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Reviva Pharmaceuticals, Inc. (RVPH: NASDAQ)

RVPH: August OLE Update

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 (8/26/2024)	$1.00
Valuation	**$14.00**

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 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	**$9.25**
52-Week Low	**$2.67**
One-Year Return (%)	**-75.3**
Beta	**-0.1**
Average Daily Volume (sh)	**416,280**
Shares Outstanding (mil)	**29.8**
Market Capitalization ($mil)	**29.8**
Short Interest Ratio (days)	**14.6**
Institutional Ownership (%)	**21.7**
Insider Ownership (%)	**14.9**
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 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	-$0.26 A	-$0.21 E	-$0.21 E	-$0.91 E
2025					-$0.71 E
2026					-$0.26 E

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WHAT'S NEW

Operational and Financial Results

On August 14th, 2024, Reviva Pharmaceutical Holdings, Inc. (NASDAQ: RVPH) reported second quarter 2024 financial and operational results and filed its Form 10-Q with the SEC. Reviva has continued to advance its open label extension (OLE) trial, completing the manufacturing of clinical trial drug product and performing clinical pharmacology work. The registrational RECOVER-2 trial design was cleared with the FDA. The trial is expected to start in 3Q:24 and will be dependent on raising sufficient capital to fund its completion. We see 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. Reviva has received patents for some of its secondary indications in the US and EU. We begin our report with a summary of operational and financial results so far this year.

Highlights for 2024 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
- Closing of $3.0 million registered direct offering – May 2024
- Participation in the BIO International Convention – June 2024
- Pricing of $5.0 million underwritten offering – August 2024
- KOL Event RECOVER trial biomarker data – September 4, 2024

Reviva generated no revenues for 2Q:24 and expended ($8.1) million on operational activities including activity primarily related to the open label extension (OLE) for RECOVER, producing a net loss of ($7.9) million or ($0.26) on a per share basis. For the quarter ending June 30, 2024 and versus the same prior year period:[1]

- Research & development expense totaled $5.6 million, down 38% from $9.0 million, primarily attributable to the absence of Phase III clinical trial expenses related to the RECOVER trial which was active in the prior period. Expenses in 2Q:24 are related to the active outpatient OLE trial. Other factors contributing to the decline include lower share-based compensation, reduced external research and development costs, and decreased non-clinical safety related costs, partially offset by higher non-clinical manufacturing related costs;
- General & administrative expenses totaled $2.5 million, falling 17% from $3.1 million on account of lower stock-based compensation partially offset by higher consultant and professional expenses, greater legal expenses and increased employee-related expenses;
- Other income included a gain from the remeasurement of warrant liabilities due to a decline in the share price over the quarter partially offset by other expense which represents a foreign currency translation loss related to the company's Indian subsidiary;
- Net interest income was approximately $82,000, down compared to the prior year due to lower cash balances;
- Provision for taxes was $7,000 compared to $6,000 related to payment of state and foreign taxes;
- Net loss was ($7.9) million vs ($12.4) million, or ($0.26) and ($0.55) per share, respectively.

As of June 30th, 2024, Reviva held $6.2 million in cash on its balance sheet. 2Q:24 cash burn was ($8.5) million while cash flows from financing were $2.7 million related to the May equity raise. In August, Reviva was able to raise an additional $5.0 million in an underwritten offering.

[1] We use originally reported data for our comparisons.

Equity Offerings

On May 29, 2024, Reviva closed an equity offering which sold 1.9 million shares of its common stock and warrants to purchase up to 1.9 million shares of its common stock at $1.58 per unit. The warrants have an exercise price of $1.455 per share, are immediately exercisable and expire in five years. In connection with the offering, Reviva amended existing warrants held by the investor to purchase 1.4 million shares of common stock issued in November 2023, with a $5.00 exercise price, for $0.125 per warrant, so that the amended warrants have a reduced exercise price of $1.455 per share with a life of five years after the amendment.

On August 21st, 2024 Reviva announced that it had priced a $5.0 million capital raise. Reviva offered 4.8 million shares (or prefunded warrants) at $1.05 ($1.0499) per share. Each share carries an attached warrant with an exercise price of $0.7964.

New Patents

In July and August Reviva was granted new patents for the use of brilaroxazine in some of its secondary pipeline indications. On July 9th, Reviva announced that the European Patent Office had granted European Patent EP3244896 to the company for the treatment of pulmonary arterial hypertension (PAH). The patent recognizes brilaroxazine's a novel mechanism of action for treating the underlying disruption in serotonin signaling implicated in the pathogenesis of the disease. Other similar patents have been granted in the US, Japan and China.

A second patent grant was announced in August for brilaroxazine's use in the treatment of idiopathic pulmonary fibrosis (IPF). This patent was granted by the US Patent and Trademark Office under patent number 12,053,477. It includes treatment of co-morbidities to IPF such as pulmonary fibrosis in a subject having chronic obstructive pulmonary disease (COPD), sickle cell anemia, scleroderma. or lung cancer. A similar patent has already been approved in Japan.

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. 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.

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.

Guidance included in its second quarter results, which were reported on August 14th, calls for initiation of RECOVER-2 in 3Q:24 and topline data in 4Q: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. In the second quarter report, released in mid-August, 424 patients had been enrolled with 230 actively on treatment in the study. 65 patients had completed the 12 months of treatment. 53 patients have completed nine months of treatment and 200 have completed six months. As part of the safety study and a prerequisite for the NDA, 12 months of safety data is required for 100 patients. 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. Data from the trial is ex-

pected 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

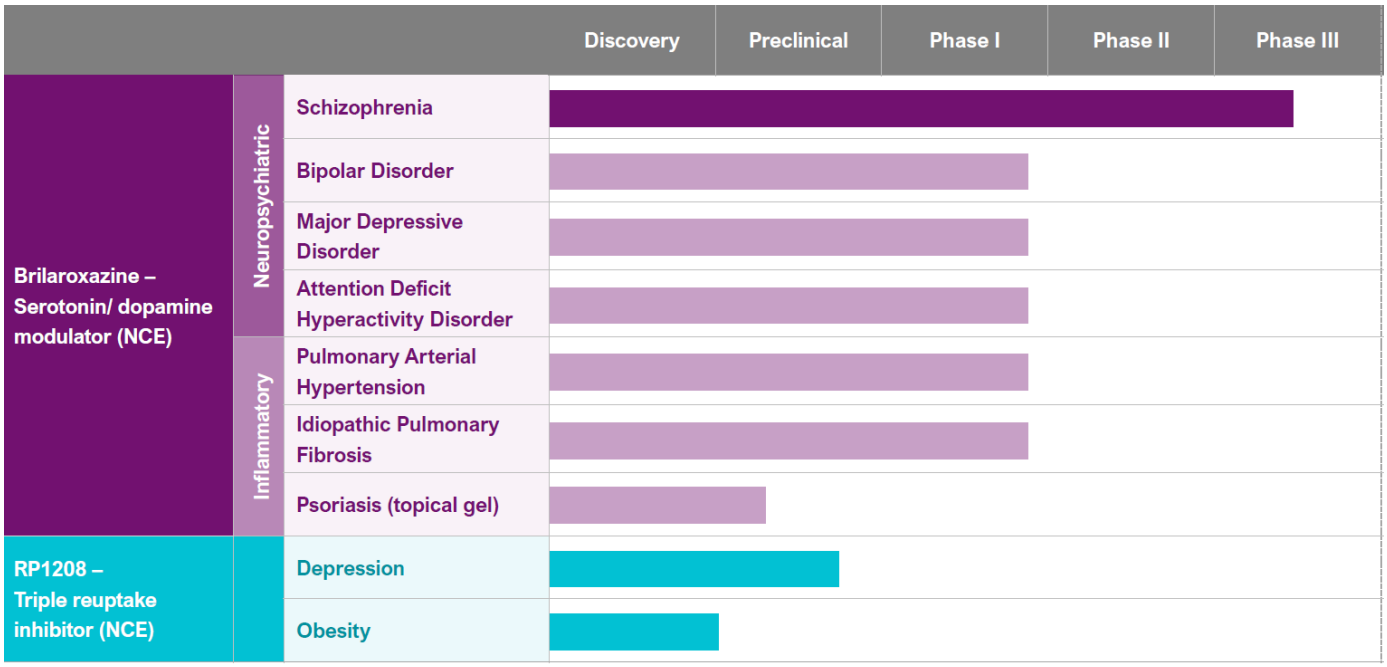
Reviva announced in its 2023 Form 10-K and in its most recent 10-Q filings that it had made several restatements related to research and development expenses in the prior year first quarter. There were certain estimated accrued clinical trial expenses that differed from the actual expenses due to improper 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. Reviva has implemented new accounting software to address this discrepancy.

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 – mid-2025
- Topline data announcement for RECOVER-2 – 4Q:25
- New Drug Application (NDA) submission to FDA – 1Q:26

Company Pipeline

Exhibit I – Reviva Pipeline



Source: Reviva July 2024 Corporate Presentation

Valuation

We reduce our valuation to $14 based on a lower expected share price for upcoming capital raises. Our enterprise value does not change.

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. We think a strategic partnership may be in the works. 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 after sufficient capital is raised.

PROJECTED FINANCIALS

Reviva Pharmaceutical Holdings Inc. - Income Statement[2]

Reviva Pharmaceuticals	2023 A	Q1 A	Q2 A	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	$5,584	$8,800	$8,700	$28,868	$32,125	$7,000
General & Administrative	$8,084	$2,138	$2,545	$2,250	$2,450	$9,384	$10,200	$10,600
Income from operations	($39,504)	($7,922)	($8,130)	($11,050)	($11,150)	($38,252)	($42,325)	($17,600)
Other Income (Expense)	$260	$496	$277	$0	$0	$773	($409)	($408)
Pre-Tax Income	($39,244)	($7,426)	($7,853)	($11,050)	($11,150)	($37,479)	($42,734)	($18,008)
Provision for Income Tax	$17	$7	$7	$4	$4	$23	$0	
Net Income	**($39,261)**	**($7,434)**	**($7,860)**	**($11,054)**	**($11,154)**	**($37,502)**	**($42,734)**	**($18,008)**
Reported EPS	**($1.65)**	**($0.25)**	**($0.26)**	**($0.21)**	**($0.21)**	**($0.91)**	**($0.71)**	**($0.26)**
YOY Growth	*32%*					*-45%*	*-22%*	*-64%*
Basic Shares Outstanding	23,798	29,887	30,555	51,900	52,000	41,086	60,000	70,000

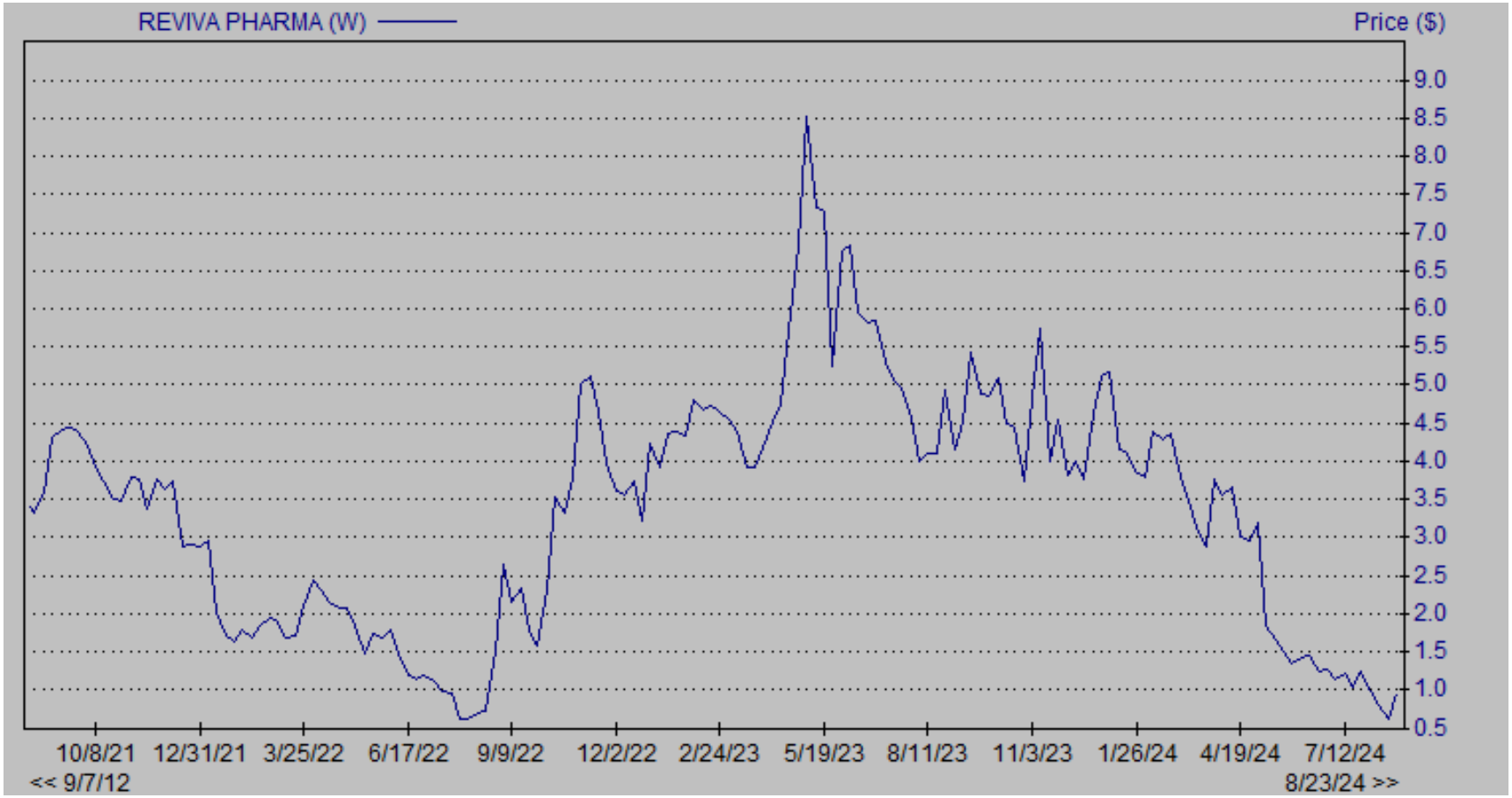
Source: Company Filing // Zacks Investment Research, Inc. Estimates

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

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HISTORICAL STOCK PRICE

Reviva Pharmaceutical Holdings, Inc. – Share Price Chart[3]



[3] Source: Zacks Research System

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