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Reviva Pharmaceuticals, Inc. (RVPH: NASDAQ)

RVPH: There May Be A Faster Way

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 (8/18/2025)	$0.52
Valuation	**$7.00**

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	**$0.30**
One-Year Return (%)	**-18.9**
Beta	**-0.1**
Average Daily Volume (sh)	**2,418,893**
Shares Outstanding (mil)	**68.0**
Market Capitalization ($mil)	**35.4**
Short Interest Ratio (days)	**3.7**
Institutional Ownership (%)	**21.1**
Insider Ownership (%)	**7.3**
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 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 A	$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	-$0.12 A	-$0.13 E	-$0.14 E	-$0.52 E
2025					-$0.33 E
2026					-$0.16 E

WHAT'S NEW

Reviva Pharmaceutical Holdings, Inc. (NASDAQ: RVPH) reported 2Q:25 results, highlighting the June release of the dataset for the open-label extension (OLE) RECOVER trial. In its second quarter report, Reviva announced the possibility of submitting its new drug application (NDA) to the FDA without conducting a second Phase III trial. The team will consult with the FDA in a meeting planned for 4Q:25 to see if an NDA application can be accepted using existing data. If the FDA gives Reviva a positive response, brilaroxazine could be submitted for approval in 2Q:26. Reviva is also developing another indication in schizophrenia focusing on negative symptoms which could provide extended protection for brilaroxazine and expand the market into an area with unmet need.

Reviva also plans to submit an investigational new drug (IND) application for a liposomal gel formulation of brilaroxazine in psoriasis expected by 2Q:26. This could provide alternate patent protection and pricing differentiation with the oral form of the drug if successful. Other notable events since our previous quarterly update include a poster presentation at American Society of Clinical Psychopharmacology (ASCP), execution of a $10 million capital raise and participation in several investor conferences.

Operational and Financial Results

On August 15th, 2025, Reviva reported 2Q:25 financial and operational results and filed its Form 10-Q with the SEC. Reviva generated no revenues in the quarter and posted an operational loss of ($6.1) million with expenses primarily related to RECOVER's OLE. For the quarter ending June 30th, 2025 and versus the same prior year period:

- Research & development expense totaled $3.7 million, down 33% from $5.6 million, with the change attributable to a decrease in external clinical research and development costs, partially attributed to a decrease in costs associated with patient visits as the OLE trial proceeded toward completion with ongoing expenses consisting of post-data readout activities and trial conclusion;
- General & administrative expenses totaled $2.3 million, falling 8% from $2.5 million on account of lower professional expenses with other expense categories remaining relatively flat;
- Other income of $27,000 compared to $277,000 with the difference almost entirely attributable to a lower gain on remeasurement of warrant liabilities. Net interest income is lower 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 $8,000 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 June 30th, 2025, Reviva held $10.4 million in cash on its balance sheet. 1H:25 cash burn was ($13.2) million while cash flows from financing were $10.0 million. Financing transactions from a public offering, an at the market facility and warrant exercise contributed to the total. We anticipate further capital raises over the remainder of the year.

$10 Million Public Offering

On June 25th, Reviva announced a public offering which was closed the next day. The company sold 20 million shares of common stock at $0.50 per share along with 40 million attached warrants with an exercise price of $0.50. The capital raise closed on June 27th generating net proceeds of $9.0 million which will be used to fund research and development activities and for working capital and other general corporate purposes. 20 million of the warrants will have a five-year life and the other 20 million will have a 12-month life.

Regulatory Path

Reviva is exploring the possibility of submitting a new drug application (NDA) with existing data. The company has conducted a Phase II, a Phase III and a safety study for brilaroxazine in schizophrenia. Previous schizophrenia drug developers have submitted to the FDA with only one Phase III including Minerva Neurosciences with roluperidone and Intra-Cellular Therapies with Caplyta. Reviva is seeking a meeting with the FDA in 4Q:25 to explore such a possibility. Skipping the second RECOVER trial would be a substantial positive for shareholders and would eliminate the overhang related to the near-term capital raise necessary to run RECOVER 2. Reviva is looking at other alternatives to extend brilaroxazine's patent life including finding a closely related indication such as one centered on the negative symptoms of schizophrenia using a new, possibly more concentrated, formulation.

Exhibit I – Registrational Trials for Brilaroxazine in Schizophrenia

PHASE 1A and 1B, Clin Pharm Studies (N≈150)	PHASE 2 REFRESH NCT01490086	PHASE 3 RECOVER DB NCT05184335	PHASE 3 RECOVER OLE NCT05184335
Phase 1A Healthy subjects, double-blind, safety and tolerability, pharmacokinetics (PK)	**N = 234 (4-Week) Acute schizophrenia or schizoaffective disorder**	**N = 411 (4-Week) Acute schizophrenia**	**N = 446 (52-Week/1-Year) Stable schizophrenia**
Phase 1B Stable schizophrenia patients, double-blind, POC efficacy, safety and tolerability, PK	Efficacy and safety of brilaroxazine vs placebo	Efficacy and safety of brilaroxazine vs placebo	Long-term safety/tolerability, efficacy and compliance of brilaroxazine
ADME & Bioavailability Once daily brilaroxazine, ~72% bioavailability	3:3:2 Randomized, 4-week, double-blind, placebo-controlled, multicenter	1:1:1 Randomized, 4-week, double-blind, placebo-controlled, multicenter	Open label,1-year outpatient extension of RECOVER
Drug-drug Interactions No clinically significant drug-drug interactions	Once daily brilaroxazine 15, 30, 50 mg	Once daily brilaroxazine 15, 50 mg	Once daily brilaroxazine 15, 30, 50 mg flexible dose
	Completed and met primary and multiple secondary endpoints	Completed and met primary and multiple secondary endpoints	Completed and met primary and multiple secondary endpoints

Source: Reviva KOL Webinar Presentation, June 2025

Open Label Extension Key Opinion Leader Event

Reviva Pharmaceuticals Holdings, Inc. (NASDAQ: RVPH) held a key opinion leader (KOL) event featuring two luminaries in the schizophrenia space to discuss brilaroxazine and the RECOVER open label extension (OLE) full data set. Dr. Stephen Marder, professor of Psychiatry and Biobehavioral Sciences at UCLA and Dr. Larry Ereshefsky, retired professor of Pharmacology and Psychiatry at the University of Texas joined Reviva CEO Laxminarayan Bhat to review the data.

Exhibit II – Brilaroxazine Phase III Trial Data Summary

Strong broad-spectrum efficacy further supported by vocal biomarker (VBM) and blood biomarkers

	Symptom Domains & Adherence		Digital Biomarkers, VBM		Blood Biomarkers
	All Patients Brila 50mg vs Placebo		Prominent Negative Symptoms Brila 50mg vs Placebo (VBM Positive)		All Patients
	Point Improvement	*Cohen's d Effect Size*	Point Improvement	*Cohen's d Effect Size*	
PANSS Total Score	10.1	*0.6*	15	*0.9*	**Neurotrophins*** BDNF
Positive Symptoms	2.8	*0.5*	3.5	*0.8*	**Hormones*** Prolactin* Thyroid T3*
Negative Symptoms	2.0	*0.4*			
Negative Marder Factor	2.1	*0.4*	3.7	*0.6*	
PANSS Social Cognition	1.6	*0.5*	3.8	*0.8*	**Cytokines*** IL-6# IL-8 IL-10 IFN-γ/IP-10 MIP-1
Personal & Social Performance	6.3	*0.5*	6.3	*0.6*	
CGI-S score	≥1	*0.5*	≥1	*0.7*	
PANSS Excitement/Agitation	2.1	*0.5*			
PANSS Gen Psychopathology	-8.7	*0.6*			
Treatment Discontinuation	**16%** brilaroxazine	**22%** placebo			

Cohen et al CNS Summit 2024, ISCTM 2025

*Significant improvement, P≤0.05
#Separated from placebo but NS

Source: Reviva KOL Webinar Presentation, June 2025

The event began with introductions of the featured KOLs and background on Reviva's lead candidate brilaroxazine. Four trials have been run for brilaroxazine including a Phase Ia/Ib, the Phase II REFRESH trial, Phase III RECOVER trial and the OLE. The trials have evaluated 15, 30 and 50 mg doses of brilaroxazine of periods ranging from four weeks to 12 months. The drug is being developed to treat schizophrenia, a psychiatric condition that affects over 1% of the world population and an estimated 24 million people globally and 3.5 million in the United States. While there are many approved compounds to treat schizophrenia, there are also several shortcomings. Two of the most salient include addressing negative symptoms such as avolition and asociality and adherence to treatment which is impacted by unpleasant side effects.

Dr. Marder began his section of the presentation with a review of brilaroxazine's mechanism of action, highlighting the receptor activity for the drug noting strong binding to the serotonin 5-HT_{2B} and dopamine D_2 receptors and little activity off target which is associated with negative side effects. He pointed to the large effect sizes for brilaroxazine in trials conducted to date and noted that they were sustained over a one-year period. Tolerability was another positive attribute with treatment discontinuations of only 35% over the one-year period. Based on our review of several resources,[1,2,3,4] discontinuation for this class ranges anywhere from the mid-40% range to 70%. For Bristol Myers' recently approved KarXT, discontinuation was 53% after 52 weeks of treatment.

Dr. Marder's conclusions noted consistent, wide spectrum efficacy particularly in the negative domain, a well-run trial that generated high-quality data, a favorable efficacy to side effect ratio[5] which yields a low discontinuation rate and the potential to significantly address unmet needs.

The event continued with the presentation by Dr. Larry Ereshefsky, who has been a regular KOL contributor to brilaroxazine data analyses and who was calling in via Starlink from near the North Pole. Dr. Ereshefsky's presentation began with a summary of the unmet needs in the space. He noted that standard-of-care antipsychotics are suboptimal to treat chronic conditions, negative, mood and cognitive symptoms.

Unmet needs:

- Poor tolerability and prevalence of long-lasting side effects
- Recovery or remission is a rarity
- Relapse prevention is less than half by year two
- Population has high use of multiple medications and high incidences of drug-drug interactions
- Poor quality of life
- High treatment discontinuation rate

Dr. Ereshefsky reviewed the population characteristics and trial outcomes for RECOVER, noting the minimal weight gain in patients of about 1.5 kg more than placebo during the initial four weeks. At the end of 12 months, brilaroxazine subjects had gained about 1.5 kg versus baseline which was lower than the 2.4 kg gain at the end of the first four weeks. Rollover patients, who began on placebo then moved to brilaroxazine gained 1.2 kg after 13 months.

OLE results showed that the prolactin hormone, which is associated with sexual side effects, was lower for brilaroxazine subjects at the end of the trial. Pooled, 15 mg, 30 mg and 50 mg groups all showed materially lower prolactin levels compared to baseline and all were statistically significant. Elevated prolactin levels, medically termed hyperprolactinemia, represent a significant endocrinological disorder characterized by abnormally high concentrations of prolactin hormone in the blood. The clinical manifestations are diverse and primarily affect reproductive function, causing symptoms ranging from galactorrhea and menstrual irregularities in women to erectile dysfunction and reduced muscle mass in men.[6] Thyroid hormone increased in brilaroxazine subjects for all groups, with the pooled data for 446 subjects significant at a p value below 0.05. Hypothyroidism is common in schizophrenia and mood disorder patients and can further exacerbate these symptoms. Thyroid hormones are important for modulation of dopaminergic, serotonergic, glutamatergic and GABAergic receptors.

Brilaroxazine's lipid profile is another key differentiator relative to other approved antipsychotics. For all doses, patients experienced a decline in serum cholesterol and in serum low-density lipoprotein (LDL) (bad) cholesterol. Hypercholesterolemia and dyslipidemia represent clinically significant metabolic side effects associated with atypical antipsychotic therapy, posing substantial cardiovascular risks that can dramatically impact patient morbidity and mortality.[7] RECOVER placebo patients experienced an increase in both cholesterol and LDL cholesterol over the 12-month period of 3.65 and 4.07 mg/dL respectively.

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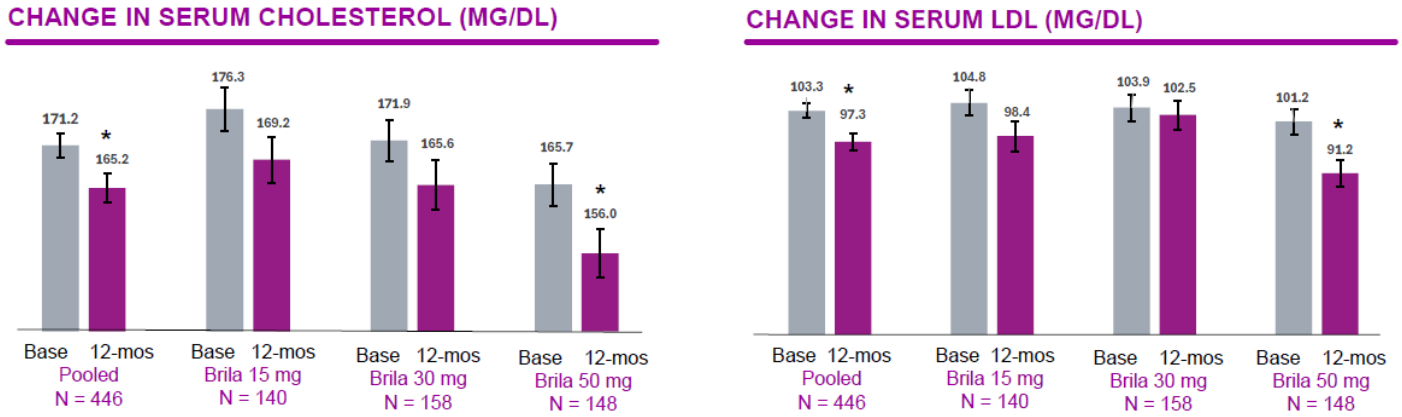
[1] Liberman, J.A., *et al*. Effectiveness of Antipsychotic Drugs in Patients with Chronic Schizophrenia. New England Journal of Medicine. September 2005.
[2] Zhang, C., *et al*. Rates and predictors of one-year antipsychotic treatment discontinuation in first-episode schizophrenia: Results from an open-label, randomized, "real world" clinical trial. Psychiatry Research. March 2019.
[3] 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.
[4] 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.
[5] See our April 2024 Note that compares brilaroxazine with other leading antipsychotics: Update to Brilaroxazine Safety vs. Efficacy Comparison – Adding RECOVER Data
[6] Prolactinoma. Mayo Clinic.
[7] Carli, M *et al*. Atypical Antipsychotics & Metabolic Syndrome: From Molecular Mechanisms to Clinical Differences. Pharmaceuticals. March 2021.

Exhibit III – RECOVER Change in Lipid Profile

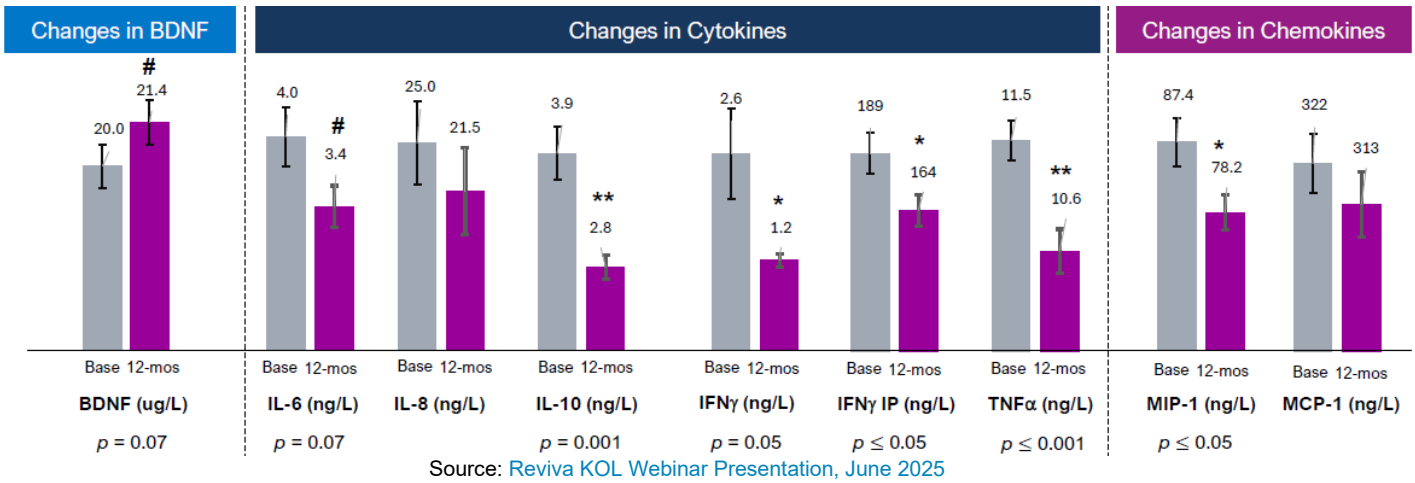


Source: Reviva KOL Webinar Presentation, June 2025

Inflammation is another area of dysregulation characteristic of schizophrenia patients. People with schizophrenia often show elevated levels of inflammatory biomarkers and research suggests that there is an association between immune system dysfunction, chronic inflammation and schizophrenia. There is a body of evidence that a meaningful proportion of schizophrenia patients are in a pro-inflammatory state where cytokine dysregulation and immune activation interplay with genetic and environmental stressors in driving the disease. Inflammatory cytokines and chemokines are thought to contribute to schizophrenia's pathophysiology through multiple mechanisms.[8,9]

Brain derived neurotrophic factor (BDNF) is a neurotrophin fundamental to neuronal development, synaptic plasticity, and survival. Given that schizophrenia is seen as a disorder of aberrant neurodevelopment and impaired plasticity, BDNF has attracted attention as a potential mediator in its pathophysiology. BDNF supports neurogenesis and synaptic connectivity, particularly in cortical and hippocampal circuits involved in cognition and memory. An aberration in BDNF signaling could contribute to cortical atrophy, dysconnectivity, and cognitive deficits observed in schizophrenia.[10] In contrast, higher BDNF levels are associated with clinical improvement in the disorder. Results from the OLE show that BDNF levels rose over the 12 months of the study while cytokine and chemokine levels declined.

Exhibit IV – RECOVER OLE Trial Inflammatory Biomarker Data



Source: Reviva KOL Webinar Presentation, June 2025

Dr. Ereshefsky summarized his assessment of the trial results noting that brilaroxazine was well tolerated at all dose strengths with minimal adverse events and low discontinuation. There were also no clinically meaningful changes in movement disorder scales used for evaluating motor side effects such as akathisia and extrapyramidal symptoms. Weight gain was minimal and moderated by the end of the twelve-month measurement period while cholesterol levels declined. No endocrine or sexual side effects were noted and elevated prolactin levels at the beginning of the trial declined by its end. Inflammation markers were also improved after a year-long course of brilaroxazine, correlated with improved PANSS scores.

[8] Reale, M., *et al.* Cytokine Imbalance in Schizophrenia. From Research to Clinic: Potential Implications for Treatment. Psychiatry, March 2021.
[9] Ermakov, E., *et al.* Chemokine Dysregulation and Neuroinflammation in Schizophrenia: A Systematic Review. International Journal of Molecular Science. January 2023.
[10] Goren, J. Brain-derived neurotrophic factor and schizophrenia. Mental Health Clinician. November 2016.

At the end of the KOL event, the lines were opened for questions. These revolved around the efficacy profile of brilaroxazine compared with other antipsychotics and the biomarker results relative to other prescribed atypical antipsychotics. Other queries centered on the regulatory pathway and the need for a second Phase III study.

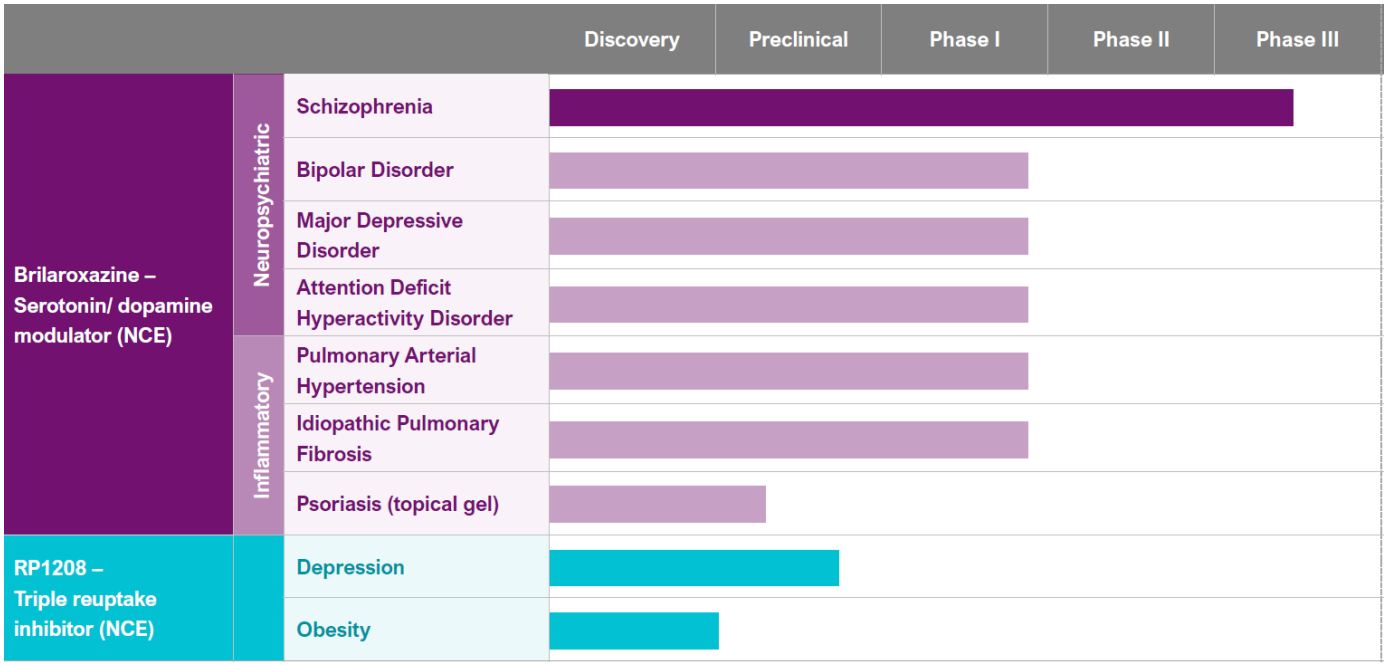
RECOVER Trial Background
RECOVER was a global Phase 3, randomized, double-blind, placebo-controlled, multicenter study designed to assess the safety and efficacy of brilaroxazine in 412 patients with acute schizophrenia compared to placebo. Brilaroxazine was administered at fixed doses of 15 mg or 50 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. Topline for the trial was first announced in October 2023. The primary endpoint was met with the trial producing a 10.1-point reduction in PANSS score relative to placebo at four weeks for the 50 mg dose. 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.

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. To be valid, it was designed to evaluate at least 100 subjects 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 RECOVER. 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.

Company Pipeline

Exhibit V – Reviva Pipeline



Source: Reviva July 2024 Corporate Presentation

At-The-Market Facility

In a Form 8-K filed on May 30th, 2025, Reviva disclosed that it had established an at-the-market (ATM) facility with B. Riley Securities and Alliance Global Partners to offer up to $50 million in equity. Each transaction carries a 3% commission. While ATMs are helpful for covering day to day expenses, we believe the ATM will be inadequate to fund the RECOVER 2 trial if it turns out to be necessary and a public offering will be necessary to provide enough capital to fund the pivotal study.

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
- Benchmark Healthcare Virtual Conference – May 2025
- Lytham Partners Spring Conference – May 2025
- Full data release for OLE study – 2Q:25
- H.C. Wainwright Neuro Perspectives Hybrid Conference – June 2025
- Key Opinion Leader Event – June 2025
- Meeting with FDA to discuss abbreviated pathway to approval – 4Q:25
- Topline data announcement for RECOVER-2 – 2026
- Liposomal-gel formulation of brilaroxazine IND submission – 2Q:26
- Brilaroxazine NDA submission to FDA for schizophrenia with FDA assent – 2Q:26

Valuation

We adjust our valuation to $7.00 per share to reflect the updated share and warrant balance as well as further capital raises in the near term. 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, investors must account for dilutive funding and we reflect the change in our assumptions and price target.

Summary

Reviva reported second quarter 2025 financial results following the release of its full data set for its OLE study and a capital raise. A new pathway is emerging which may allow Reviva to pursue approval for brilaroxazine in schizophrenia using existing data. The company will meet with the FDA later this year and if given the agency's nod, will submit its NDA in 2026. In parallel, the company is taking other actions to help further penetrate brilaroxazine into the market and extend its intellectual property protection. It will seek approval in addressing the negative symptoms of schizophrenia first by launching another Phase III study in parallel with its NDA submission for the broader indication. Reviva will also pursue an IND for a liposomal-gel formulation of brilaroxazine in psoriasis. We adjust our target price to $7 per share to reflect existing and anticipated share and warrant balances.

PROJECTED FINANCIALS

Reviva Pharmaceutical Holdings Inc. - Income Statement[11]

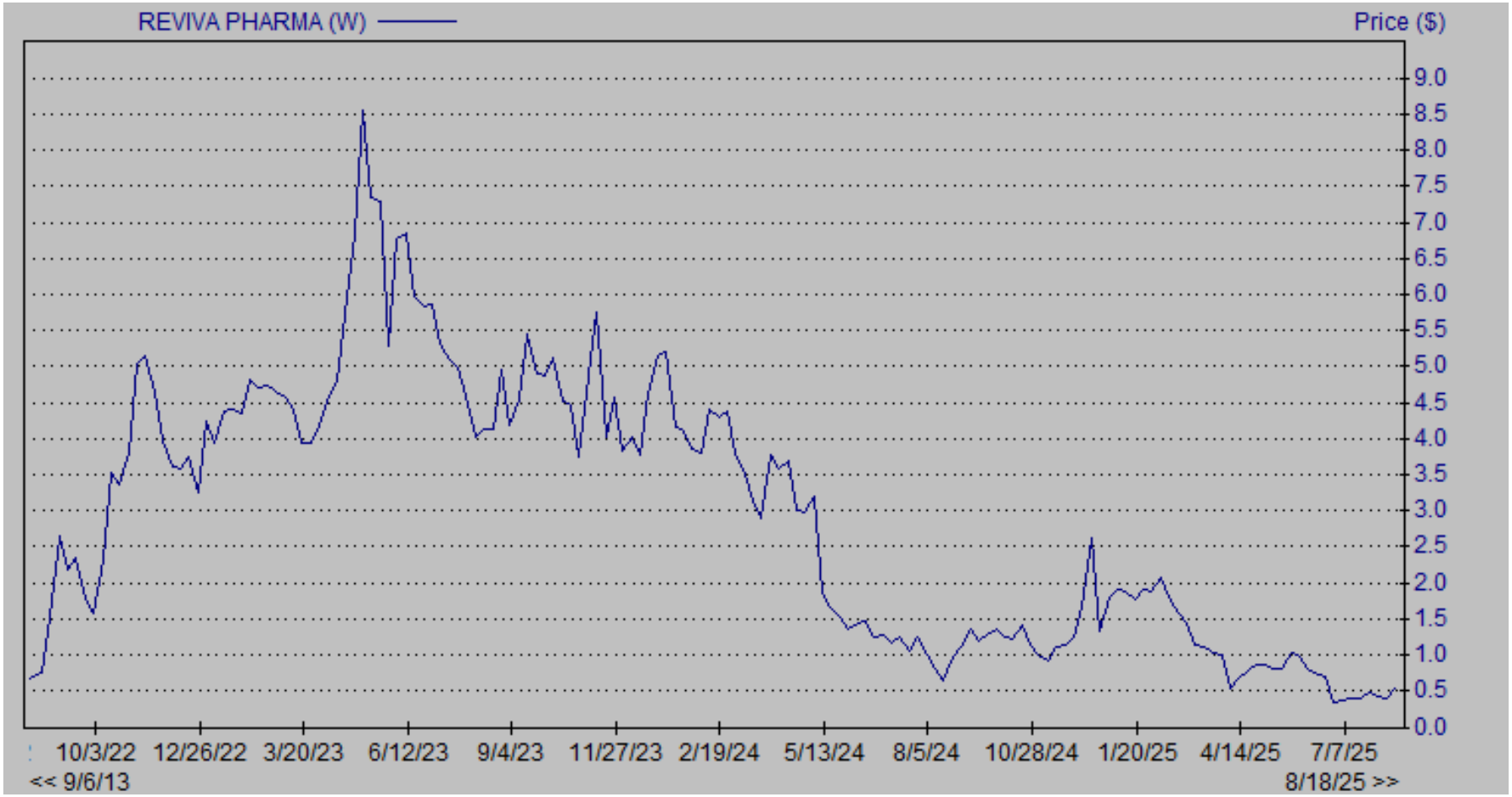
Reviva Pharmaceuticals	2024 A	Q1 A	Q2 A	Q3 E	Q4 E	2025 E	2026 E	2027 E
Total Revenues ($US ,000)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
Research & Development	$22,907	$4,114	$3,725	$8,000	$9,000	$24,838	$15,000	$7,000
General & Administrative	$7,892	$2,425	$2,348	$1,800	$1,800	$8,373	$10,600	$6,100
Income from operations	($30,799)	($6,538)	($6,073)	($9,800)	($10,800)	($33,211)	($25,600)	($13,100)
Other Income (Expense)	$900	$111	$27	$100	$120	$358	($408)	($407)
Pre-Tax Income	($29,899)	($6,428)	($6,046)	($9,700)	($10,680)	($32,853)	($26,008)	($13,507)
Provision for Income Tax	$20	$5	$8	$5	$5	$23		
Net Income	**($29,919)**	**($6,433)**	**($6,054)**	**($9,705)**	**($10,685)**	**($32,876)**	**($26,008)**	**($13,507)**
Reported EPS	**($0.90)**	**($0.13)**	**($0.12)**	**($0.13)**	**($0.14)**	**($0.52)**	**($0.33)**	**($0.16)**
YOY Growth	*-45%*					*-42%*	*-38%*	*-51%*
Basic Shares Outstanding	33,147	48,644	49,848	76,000	78,000	63,123	80,000	85,000

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

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

HISTORICAL STOCK PRICE

Reviva Pharmaceutical Holdings, Inc. – Share Price Chart[12]



[12] Source: Zacks Research System

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