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April 25, 2024

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Reviva Pharmaceuticals, Inc. (RVPH: NASDAQ)

RVPH: Full Year 2023 Results

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 (4/24/2024)	$3.02
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	**$2.67**
One-Year Return (%)	**-53.8**
Beta	**0.0**
Average Daily Volume (sh)	**298,196**
Shares Outstanding (mil)	**29.3**
Market Capitalization ($mil)	**88.5**
Short Interest Ratio (days)	**3.4**
Institutional Ownership (%)	**18.8**
Insider Ownership (%)	**17.8**
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 A	$0.0 A
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	-$0.37 A	-$1.65 A
2024					-$0.82 E
2025					-$0.76 E

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WHAT'S NEW

2023 Financial and Operational Results

On April 15th, 2024, Reviva Pharmaceutical Holdings, Inc. (NASDAQ: RVPH) reported full-year 2023 financial and operational results and filed its Form 10-K with the SEC. Since the company's previous financial update in November, the company raised $30 million to fund the RECOVER II trial, and participated in several investor and scientific events including a key opinion leader (KOL) presentation in February. The RECOVER II trial is now expected to begin before the end of the second quarter and management has provided guidance for several anticipated milestones.

Highlights for 2023 and to date:

- Multiple parallel studies in support of schizophrenia program completed – March 2023
- Company added to Russell Microcap index - June 2023
- RECOVER topline results reported – October 2023
- $30 million capital raise – November 2023
- KOL Event – February 2024
- Poster at American Society for Clinical Pharmacology & Therapeutics (ASCPT) Meeting – March 2024
- Poster at Schizophrenia International Research Society (SIRS) Meeting – April 2024

Reviva generated no revenues for 2023 and expended ($39.5) million on operational activities, producing a net loss of ($39.3) million or ($1.65) on a per share basis. For the year ending December 31, 2023 and versus the same prior year period:

- Research & development expense totaled $31.4 million, up 66% from $18.9 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 $8.1 million, rising 51% from $5.4 million on account of greater stock-based compensation, legal expenses, recruiting expenses and consultant and professional expenses;
- Other income included a greater loss from remeasurement of warrant liabilities offset by a larger increase in interest and other income due to higher interest rates on greater cash balances;
- Provision for taxes was $17,000 down from $21,000 related to payment of state and foreign taxes;
- Net loss was ($39.3) million vs ($24.3) million, or ($1.65) and ($1.25) per share, respectively.

At year end 2023, Reviva held $23.4 million in cash on its balance sheet. 2023 cash burn was ($28.3) million and cash flows from financing were $33.2 million. Following the end of the quarter, Reviva entered into a small financing agreement to pay 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 early 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 4 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 to have completed all of the NDA submission requirements by 3Q:25.

Reviva Video Series

Reviva Pharmaceuticals Holdings, Inc.'s (NASDAQ: RVPH) CEO Laxminarayan Bhat participated in a video series which covered several topics germane to the company. This included reviewing the most recent key opinion leader (KOL) event, elaborating on the unmet needs in schizophrenia, summarizing the results of the RECOVER trial, looking ahead to the RECOVER 2 trial and evaluating recent merger and acquisition activity in the CNS space. Follow the links below to access the interviews.

Exhibit I – Reviva CEO Dr. Laxminarayan Bhat



Source: Screenshot from Reviva Pharmaceuticals Upcoming RECOVER 2 Trial Video Clip

- Reviva Pharmaceuticals RECOVER Trial Findings
- RECOVER Trial Results
- RECOVER Trial Additional Findings
- What's Going on with M&A in CNS?
- Unmet Needs in Schizophrenia
- Reviva's Upcoming RECOVER 2 Trial
- Key Opinion Leader Event
- Reviva Pharmaceuticals CEO Fireside Chat

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 se-

[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

verity (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 *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.

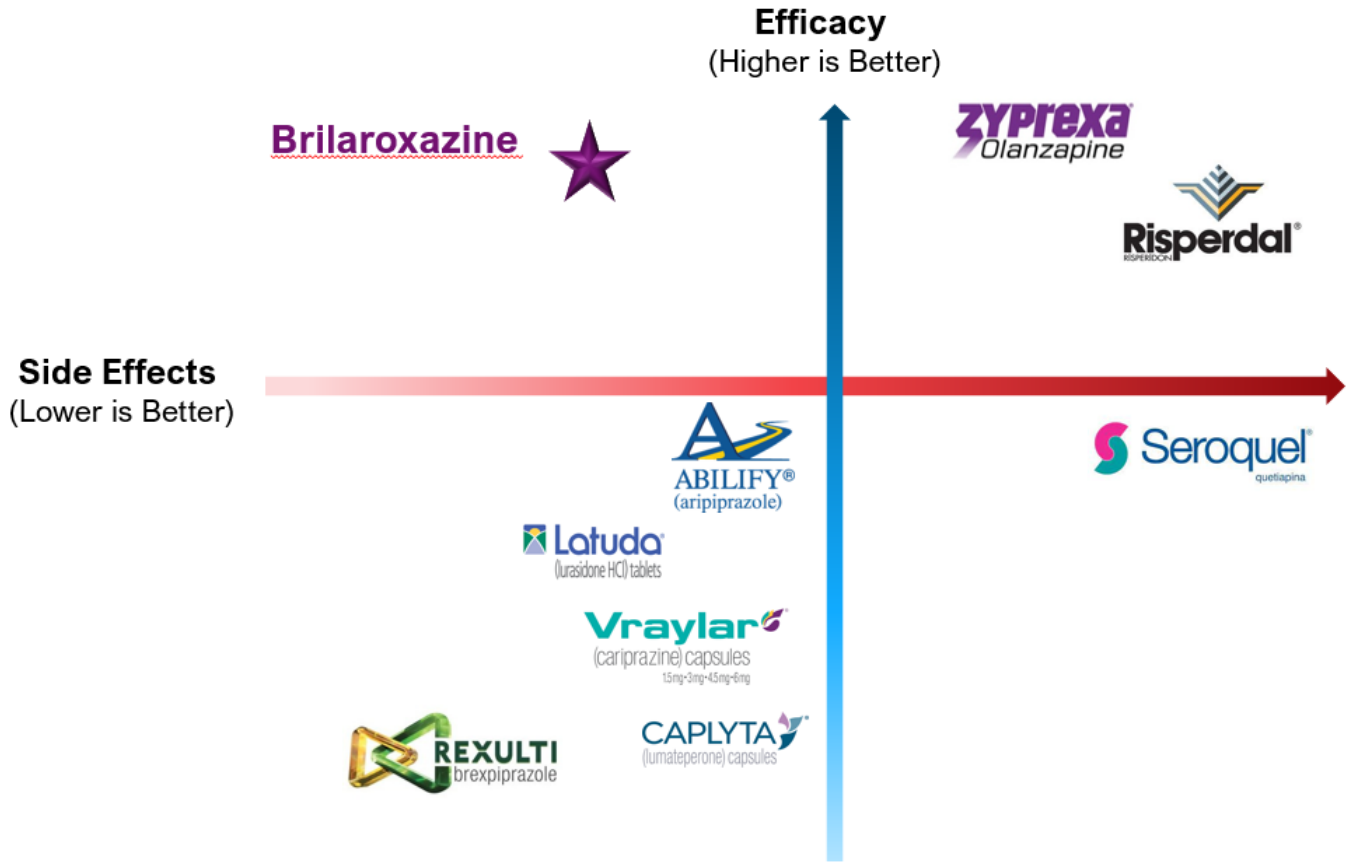
[4] The CGI-S is a measure of clinician's view of patient's global functioning

[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.

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].

Exhibit II – 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.

[6] Yu, Theodore. Reviva Pharmaceuticals. Brilaroxazine vs. Major Antipsychotics: A Reduction in Side Effects. March 2024. Unpublished.

Valuation

We update our valuation to reflect the share balance outstanding including the prefunded warrants, warrants, options and other near term anticipated shares. Our revenue, expense and cash flow estimates do not change.

Capital Raise

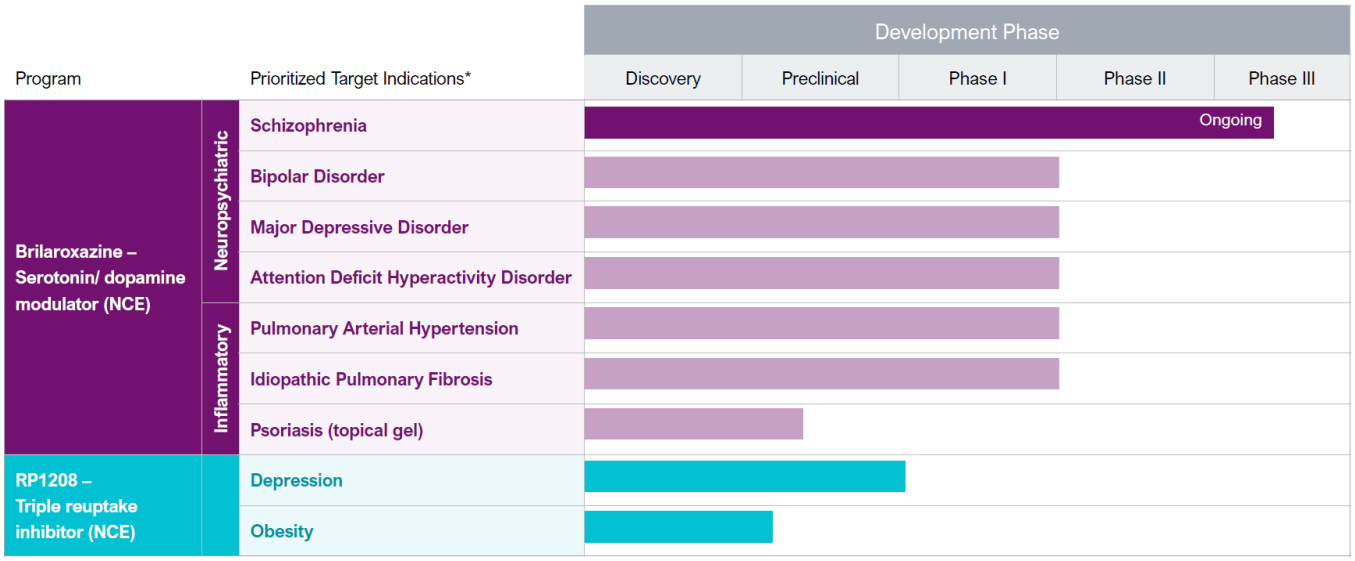
Following the topline results from the RECOVER trial and the report of third quarter results, in late November Reviva announced a $30 million registered direct offering that is backed by several healthcare focused institutional investors. The sale and issuance of 5,853,660 units, consisting of shares 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.

Milestones

- Initiation of Phase III RECOVER-2 clinical trial – 2Q:24
- Completion of RECOVER trial open label extension – 4Q:24
- Completion of RECOVER-2 clinical trial – 2Q:25
- New Drug Application (NDA) submission to FDA – 3Q:25

Company Pipeline

Exhibit III – Reviva Pipeline



Source: Reviva Corporate Presentation

Summary

As we stand on the precipice of the RECOVER-2 launch, Reviva has continued to perform additional analysis of its first Phase III study and share these results with stakeholders. The company has also laid out a number of anticipated milestones for completion of the ongoing trials and regulatory submissions. One of the more compelling analyses of brilaroxazine was the comparison of the drug's safety and efficacy against other antipsychotics in the space. The favorable balance of these two elements makes a strong argument for uptake by payors and providers assuming the product is approved. To reflect the most recent share balance, we update our valuation to $16.00 per share.

PROJECTED FINANCIALS

Reviva Pharmaceutical Holdings Inc. - Income Statement[7]

Reviva Pharmaceuticals	2022 A	Q1 A	Q2 A	Q3 A	Q4 A	2023 A	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	$8,476	$31,420	$19,250	$20,125
General & Administrative	$5,359	$1,501	$3,079	$1,992	$1,512	$8,084	$5,710	$6,100
Income from operations	($24,307)	($6,736)	($12,071)	($10,709)	($9,988)	($39,504)	($24,960)	($26,225)
Other Income (Expense)	($12)	$136	($366)	$230	$260	$260	($410)	($409)
Pre-Tax Income	($24,319)	($6,600)	($12,436)	($10,479)	($9,729)	($39,244)	($25,370)	($26,634)
Provision for Income Tax	$21	$3	$6	$12	($5)	$17	$0	$0
Net Income	**($24,339)**	**($6,603)**	**($12,443)**	**($10,491)**	**($9,724)**	**($39,261)**	**($25,370)**	**($26,634)**
Reported EPS	**($1.25)**	**($0.30)**	**($0.55)**	**($0.44)**	**($0.37)**	**($1.65)**	**($0.82)**	**($0.76)**
YOY Growth	*116%*					*32%*	*-51%*	*-7%*
Basic Shares Outstanding	19,516	21,834	22,435	24,034	26,555	23,798	31,100	35,000

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

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

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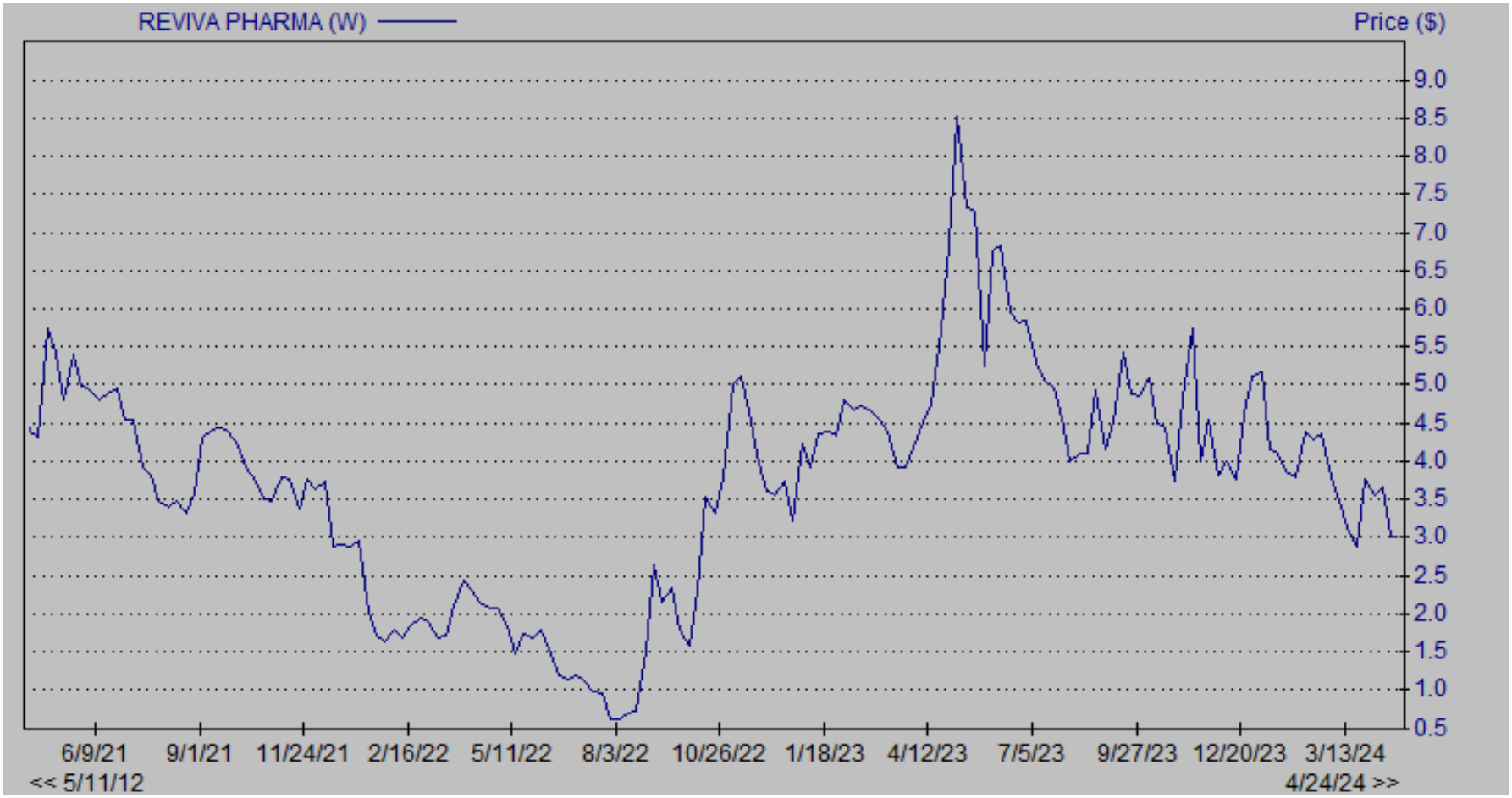
HISTORICAL STOCK PRICE

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



[8] Source: Zacks Research System

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