# Zacks Small-Cap Research

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## Reviva Pharmaceuticals, Inc. (RVPH - NASDAQ)

### *FDA Allows IND; Imminent Start to Phase III*

Based on our DCF model and a 15% discount rate, Reviva is valued at approximately $16.00 per share. Our model applies a 50% probability of ultimate approval and commercialization for RP5063 for schizophrenia. The model includes contributions from the United States and rest of world.

| | |
|---|---|
| Current Price (1/10/2022) | $2.97 |
| **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) will begin two Phase III trials in January 2022.

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 needs persist in the category, related to efficacy, side effects & discontinuation. 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.

We expect the three Phase III trials for RP5063 to generate registrational data by 2024 assuming a sufficient capital raise. After agency review in the US and other jurisdictions, we anticipate approval to be granted by the FDA in 2025 followed by other territories. Our valuation assumes commercialization in the US and rest of world in 2025 and 2026 respectively.

### SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$9.61** |
| **52-Week Low** | **$2.61** |
| **One-Year Return (%)** | **-68.0** |
| **Beta** | **-0.16** |
| **Average Daily Volume (sh)** | **75,947** |
| **Shares Outstanding (mil)** | **14.0** |
| **Market Capitalization (€mil)** | **41.6** |
| **Short Interest Ratio (days)** | **0.29** |
| **Institutional Ownership (%)** | **18.6** |
| **Insider Ownership (%)** | **38.5** |
| **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 2021 Estimate** | **N/A** |
| **P/E using 2022 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) |
|---|---|---|---|---|---|
| 2020 | $0.0 A | $0.0 A | $0.0 A | $0.0 A | $0.0 A |
| 2021 | $0.0 A | $0.0 A | $0.0 A | $0.0 E | $0.0 E |
| 2022 | | | | | $0.0 E |
| 2023 | | | | | $0.0 E |

**Earnings per Share**

| | Q1 | Q2 | Q3 | Q4 | Year |
|---|---|---|---|---|---|
| 2020 | -$0.27 A | -$0.31 A | -$0.24 A | -$0.16 A | -$1.24 A |
| 2021 | -$0.10 A | -$0.12 A | -$0.12 A | -$0.26 E | -$0.65 E |
| 2022 | | | | | -$0.76 E |
| 2023 | | | | | -$0.73 E |

## WHAT'S NEW

### FDA 'Study May Proceed' Letter Received

Reviva Pharmaceutical Holdings, Inc. (NASDAQ: RVPH) announced on January 10, 2022 the receipt of a May Proceed letter from the FDA regarding pivotal Phase III clinical trials for brilaroxazine in schizophrenia, including one long-term safety trial. Through the letter, the FDA allowed Reviva to proceed with brilaroxazine's clinical investigation. Reviva plans two Phase III trials, a four-week efficacy study and a one-year safety study in schizophrenia. Based on the construction of the study, which could be impacted by exogenous events, we see the trial lasting 16 – 18 months with results available in 2H:23. The long-term safety trial is expected to supplement efficacy and safety data from the pivotal trial; Reviva expects both to initiate simultaneously by end of January 2022.

### Phase III Trial Details

With the close of the financing in June 2021, Reviva was waiting for its Phase III protocol to be affirmed by the FDA prior to launching the trial. The protocol was cleared in a Study May Proceed letter received on January 10, 2022. Reviva is now ready to begin its pivotal and long-term safety trials and expects it will take two weeks to enroll the first patients. There are now 15 sites selected and two more may be added in the near future. Sufficient amounts of Brilaroxazine are available to start and complete the trial and are now being shipped to the sites.

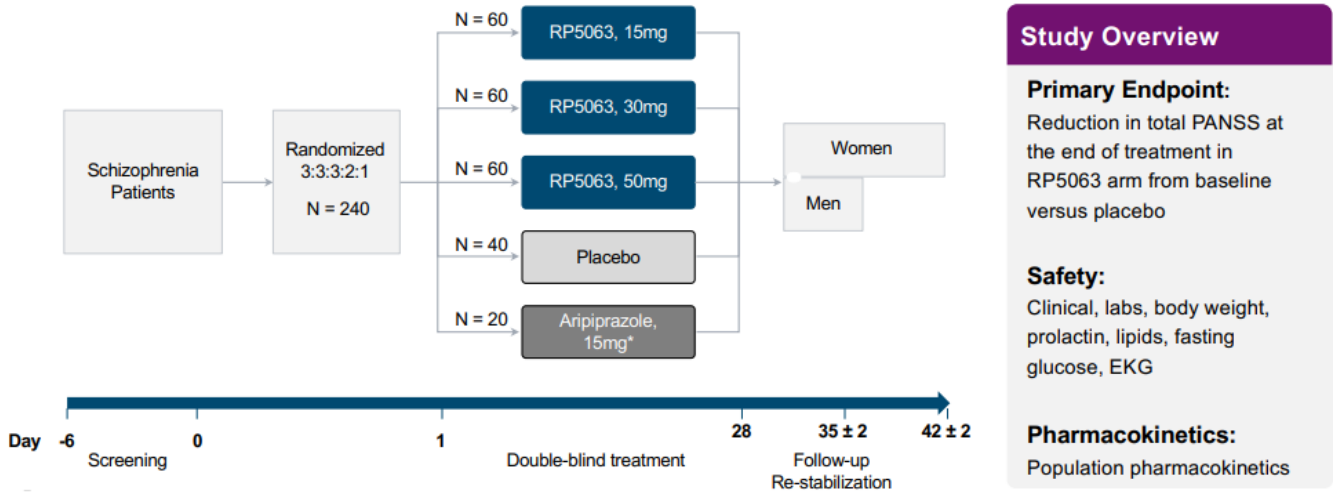
As we elaborated in our initiation, two Phase III trials will be launched including a four week efficacy study and a one year safety study in schizophrenia. Based on the construction of the study, which could be impacted by exogenous events, we see the trial lasting 16 – 18 months with results available in 2023.

### Full Details of Phase II Trial in Acute Schizophrenia

Last April, Reviva provided details regarding its Phase II trial of Brilaroxazine in acute schizophrenia. Among highlights from the study results, the trial met safety and efficacy endpoints, met primary endpoint of reduction in PANSS[1], achieved well-rounded effects by reducing both positive and negative symptoms and improving social functioning and cognition, and, perhaps most importantly, presented no metabolic and endocrine side effects[2] and no increase in suicidal ideation compared to placebo.

The trial was a randomized, double-blind, placebo-controlled, multicenter Phase II effort to assess safety and efficacy of Brilaroxazine in acute exacerbation of schizophrenia or schizoaffective disorder. It enrolled 234 subjects. Total PANSS was reduced by 20 points from baseline, statistically significant when compared to placebo.

**Exhibit I – Phase I Schizophrenia Trial Design[3]**




[1] Positive and Negative Syndrome Scale (PANSS)
[2] Metabolic and endocrine side effects include weight gain, elevated blood sugar, increase in lipids, hypothyroidism, and hyperprolactinemia
[3] Source: Reviva Pharmaceuticals January 2022 Corporate Presentation.

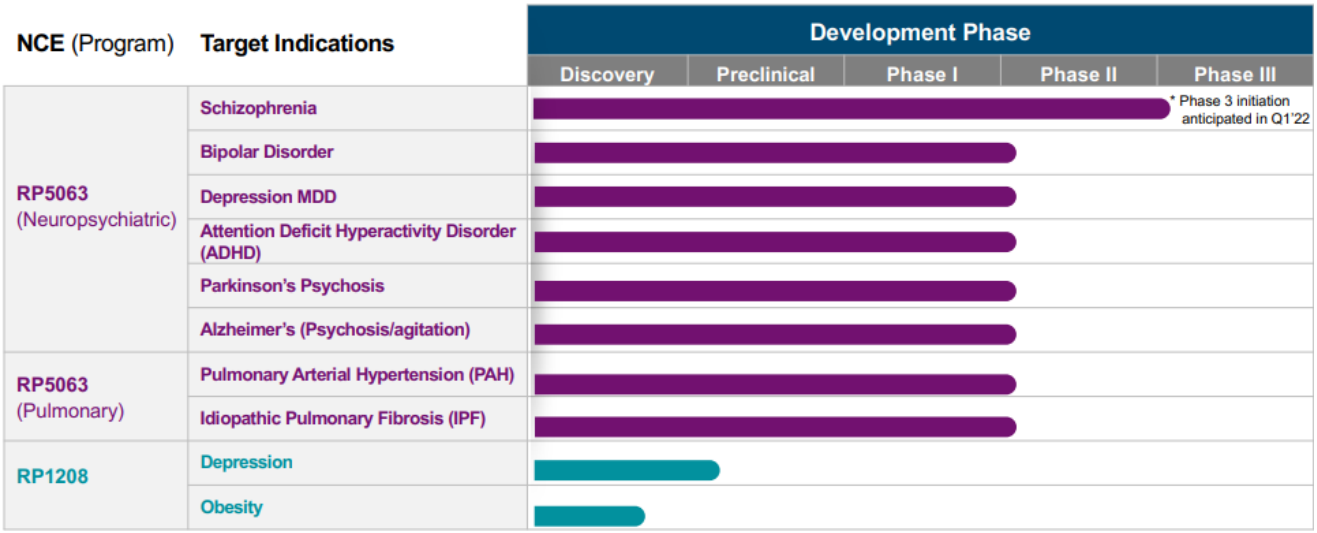
## Milestones

Reviva has a number of upcoming milestones that relate to the launch of its Phase III trial in schizophrenia. Preparation for Phase II trials for Brilaroxazine in additional indications is underway with regulatory work expected in the next quarters followed by launch. We provide additional detail on recent and anticipated achievements below:

- **Phase III trial design finalization with FDA – January 2022**
- **Launch of Phase III RP5063 trial in acute and maintenance schizophrenia – 1Q:22**
- **Regulatory submissions for PAH & IPF – 1Q:22**
- **KOL event – March 2022**
- **Launch of PAH and IPF Phase II trials – mid-2022**
- **Launch two smaller dose finding studies for ADHD / MDD – mid-2022**
- **ADHD / MDD dose finding study readouts – before year end 2022**
- **Phase III schizophrenia topline data – 1Q:23**

## Company Pipeline

**Exhibit II – Reviva Pipeline[4]**




## Summary

Reviva announced FDA clearance for its Phase III protocol and is now planning to start its two anticipated trials for schizophrenia in the next couple weeks. Upcoming milestones for 2022 also include regulatory submissions to the FDA for Phase II studies in pulmonary arterial hypertension (PAH) and idiopathic pulmonary fibrosis (IPF). We also expect to see some smaller dose finding studies in attention deficit hyperactivity disorder (ADHD) and major depressive disorder (MDD) that should begin in the next few months and read out before year end. A key opinion leader (KOL) event is also in the works and is expected to occur in March. We maintain our valuation of $16.00 per share.

[4] Source: Reviva Pharmaceuticals January 2022 Corporate Presentation.

## PROJECTED FINANCIALS

**Reviva Pharmaceutical. - Income Statement[5]**

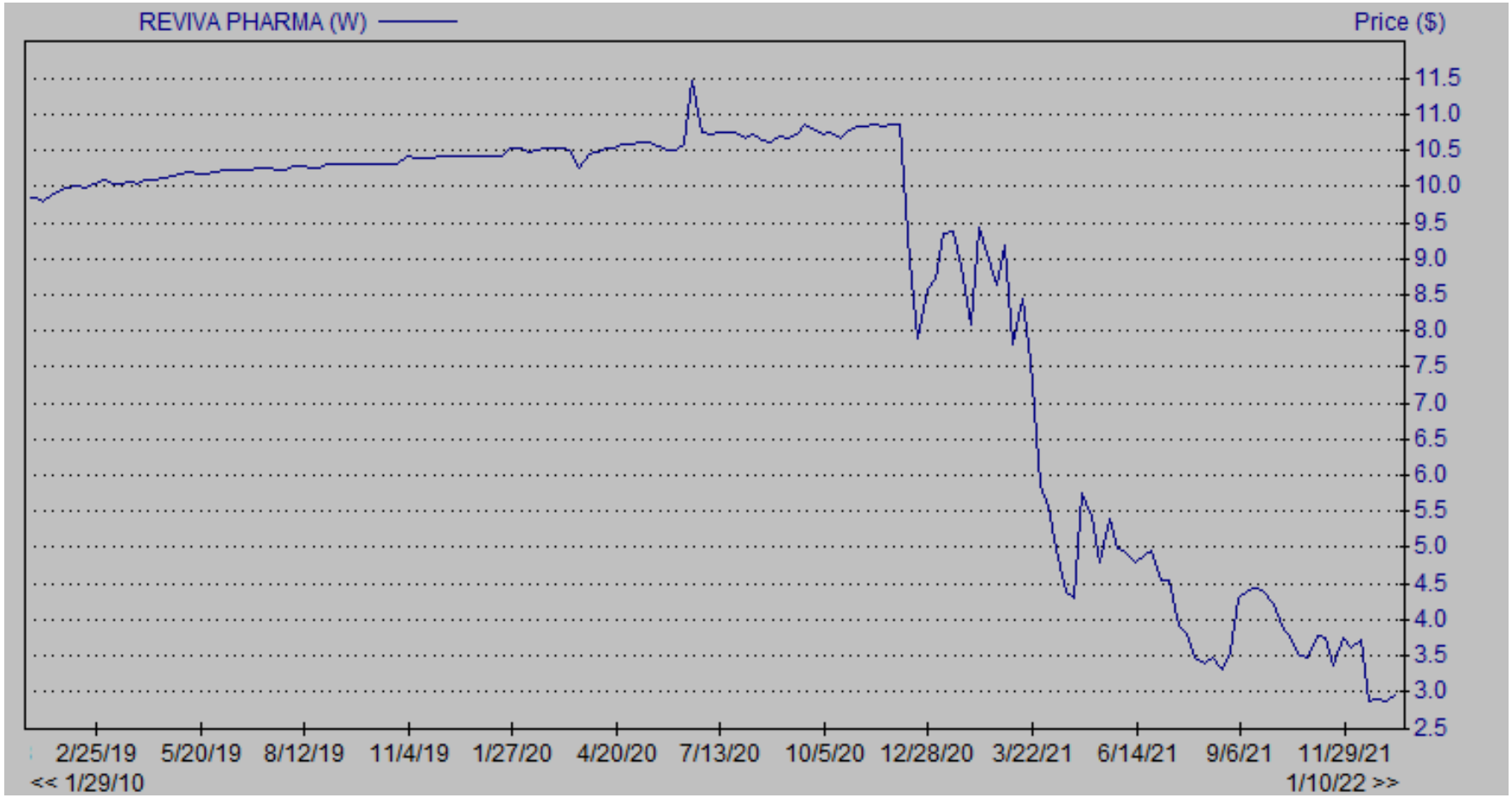
| Reviva Pharmaceuticals | 2020 A | Q1 A | Q2 A | Q3 A | Q4 E | 2021 E | 2022 E | 2023 E |
|---|---|---|---|---|---|---|---|---|
| **Total Revenues ($US ,000)** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** |
| *YOY Growth* | | | | | | | | |
| Research & Development | $295 | $391 | $374 | $1,423 | $3,820 | $6,009 | $10,500 | $9,250 |
| General & Administrative | $2,140 | $1,481 | $1,416 | $1,053 | $988 | $4,938 | $4,202 | $5,850 |
| Income from operations | ($2,435) | ($1,872) | ($1,790) | ($2,477) | ($4,808) | ($10,947) | ($14,702) | ($15,100) |
| *Operating Margin* | | | | | | | | |
| Other Income (Expense) | ($1,348) | $924 | $186 | $200 | ($101) | $1,208 | ($422) | ($441) |
| Pre-Tax Income | ($3,783) | ($949) | ($1,605) | ($2,277) | ($4,909) | ($9,739) | ($15,124) | ($15,541) |
| Provision for Income Tax | $1 | $1 | $4 | $0 | $0 | $5 | $0 | |
| *Tax Rate* | *0.0%* | | | | | *0.0%* | *0.0%* | |
| **Net Income** | **($3,783)** | **($949)** | **($1,608)** | **($2,277)** | **($4,909)** | **($9,744)** | **($15,124)** | **($15,541)** |
| *Net Margin* | *# DIV/0!* | *# DIV/0!* | *# DIV/0!* | *# DIV/0!* | *# DIV/0!* | *# DIV/0!* | *# DIV/0!* | *# DIV/0!* |
| **Reported EPS** | **($1.24)** | **($0.10)** | **($0.12)** | **($0.12)** | **($0.26)** | **($0.65)** | **($0.76)** | **($0.73)** |
| *YOY Growth* | *304%* | *-62.0%* | *-59.4%* | *-48.2%* | *56.7%* | *-47%* | *16%* | *-0.03287335* |
| Basic Shares Outstanding | 3,062 | 9,232 | 12,875 | 18,456 | 19,100 | 14,916 | 20,000 | 21,250 |

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

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

## HISTORICAL STOCK PRICE

**Reviva Pharmaceutical Holdings, Inc. – Share Price Chart[6]**




[6] Source: Zacks Research System

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