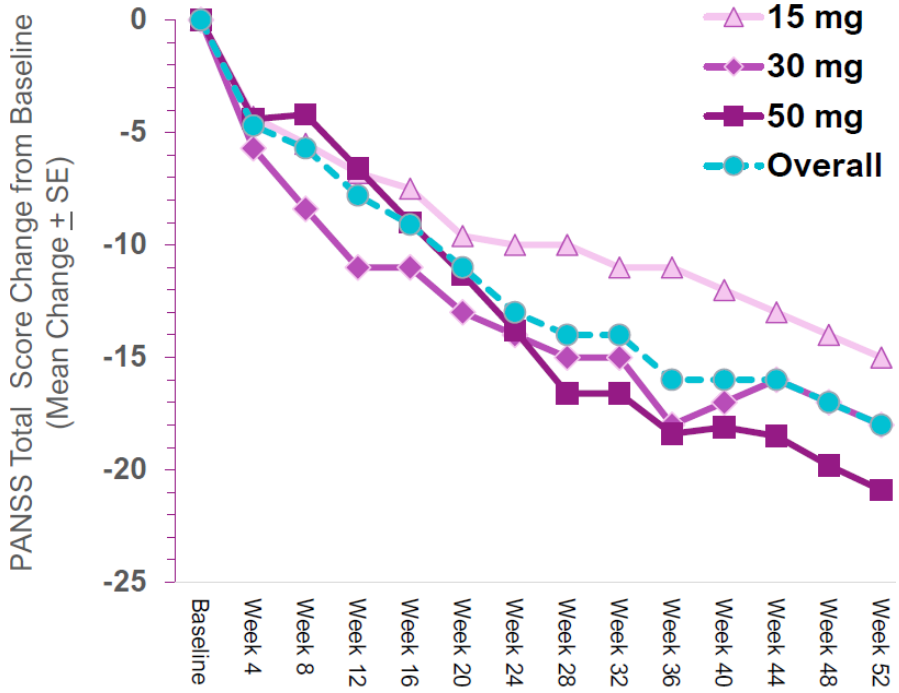
Reviva Pharmaceutical Holdings, Inc. (NASDAQ: RVPH) reported preliminary results from its open-label extension (OLE) from the Phase III RECOVER trial. Brilaroxazine showed a favorable long-term safety profile and improving efficacy over the one-year observation period. The schizophrenia candidate produced 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. A total of 435 patients were actively on treatment in the study across the three doses of 15 mg (139), 30 mg (155) and 50 mg (141). 156 subjects rolled over from the double-blind portion of the Phase III trial and 279 were new participants in the OLE.

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 PANSS 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 is 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.

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 and three drug-related SAEs occurred. 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

[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.

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.

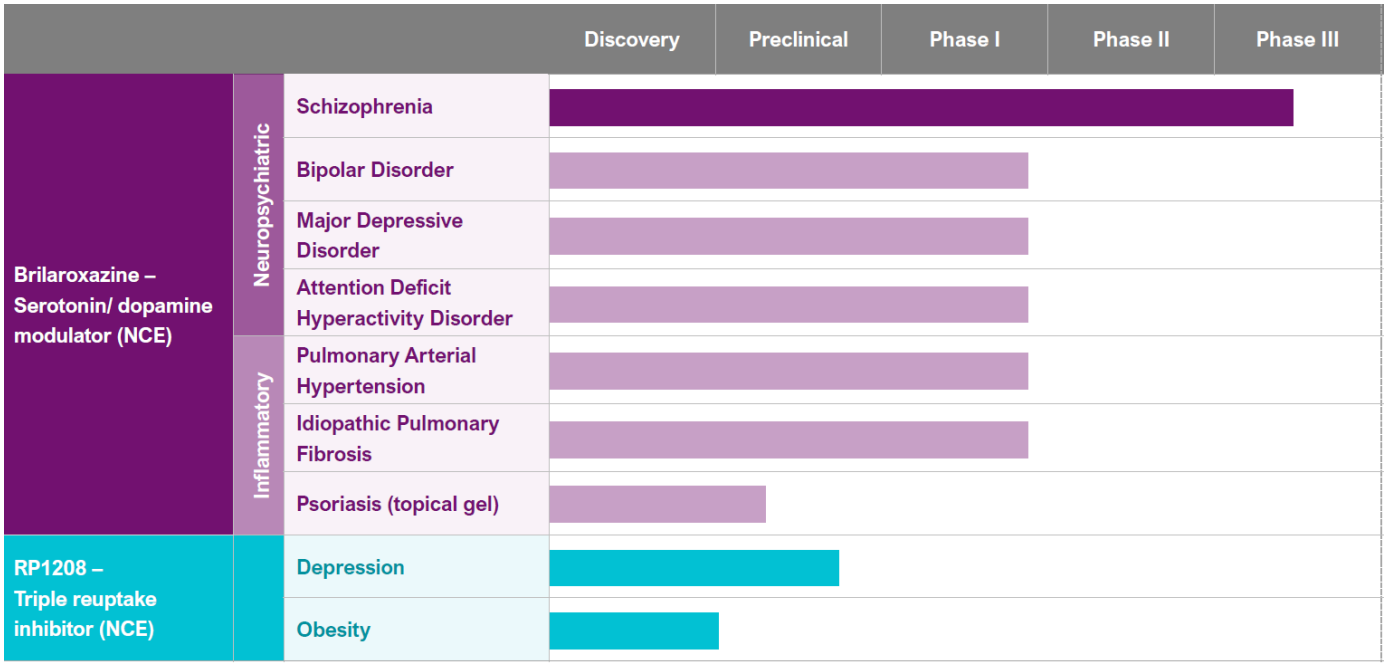
Last April, a press release announced that Reviva had come to an agreement with the FDA regarding the content desired in a new drug application (NDA). The agency wants to see two positive Phase III studies showing efficacy at week four that are accompanied by safety data of at least 12 months. It will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

Milestones

- Initiation of Phase III RECOVER-2 clinical trial – 2025
- Completion of RECOVER trial open-label extension (OLE) – 4Q:24
- Topline data announcement for RECOVER-2 – 2026
- New Drug Application (NDA) submission to FDA – 2026
- FDA meeting on NDA submission – April 2024
- Presentation of Speech Latency Data at the CNS Summit – November 2024
- OLE Topline – December 2024
- Poster presentation at the Schizophrenia International Research Society (SIRS) Congress – March 2025
- Full data release for OLE study – 2Q:25

Company Pipeline

Exhibit IV – Reviva Pipeline



Source: Reviva July 2024 Corporate Presentation

Summary

Reviva reported 2024 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. 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 transactions over the last 18 months, valuing schizophrenia assets in the multi-billion dollar range. While 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 maintain our target price of $12 per share.

PROJECTED FINANCIALS

Reviva Pharmaceutical Holdings Inc. - Income Statement[8]

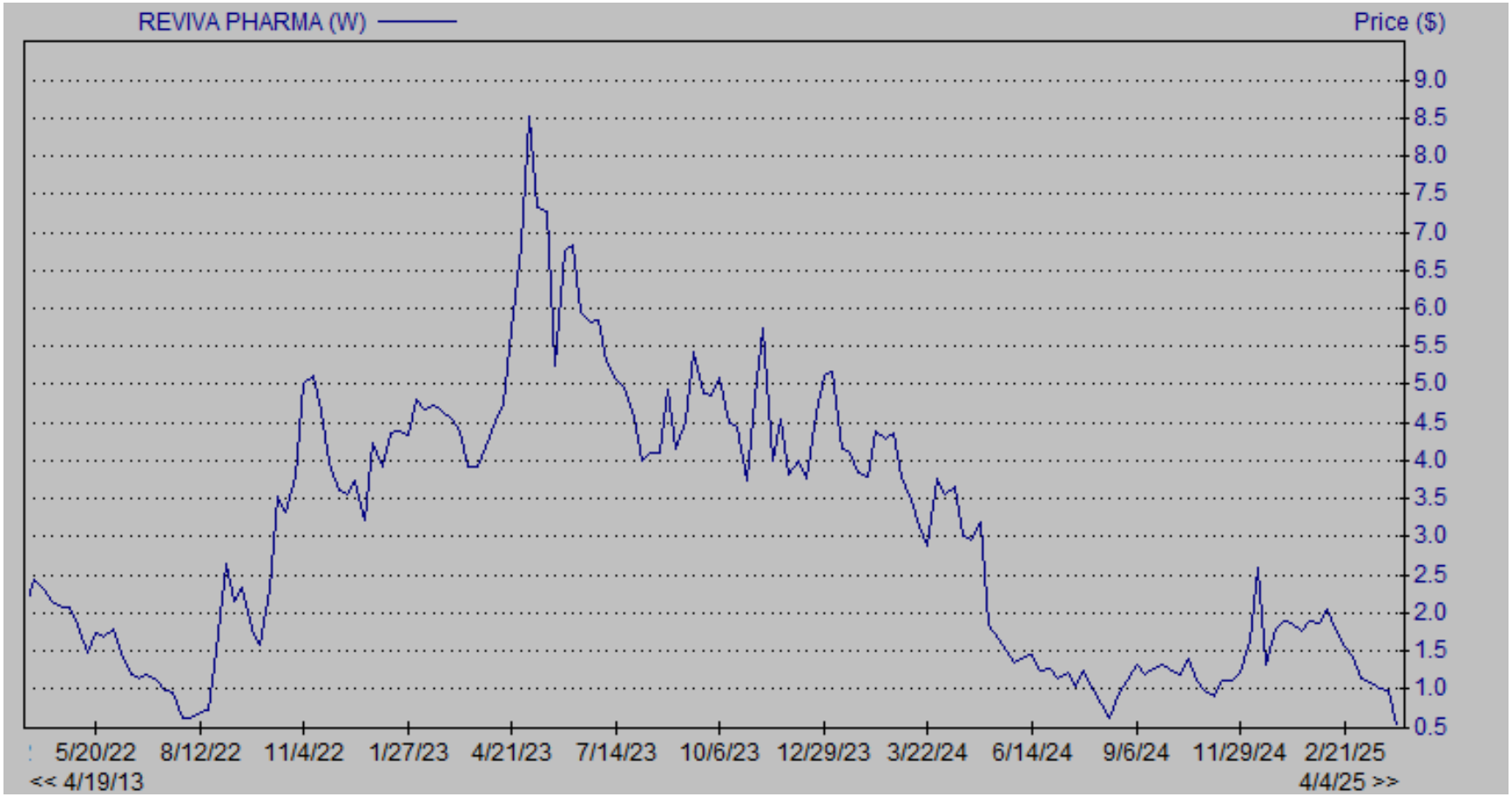
Reviva Pharmaceuticals	2023 A	Q1 A	Q2 A	Q3 A	Q4 A	2024 A	2025 E	2026 E
Total Revenues ($US ,000)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
Research & Development	$31,420	$5,784	$5,584	$6,858	$4,681	$22,907	$32,125	$7,000
General & Administrative	$8,084	$2,138	$2,545	$1,604	$1,604	$7,892	$10,200	$10,600
Income from operations	($39,504)	($7,922)	($8,130)	($8,463)	($6,285)	($30,799)	($42,325)	($17,600)
Other Income (Expense)	$260	$496	$277	$97	$30	$900	($409)	($408)
Pre-Tax Income	($39,244)	($7,426)	($7,853)	($8,366)	($6,255)	($29,899)	($42,734)	($18,008)
Provision for Income Tax	$17	$7	$7	$0	$5	$20	$0	
Net Income	**($39,261)**	**($7,434)**	**($7,860)**	**($8,366)**	**($6,259)**	**($29,919)**	**($42,734)**	**($18,008)**
Reported EPS	**($1.65)**	**($0.25)**	**($0.26)**	**($0.25)**	**($0.17)**	**($0.90)**	**($0.71)**	**($0.26)**
YOY Growth	*32%*					*-45%*	*-21%*	*-64%*
Basic Shares Outstanding	23,798	29,887	30,555	33,805	35,855	33,147	60,000	70,000

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

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

HISTORICAL STOCK PRICE

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



[9] Source: Zacks Research System

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