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May 22, 2024

John D. Vandermosten, CFA
312-265-9588 / jvandermosten@zacks.com

scr.zacks.com **10 S. Riverside Plaza, Suite 1600, Chicago, IL 60606**

Reviva Pharmaceuticals, Inc. (RVPH: NASDAQ)

RVPH: Enrollment Right Around the Corner

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 (5/21/2024)	$1.31
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) completed its 1st Phase III trial & began its 2nd in 2Q: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	**$2.67**
One-Year Return (%)	**-81.3**
Beta	**0.0**
Average Daily Volume (sh)	**298,196**
Shares Outstanding (mil)	**29.4**
Market Capitalization ($mil)	**38.5**
Short Interest Ratio (days)	**7.1**
Institutional Ownership (%)	**18.4**
Insider Ownership (%)	**17.7**
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 E	$0.0 E	$0.0 E	$0.0 E
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	-$0.27 E	-$0.21 E	-$0.21 E	-$0.92 E
2025					-$0.71 E
2026					-$0.26 E

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WHAT'S NEW

2023 Operational and Financial Results

On May 14th, 2024, Reviva Pharmaceutical Holdings, Inc. (NASDAQ: RVPH) reported first quarter 2024 financial and operational results and filed its Form 10-Q with the SEC. Over the last several months Reviva has been industriously advancing its open label extension (OLE) trial, manufacturing clinical trial drug product and performing clinical pharmacology work. The company was also able to gain acceptance of its registrational RECOVER-2 trial design with the FDA. Management is in the process of raising capital prior to launching the trial and expects to attract sufficient funds to fully fund the second Phase III. The preparation work for RECOVER-2 has been completed and we anticipate a rapid enrollment once started. We begin our report with a summary of first quarter operational and financial results.

Highlights for 1Q:24 and to date:

- KOL Event – February 2024
- Presentation at American Society for Clinical Pharmacology & Therapeutics (ASCPT) – March 2024
- Poster at American Society for Clinical Pharmacology & Therapeutics (ASCPT) Meeting – March 2024
- Poster at Schizophrenia International Research Society (SIRS) Meeting – April 2024
- FDA meeting on NDA submission – April 2024
- Presentations at American Society for Pharmacology and Experimental Therapeutics – May 2024
- Presentation at American Thoracic Society – May 2024

Reviva generated no revenues for 1Q:24 and expended ($7.9) million on operational activities, producing a net loss of ($7.4) million or ($0.25) on a per share basis. For the quarter ending March 31, 2024 and versus the same prior year period:

- Research & development expense totaled $5.8 million, up 10% from $5.2 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 $2.1 million, rising 42% from $1.5 million on account of greater stock-based compensation and consultant and professional expenses that were partially offset by a decrease in legal expenses;
- Other income included a gain from the remeasurement of warrant liabilities due to a decline in the share price over the quarter offset by other expense which represents a foreign currency translation loss related to the company's Indian subsidiary;
- Net interest income was approximately $173,000, up over the prior year due to higher interest rates on higher cash balances;
- Provision for taxes was $7,000 compared to $3,000 related to payment of state and foreign taxes;
- Net loss was ($7.4) million vs ($6.6) million, or ($0.25) and ($0.30) per share, respectively.

As of March 31st, 2024, Reviva held $12.0 million in cash on its balance sheet. 1Q:24 cash burn was ($11.7) million with the difference between net loss and cash burn explained by a reduction in accrued expenses and other current liabilities of ($4.9) million. Cash flows from financing were $332,000 related to net issuance of short-term debt for its directors' and officers' policy.

RECOVER-2

Reviva is planning to launch its confirmatory Phase III RECOVER-2 trial in 2Q: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 4-week period and will randomize 450 patients 1:1:1 with 30 mg (in place of 15 mg), 50 mg and placebo arms. Completion is expected in 2025. This primes Reviva to submit its new drug application (NDA) in 2H:25.

On January 9th, the company entered into a start-up agreement with an additional contract research organization to conduct the RECOVER-2 trial. $1.1 million was paid to the group to start its activities.

An April 15th 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. Reviva expects it will be able to complete all of the NDA submission requirements by 3Q:25.

Update on Open Label Extension Study

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 open label extension (OLE) study. Following the report of first quarter earnings, Reviva provided an update on the study noting that there are 358 subjects enrolled and 223 on treatment at trial sites around the globe. Management reiterated that data from the trial is expected to be reported in 4Q:24.

The OLE was designed to take place in parallel with RECOVER and evaluate the long-term safety of brilaroxazine. It must evaluate at least 100 subjects 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 will evaluate flexible doses of brilaroxazine of 15, 30 or 50 mg. Management's qualitative assessment is that the drug has been generally well-tolerated across patients with acute and stable schizophrenia. Of the 358 patients enrolled in the study, 223 remained on treatment as of May 15, 2024. Over 130 of the patients have completed up to six months of treatment, over 90 patients have completed six to nine months of treatment and 23 have completed the full year. Data from the trial is expected to be finalized before the end of the year and will be part of the new drug application (NDA) package that Reviva will submit to the FDA along with anticipated RECOVER-2 data.

Restatements

Reviva announced in its 2023 Form 10-K and in its 1Q:24 10-Q that it had made several restatements related to research and development expenses in the prior year first quarter. There were certain estimated accrued clinical trial expenses that differed from the actual expenses due to improper review and evaluation of those expenses. The company attributes the errors to a material weakness in its internal control activities due to a failure in the design and implementation of its controls to review clinical trial expenses, including the evaluation of the terms of clinical trial contracts. While the reported income statement items were restated, there was no impact on net cash used in operating activities.

Key Opinion Leader Event

On February 15th, Reviva Pharmaceuticals hosted a key opinion leader (KOL) event. It featured Dr. Mark Opler, the Chief Research Officer at WCG Inc and Executive Director of the PANSS Institute and Dr. Larry Ereshefsky, retired professor of Psychiatry, Pharmacology and Psychiatry at the University of Texas. The panel was moderated by Reviva CEO, Dr. Bhat who introduced each of the speakers.

Dr. Opler began with a summary of schizophrenia's epidemiology with a review of prevalence and positive and negative symptoms. He also shared the scales and tools used to evaluate schizophrenia and the measures used in the RECOVER trial. The design of the trial, subject demographics and baseline characteristics were provided prior to a discussion of RECOVER's endpoints. In summary, trial results were statistically significant and clinically meaningful across all major symptom domains with brilaroxazine 50 mg vs. placebo at week four.

Dr. Ereshefsky provided a history of antipsychotics along with an update on improvement in side effects over time. However, there remain unmet needs including metabolic, endocrine, neuroleptic and autonomic side effects. Brilaroxazine may address several of the most burdensome of the antipsychotic side effects due to its mechanism of action. Several circuits are engaged to achieve the desired endpoints of reduced inflammation through inhibition of pro-inflammatory and increase of anti-inflammatory cytokines and chemokines.

Dr. Ereshefsky continued with a review of RECOVER brilaroxazine results pointing out important elements of weight gain, lipid markers, decrease in prolactin which is associated with sexual function, change in thyroid hormones, and variations in brain derived neurotrophic factor. The KOL noted the reduced level of drug-drug interactions for brilaroxazine compared with other approved antipsychotics. One of the more important features presented was the compliance for patients in the active arm with discontinuation rates for brilaroxazine-dosed subjects lower than those on placebo.

Dr. Bhat wrapped up the formal presentation section of the event with a review of Reviva's pipeline and future goals for the company. The last segment provided an opportunity for investors and other stakeholders to ask questions. The following is a link to the full event: KOL Event to Discuss Topline Data from Phase 3 RECOVER Trial of Brilaroxazine in Schizophrenia.

Update on 2021 Brilaroxazine Comparison

In an April 2021 report, we developed an analysis that compared efficacy benefits against the side effect profile for the leading antipsychotics and brilaroxazine and found that brilaroxazine produced the best balance of efficacy and side effects for the group. This analysis was updated using data from Reviva's 2023 RECOVER trial using the same methodology.

The 2021 analysis used data from brilaroxazine's Phase II trial and Huhn *et al*. published in The Lancet. Huhn *et al.* is the largest known, most comprehensive systematic review and network meta-analysis comparing the efficacy and side effects of 32 oral antipsychotics in acute treatment of adults with multi-episode schizophrenia.[1] The publication provided a comprehensive comparison of first- and second-generation antipsychotic drugs. The meta-analysis evaluated each of the antipsychotics on measures of efficacy and side-effects. The study employed a meta-analysis that combined the results from 402 studies, including 53,463 participants and built on the group's past efforts. The 32 drugs were compared, in terms of efficacy, by reduction in overall, positive, and negative symptoms. Dropout, depression, quality of life and functioning were also assessed. Side effects compared included use of antiparkinsonian drugs, extrapyramidal side effects, akathisia, weight gain, prolactin levels, sedation, QTc prolongation and anticholinergic side effects.

Comparison parameters included in the review were standardized to accommodate studies of varying measures. The studies' results were standardized via Standardized Mean Difference (SMD), Risk Ratio (RR) and Mean Difference (MD) where appropriate. To facilitate our comparison, data from the Phase II study of RP5063 (brilaroxazine) (NCT01490086) was standardized in a similar manner, using SMD, RR and MD, to the extent the collected data was analogous[2] and the data compared against those published in the meta-analysis.

REFRESH: Phase II Evaluation of Brilaroxazine in Schizophrenia
Reviva's Phase II (REFRESH) was a randomized, double blind, placebo controlled, multi-center trial intended to assess safety and efficacy of brilaroxazine in acute exacerbation of schizophrenia or schizoaffective disorder.[3] 22 clinical sites located in the Philippines, India, Malaysia, Moldova and the United States participated in the trial. The primary endpoint for the study was reduction in total PANSS at end of treatment from baseline vs placebo. Secondary endpoints included change from baseline to day 4, 8 15, 22 and 28 on PANSS total, positive and negative subscales, 20% improvement in PANSS total and one-point improvement on the clinical global impressions scale severity (CGI-S).[4] 234 subjects were enrolled. Patients were randomized into five arms including 15 mg (n=60), 30 mg (n=60) and 50 mg (n=60) doses as well as placebo (n=40) and aripiprazole 15 mg (n=20). Approximately one week of screening was followed by 28 days of dosing and follow-up afterward of one and two weeks for men and women, respectively. Pharmacokinetic analysis was also performed. 186 of 234 enrolled subjects completed the study.

Data Compilation and Presentation
Data from the REFRESH study was compared to the data presented in the Huhn meta-analysis. The meta-analysis compared 32 antipsychotics by their reduction in overall, positive, and negative symptoms, dropout, depression, quality of life and functioning. Side effects compared included use of antiparkinsonian drugs, extrapyramidal side effects, akathisia, weight gain, prolactin levels, sedation, QTc prolongation and anticholinergic side effects. Of these parameters, overall, positive and negative change in symptoms, dropout, akathisia, weight gain, change in prolactin levels and sedation were comparable based on data available from the REFRESH study publication. As positive and negative symptom reduction were endogenous to overall symptom reduction, reduction in overall symptoms was solely used as a measure of efficacy. Side-effects ultimately compared included akathisia, weight gain, change in prolactin levels and sedation. All-cause discontinuation is compared on its own to evaluate treatment adherence across the antipsychotics. The analysis was centered on data specific to the 15 mg dose. Furthermore, though the

[1] Huhn, M., Nikolakopoulou, A., Schneider-Thoma, J., Krause, M., Samara, M., Peter, N., ... & Leucht, S. (2019). Comparative efficacy and tolerability of 32 oral antipsychotics for the acute treatment of adults with multi-episode schizophrenia: a systematic review and network meta-analysis. *The Lancet*, *394*(10202), 939-951.
[2] Cantillon, M., Prakash, A., Alexander, A., Ings, R., Sweitzer, D., & Bhat, L. (2017). Dopamine serotonin stabilizer RP5063: a randomized, double-blind, placebo-controlled multicenter trial of safety and efficacy in exacerbation of schizophrenia or schizoaffective disorder. *Schizophrenia research*, *189*, 126-133.
[3] Schizoaffective disorder is a combination of schizophrenia symptoms and mood disorder symptoms
[4] The CGI-S is a measure of clinician's view of patient's global functioning

Lancet review featured 32 antipsychotics, we focused our attention on the major antipsychotics that are most frequently prescribed: olanzapine, risperidone, quetiapine, aripiprazole, cariprazine and brexpiprazole.

REFRESH study data was then standardized to be comparable with the meta-analysis data. Symptom reduction measures were standardized using Standardized Mean Difference (SMD), where the mean difference between symptom reduction in the 15 mg and placebo arms was determined, and the standard deviation (SD), derived from standard error (SE) of the placebo arm was used to standardize the therapeutic reduction. This number was then directly compared to the results presented in the *Lancet* meta-analysis review which were also presented in SMD. This was performed for change in total PANSS, which correlated with the meta-analysis' change in overall symptoms parameter.

Other parameters, such as all-cause discontinuation, were presented as Risk Ratio (RR) in the meta-analysis, and REFRESH data was treated accordingly, taking the percentage discontinued in the 15 mg arm, and dividing by the same in the placebo arm. Akathisia and sedation parameters were processed in the same manner. We note that no placebo arm patients experienced akathisia in the REFRESH trial, rendering an error in the RR calculation. We used a surrogate datapoint for akathisia placebo prevalence of 3.7%.[5] No patients experienced sedation in treated and placebo arms and the RR was taken to be one.

Finally, in cases where Mean Difference (MD) was compared, such as change in weight, the mean weight gain for the placebo arm was subtracted from the treatment arm. Change in prolactin, another factor compared using MD, was in mIU/L, or milli-international units per liter, in the REFRESH trial, and was converted at a rate of 21.2 µg per mIU to ng/mL, as presented in the meta-analysis.

Data was compiled from REFRESH and the meta-analysis, and percentile rankings were determined for each antipsychotic, for each parameter. Missing data was ignored. The efficacy (y) axis reflected only the overall reduction in symptoms parameter to rank the antipsychotics, where no average was taken. Side-effect parameters were averaged with equal weighting. An equal weighting was determined to be best practice, in this application, as assigning weights to the side effects implied that one side effect was less desirable than another. The ranking and averaging also reconciled differences between the standardization measures and minimized distortion from missing data. The overall reduction in symptoms and average of side effect ranking were used to produce a two-dimensional projection of efficacy versus side effects. A higher efficacy ranking and lower side effect ranking are most desirable.

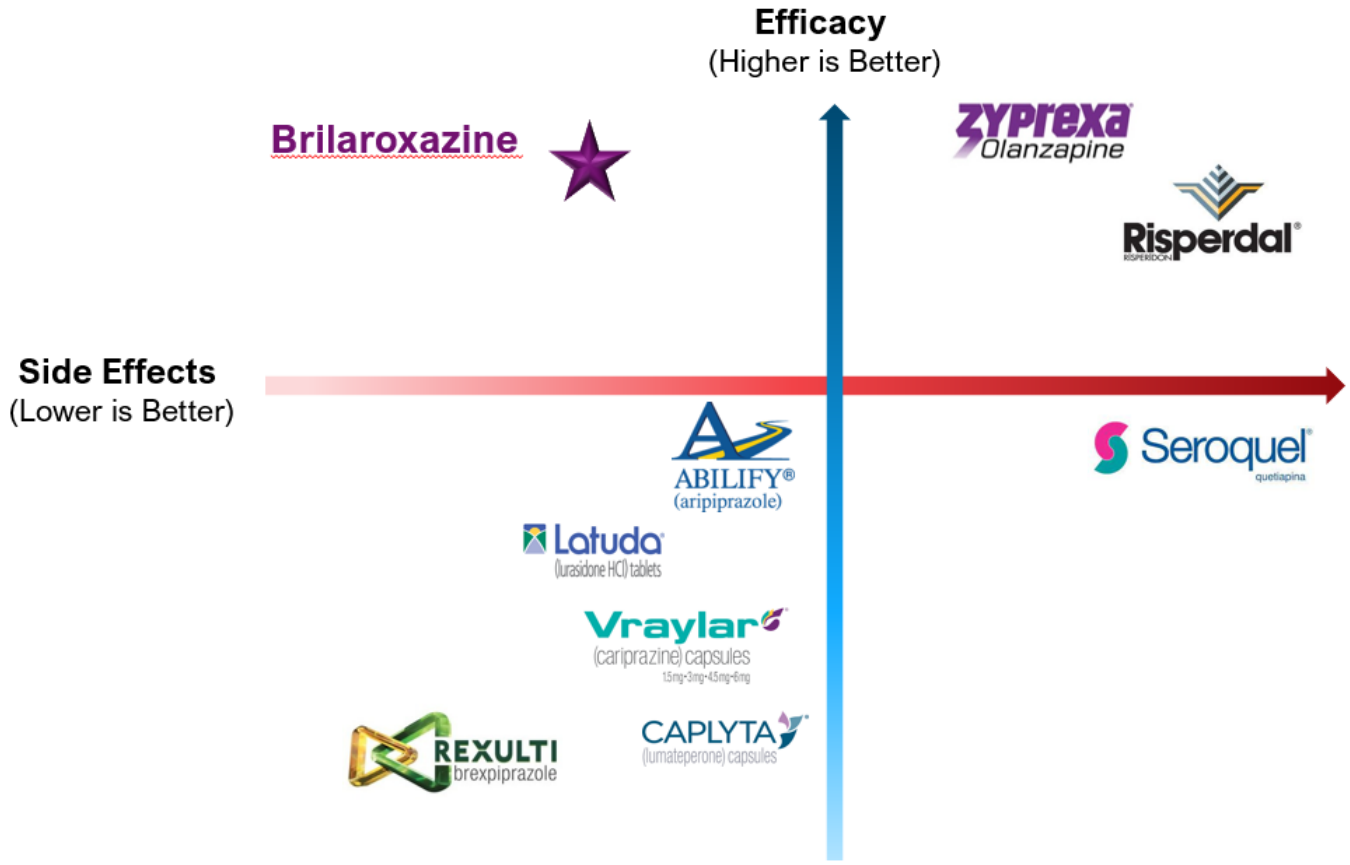
Based on the analysis, brilaroxazine is differentiated among the major antipsychotics. Brilaroxazine efficacy is above average compared with other treatments but really differentiates itself with its class-leading lack of side-effects. Side effects are a material deterrent to treatment adherence and patients are forced to consider this when seeking the benefits. Also noteworthy is that brilaroxazine is superior to aripiprazole in both efficacy and side effects. It is a chemical evolution of aripiprazole, sharing the same underlying structure but replacing a carbon atom with an oxygen atom in the quinoline ring, resulting in a benzoxazinone ring. Brilaroxazine is also structurally similar to cariprazine and brexpiprazole. The attributes of above average efficacy combined with class-leading lack of side effects holds up when the analysis is extended to all 32 available antipsychotics included in the meta-analysis.

Meta-Analysis Comparison with RECOVER Data

Reviva commissioned a study in 2024 to update this analysis for data provided in the RECOVER trial. RECOVER data was announced in October 2023 promulgating the results from 411 patients with acute schizophrenia. Patients in the trial were randomized into placebo, 15 mg and 50 mg groups, respectively enrolling 137, 140 and 134 patients. The comparative analysis standardized the data in Huhn *et al*. along the dimensions of efficacy and side effects and applied the same methodology as used in the 2021 analysis to the RECOVER data and new addition lumateperone (Caplyta) which was approved in 2019. The updated results from RECOVER were placed in a scatter plot along with the meta-analysis data from Huhn. On the x axis is a measure for side effects, where lower is better and on the y axis is efficacy, where higher is better. The optimal region on the scatter plot is in the Northwest corner which is associated with an effective antipsychotic producing low side effects. In the following image we share a graphical comparison provided in Yu, 2024[6].

[5] Chow, C. L., Kadouh, N. K., Bostwick, J. R., & VandenBerg, A. M. (2020). Akathisia and Newer Second-Generation Antipsychotic Drugs: A Review of Current Evidence. Pharmacotherapy: The Journal of Human Pharmacology and Drug Therapy, 40(6), 565-574.
[6] Yu, Theodore. Reviva Pharmaceuticals. Brilaroxazine vs. Major Antipsychotics: A Reduction in Side Effects. March 2024. Unpublished.

Exhibit I – Efficacy vs. Side Effects: Brilaroxazine and Other Major Antipsychotics, 2024 Analysis



Source: Reviva commissioned study, Brilaroxazine vs. Major Antipsychotics

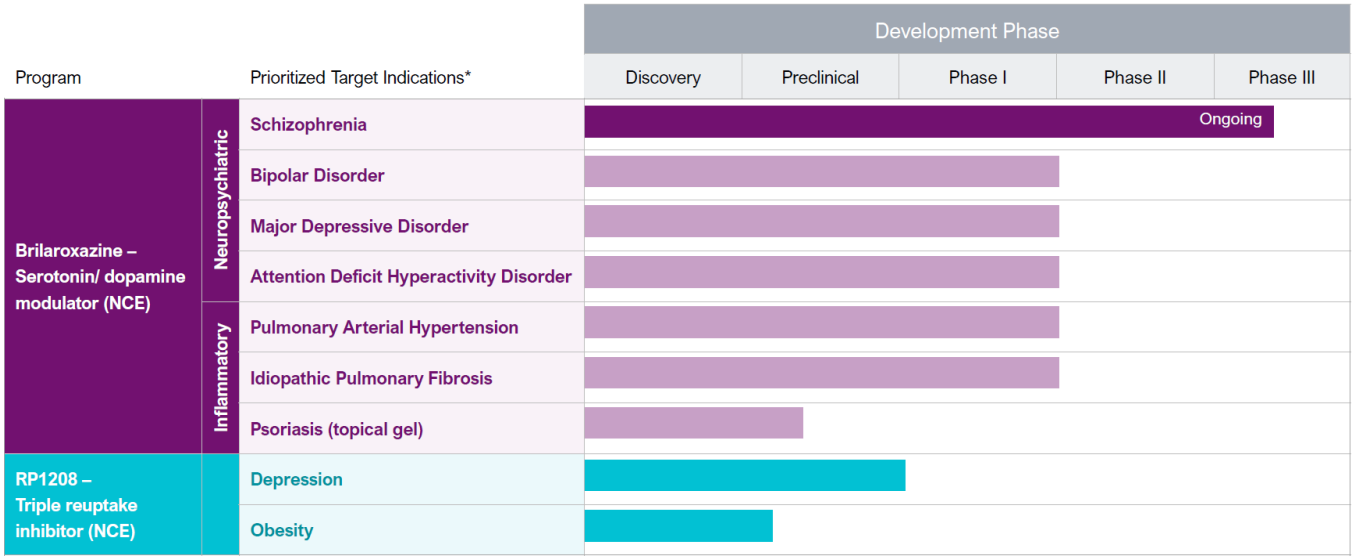
As shown in the exhibit, Reviva's brilaroxazine inhabits the furthest position in the Northwest or upper left corner of the scatter plot demonstrating both better efficacy and a better side effect profile versus the other data points. This position suggests that brilaroxazine provides the best balance of efficacy and side effects which should translate into substantial penetration into the schizophrenia market if the product is approved.

Milestones

- Initiation of Phase III RECOVER-2 clinical trial – 2Q:24
- Presentation at BIO International – June 2024
- Completion of RECOVER trial open label extension (OLE) – 4Q:24
- Completion of RECOVER-2 clinical trial – 2Q:25
- Topline data announcement for RECOVER-2 – 3Q:25
- New Drug Application (NDA) submission to FDA – 4Q:25

Company Pipeline

Exhibit II – Reviva Pipeline



Source: Reviva Corporate Presentation

Summary

As Reviva prepares to start the RECOVER-2 trial, the company has been tirelessly advancing its drug development efforts for brilaroxazine in schizophrenia. These efforts are manifested in its advancement of the OLE trial, site preparations for the RECOVER-2 study, NDA preparation activities and drug manufacturing efforts. The company is now in the process of securing sufficient capital so that it may complete the upcoming Phase III trial without having to access the markets again. With the first Phase III, under its belt and having completed the preparatory arrangements for the second Phase III, we anticipate that RECOVER-2 will enroll quickly and be able to announce topline results by 3Q:25 and NDA submission by 4Q:25.

PROJECTED FINANCIALS

Reviva Pharmaceutical Holdings Inc. - Income Statement[7]

Reviva Pharmaceuticals	2023 A	Q1 A	Q2 E	Q3 E	Q4 E	2024 E	2025 E	2026 E
Total Revenues ($US ,000)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
Research & Development	$31,420	$5,784	$5,800	$8,800	$8,700	$29,084	$32,125	$7,000
General & Administrative	$8,084	$2,138	$3,000	$2,250	$2,450	$9,838	$10,200	$10,600
Income from operations	($39,504)	($7,922)	($8,800)	($11,050)	($11,150)	($38,922)	($42,325)	($17,600)
Other Income (Expense)	$260	$496	$0.0	$0.0	$0.0	$496	($409)	($408)
Pre-Tax Income	($39,244)	($7,426)	($8,800)	($11,050)	($11,150)	($38,426)	($42,734)	($18,008)
Provision for Income Tax	$17	$7	$4	$4	$4	$19	$0	
Net Income	**($39,261)**	**($7,434)**	**($8,804)**	**($11,054)**	**($11,154)**	**($38,446)**	**($42,734)**	**($18,008)**
Reported EPS	**($1.65)**	**($0.25)**	**($0.27)**	**($0.21)**	**($0.21)**	**($0.92)**	**($0.71)**	**($0.26)**
YOY Growth	*32%*					*-44%*	*-23%*	*-0.63880216*
Basic Shares Outstanding	23,798	29,887	33,000	51,900	52,000	41,697	60,000	70,000

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

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

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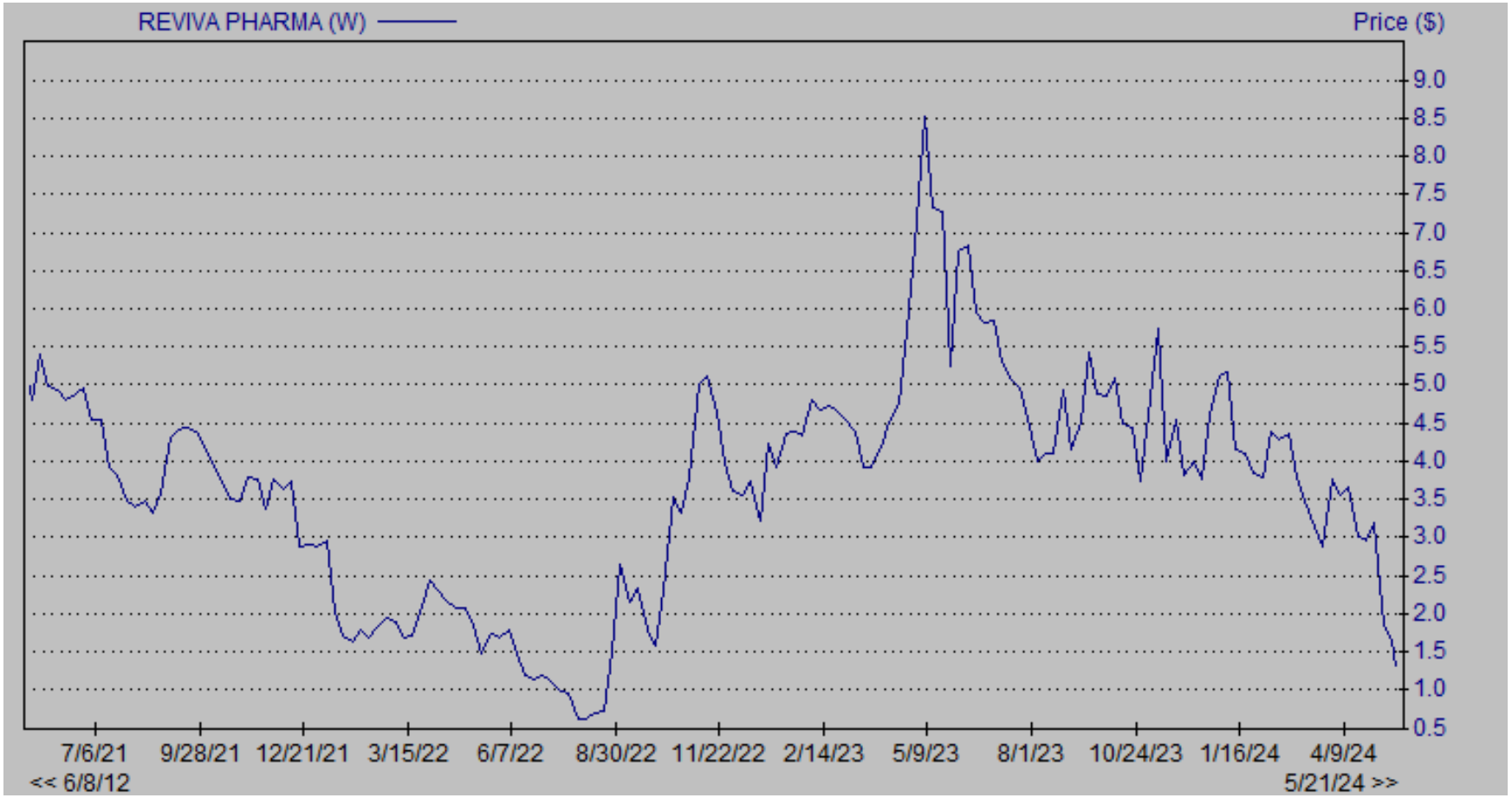
HISTORICAL STOCK PRICE

Reviva Pharmaceutical Holdings, Inc. – Share Price Chart[8]



[8] Source: Zacks Research System

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