

## Reviva Pharmaceuticals, Inc.

(RVPH: NASDAQ)

### 20% of the Way There

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 (8/18/2022)

\$0.73

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) began a Phase III trial in 2022. Complementary 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 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.

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	\$4.66
52-Week Low	\$0.53
One-Year Return (%)	-79.0
Beta	0.2
Average Daily Volume (sh)	309,316

Shares Outstanding (mil)	20.2
Market Capitalization (\$mil)	14.7
Short Interest Ratio (days)	3.0
Institutional Ownership (%)	10.3
Insider Ownership (%)	29.7

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 2022 Estimate	N/A
P/E using 2023 Estimate	N/A

Zacks Rank	N/A
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### Risk Level

Type of Stock  
Industry

Above Average  
Small-Growth  
Med-Biomed/Gene

## ZACKS ESTIMATES

### Revenue

(In millions of US\$)

	Q1	Q2	Q3	Q4	Year
	(Mar)	(Jun)	(Sep)	(Dec)	(Dec)
2021	\$0.0 A	\$0.0 A	\$0.0 A	\$0.0 A	\$0.0 A
2022	\$0.0 A	\$0.0 A	\$0.0 E	\$0.0 E	\$0.0 E
2023					\$0.0 E
2024					\$0.0 E

### Earnings per Share

	Q1	Q2	Q3	Q4	Year
2021	-\$0.10 A	-\$0.12 A	-\$0.12 A	-\$0.19 A	-\$0.58 A
2022	-\$0.40 A	-\$0.29 A	-\$0.30 E	-\$0.27 E	-\$1.28 E
2023					-\$0.73 E
2024					-\$0.54 E

## WHAT'S NEW

### Second Quarter 2022 Financial and Operational Results

On August 15, 2022, Reviva Pharmaceutical Holdings, Inc. (NASDAQ: RVPH) [announced](#) second quarter 2022 financial and operational results and filed its [Form 10-Q](#) with the SEC. Reviva's second quarter was dominated by investor conference participation with HCW, BIO and Zacks tour stops. In late July the company provided an [update](#) on the RECOVER trial noting that enrollment had exceeded 20% of targeted subjects and further enrollment would begin at European and Indian sites in 3Q:22. Reviva is also developing protocols for two Phase IIa trials in ADHD and PAH in 4Q:22, which are planned if non-dilutive funding is received.

Highlights for 2022:

- [Receipt](#) of "May Proceed" letter from the FDA for Brilaroxazine - January 2022
- First patients [dosed](#) in Phase III [RECOVER](#) trial - February 2022
- KOL webinar on Brilaroxazine for schizophrenia [hosted](#) – May 2022
- Presentation at multiple investor conferences – May/June 2022

Reviva generated no revenues in 2Q:22 and expended (\$5.5) million in operational costs, producing a net loss of (\$5.3) million or (\$0.29) on a per share basis.

For the quarter ending June 30, 2022 and versus the same period a year prior:

- Research & development expense totaled \$4.5 million, up significantly from \$0.4 million, primarily attributed to acceleration of research and development activities related to the RECOVER trial, higher drug development costs, salary expenditures and increased consulting costs;
- General & administrative expenses totaled \$1.0 million, falling 29% from \$1.4 million, primarily attributable to higher prior year costs for legal, banking and accounting related to the public offering in June 2021;
- Gain on remeasurement of warrant liabilities was \$178,000 versus \$189,000;
- Interest expense and other income was minimal in both periods;
- Net loss was (\$5.3) million vs (\$1.6) million, or (\$0.29) and (\$0.12) per share, respectively.

At the end of the reporting period, Reviva held \$19.4 million in cash on its balance sheet. Management expects this amount to sustain the firm through March 2023. 2Q:22 cash burn was (\$4.0) million and there were no financing cash flows. With RECOVER results expected in 2023, Reviva will be required to raise or secure additional funds in the near term to support active and planned trials. Proceeds from this raise and other non-dilutive financing may enable Phase IIa studies this year in bipolar disorder, MDD, and ADHD.

### "May Proceed Letter," First Patients Dosed in RECOVER

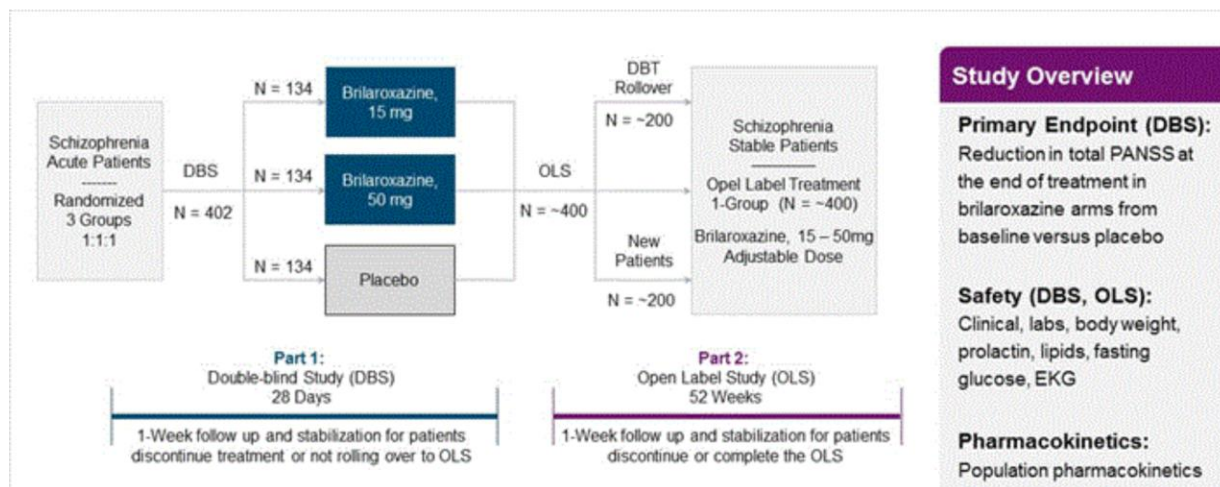
Reviva [announced](#) on January 10, 2022 the receipt of a May Proceed letter from the FDA regarding pivotal Phase III clinical trials for brilaroxazine in schizophrenia, including one long-term safety trial. Through the letter, the FDA allowed Reviva to proceed with brilaroxazine's clinical investigation. Reviva's Phase III trial designated RECOVER is now underway, a four-week efficacy study followed by a one-year safety extension. The trial will target enrollment of 400 subjects, which as of July 2022 was 20% achieved and continuing to progress slightly ahead of schedule. Based on the construction of the study, which could be extended due to exogenous events, we see the trial lasting 16 – 18 months with results available mid-2023.

Shortly after receiving its "May Proceed" letter from the FDA, Reviva announced on February 1, 2022 that the first patients had been dosed in its long-term, randomized, double-blind, multicenter Phase III RECOVER trial ([NCT05184335](#)) evaluating effect and safety of brilaroxazine in acute schizophrenia versus placebo. Reviva initiated the first clinical site in Bentonville, Arkansas with two patients dosed at the Pillar Clinical trial site led by its principal investigator, Fayz A. Hudefi, M.D. 15 trial sites are now open in the United States and additional sites are expected to enroll in Europe and India beginning in the third quarter.

Brilaroxazine will be given at fixed doses of 15 mg or 50 mg once daily and the study will assess both over 28 days in the double-blind phase in acute schizophrenia for a total of three arms, randomized 1:1:1, including placebo. In

the 52-week open-label extension in stable schizophrenia, subjects will be dosed at 15 mg, 30 mg or 50 mg. Primary outcome measures will be change in total Positive and Negative Syndrome Scale (PANSS) scores from baseline over the 28-day evaluation period. Secondary outcome measures include antipsychotic efficacy using a variety of scales and subscales. We remind investors that in the Phase II REFRESH study ([NCT01490086](#)), the 15mg arm was the best performing, with the 50mg arm a close second in terms of efficacy.

**Exhibit I - RECOVER Trial Design<sup>1</sup>**



Inclusion of the 50 mg dose arm will allow therapeutic insight, both in terms of efficacy and safety, in higher doses in a population almost double the size, and will give Reviva an additional opportunity to meet primary endpoints. The open-label cohort will comprise both subjects who participated in the double-blind phase and new (*de novo*) subjects. With a 52-week open-label extension following the 28-day double-blind phase, the trial is expected in total to last 56 weeks. As demonstrated in earlier studies, Brilaroxazine represents class-leading tolerability in terms of side-effects, a significant deterrent to treatment adherence in the patient population suffering from schizophrenia.

## Interview

We invited Reviva CEO, Dr. Laxminarayan Bhat, into the studio for an interview and discussion on Reviva and its lead candidate, brilaroxazine.

**Exhibit II - Studio Interview with CEO Dr. Laxminarayan Bhat<sup>2</sup>**



<sup>1</sup> Reviva 2021 10-K

<sup>2</sup> Reviva Pharmaceuticals: New Treatment for Schizophrenia – CEO Interview

Topics discussed include:

- [Reviva Pharmaceuticals: New Treatment for Schizophrenia](#)
- [Reviva Pharmaceuticals \(RVPH\) Active Clinical Trials](#)
- [Reviva Pharmaceuticals: Brilaroxazine - More than Schizophrenia](#)

The interview is divided into several parts and provides a conversational exploration of Reviva and its value proposition for the investor. Importantly, Reviva CEO Dr. Bhat, who founded the company over 16 years ago, delves into Reviva's lead candidate, which is discussed in terms of the unmet need and its position in the schizophrenia treatment landscape. The effect of its enhanced tolerability on treatment discontinuation is covered, which stands out as a major hurdle in the treatment of schizophrenia. Market size of the antipsychotic drug class is reviewed and clinical trial design, namely clinical measures of symptoms, are detailed. The pleiotropic effect of brilaroxazine is explained in terms of its dichotomous pursuit of both neurological and pulmonary indications. The interview concludes with an overview of the financial condition of the firm and upcoming milestones.

**Exhibit III – KOL Event Featuring Dr. Citrome and Dr. Ereshefsky<sup>3</sup>**



On May 3, 2020, Reviva hosted a key opinion leader (KOL) event featuring Leslie Citrome, MD, MPH and Larry Ereshefsky, PharmD, BCPP, FCCP and produced by LifeSci Advisors. The event began with an introduction to Reviva's drug, Brilaroxazine by CEO Dr. Laxaminarayan Bhat. It was followed by an summary of schizophrenia and major neuropsychiatric disorders with overlapping conditions that are treated with an antipsychotic and a summary of unmet medical needs in the space by Dr. Citrome. The next segment featured Dr. Ereshefsky who reviewed treatment considerations for schizophrenia and related psychiatric disorders. The last segment was presented by Dr. Bhat on the development of Brilaroxazine and was followed by a question and answer session. [A replay is available here.](#)

<sup>3</sup> Revival Pharmaceuticals: KOL Webinar on Antipsychotic Drug for Schizophrenia and other Neuropsychiatric Disorders. May 3, 2022.



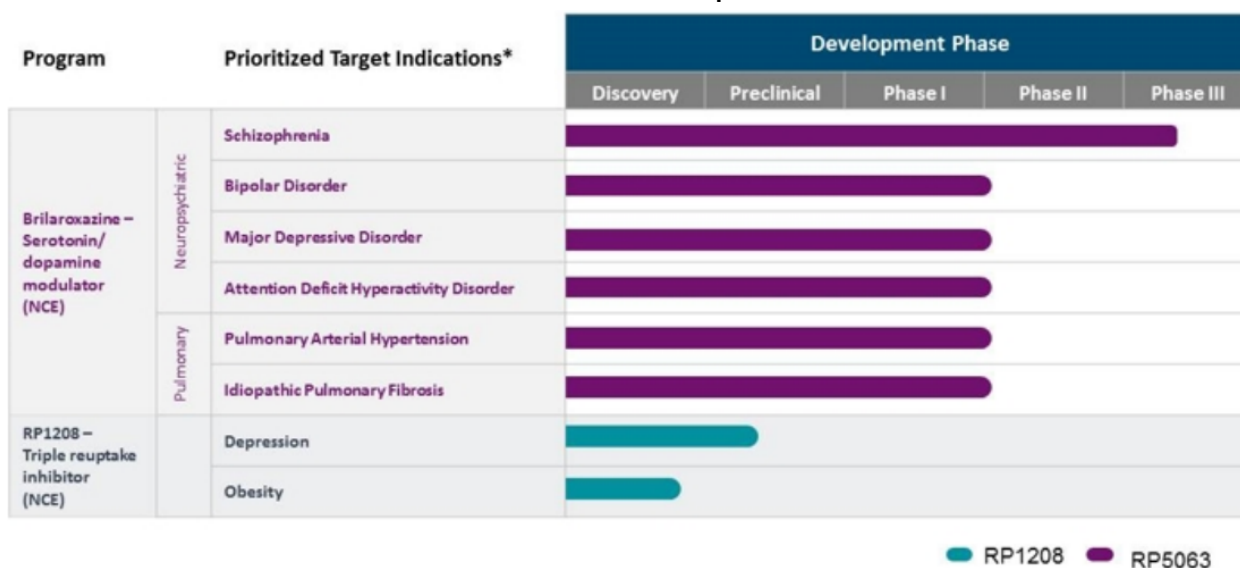
## Milestones

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, pending funding. We provide additional detail on recent and anticipated achievements below:

- Phase III trial design finalization with FDA – January 2022
- First patient enrolled in RECOVER – February 2022
- Regulatory submissions of investigational new drug (IND) application for PAH & IPF – 2022
- [KOL event](#) – May 2022
- Developing Phase II protocols for studies in PAH and ADHD – 2H:22
- Estimated last patient enrolled in RECOVER – March 2023
- Estimated last patient last visit in RECOVER – April 2023
- Phase III schizophrenia RECOVER topline data – mid-2023

## Company Pipeline

Exhibit IV – Reviva Pipeline<sup>4</sup>



\*Opportunity to expand into other indications including Parkinson's Psychosis and Alzheimer's (Psychosis/agitation)

## Summary

Reviva announced second quarter results and filed its Form 10-Q with the SEC. 2022 saw the launch of the Phase III RECOVER trial for RP5063 in acute exacerbation of schizophrenia that includes a 52-week open label extension with focus on treatment safety, which may permit a potential 'superior safety' label with the FDA. The first patients were enrolled in February 2022 and topline data is expected in mid-2023.

With the start of the pivotal trial, spending kicked into high gear with operational costs of \$5.5 million in the quarter and cash burn of (\$4.0) million. Reviva has guided towards sufficient cash to make it March 2023, but will need a financial infusion prior to the end of the RECOVER trial. Non-dilutive funding from partnerships and grants are being considered. Reviva's lead candidate, Brilaroxazine, represents class-leading tolerability in an indication where side effects deter treatment adherence. We maintain our valuation of \$16.00 per share.

<sup>4</sup> Source: Reviva Pharmaceuticals 2021 Form 10-K.

## PROJECTED FINANCIALS

### Reviva Pharmaceutical Holdings Inc. - Income Statement<sup>5</sup>

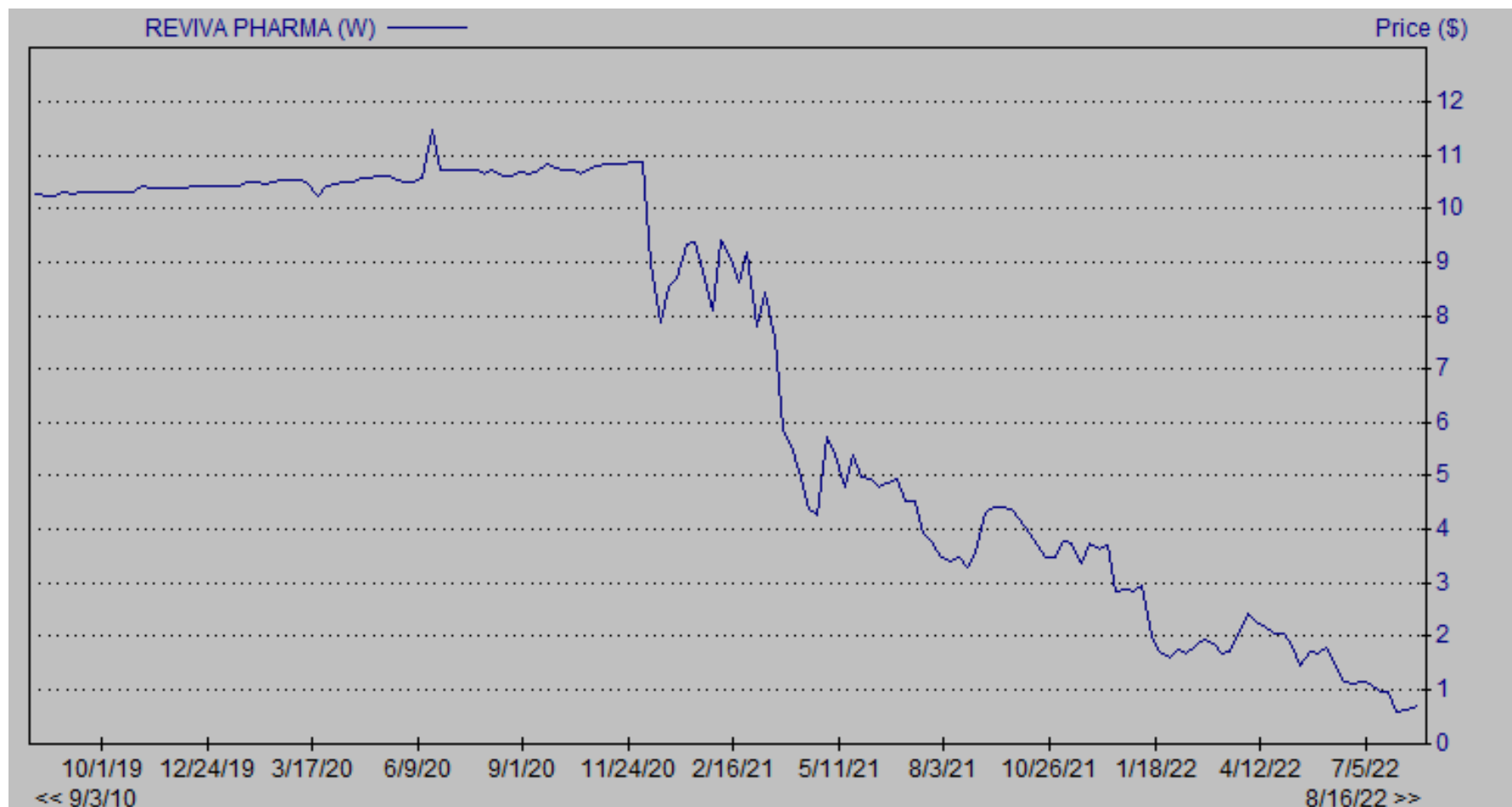
Reviva Pharmaceuticals	2021 A	Q1 A	Q2 A	Q3 E	Q4 E	2022 E	2023 E	2024 E
<b>Total Revenues (\$US ,000)</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>
<i>YOY Growth</i>								
Research & Development	\$4,852	\$5,830	\$4,514	\$4,800	\$4,200	\$19,344	\$9,250	\$7,000
General & Administrative	\$5,253	\$1,620	\$1,005	\$1,350	\$1,425	\$5,400	\$5,850	\$6,100
<b>Income from operations</b>	<b>(\$10,105)</b>	<b>(\$7,450)</b>	<b>(\$5,519)</b>	<b>(\$6,150)</b>	<b>(\$5,625)</b>	<b>(\$24,745)</b>	<b>(\$15,100)</b>	<b>(\$13,100)</b>
Other Income (Expense)	\$1,589	\$89	\$186	\$0	\$0	(\$422)	(\$441)	(\$410)
<b>Pre-Tax Income</b>	<b>(\$8,516)</b>	<b>(\$7,361)</b>	<b>(\$5,334)</b>	<b>(\$6,150)</b>	<b>(\$5,625)</b>	<b>(\$25,167)</b>	<b>(\$15,541)</b>	<b>(\$13,510)</b>
Provision for Income Tax	\$6	\$4	\$7	\$0	\$0	\$11		
<i>Tax Rate</i>	<i>0.0%</i>					<i>0.0%</i>		
<b>Net Income</b>	<b>(\$8,522)</b>	<b>(\$7,365)</b>	<b>(\$5,341)</b>	<b>(\$6,150)</b>	<b>(\$5,625)</b>	<b>(\$25,177)</b>	<b>(\$15,541)</b>	<b>(\$13,510)</b>
<b>Reported EPS</b>	<b>(\$0.58)</b>	<b>(\$0.40)</b>	<b>(\$0.29)</b>	<b>(\$0.30)</b>	<b>(\$0.27)</b>	<b>(\$1.28)</b>	<b>(\$0.73)</b>	<b>(\$0.54)</b>
<i>YOY Growth</i>	<i>-53%</i>	<i>287.9%</i>	<i>131.5%</i>	<i>141.7%</i>	<i>38.0%</i>	<i>12.3%</i>	<i>-0.42951522</i>	<i>-0.26108359</i>
<b>Basic Shares Outstanding</b>	<b>14,791</b>	<b>18,467</b>	<b>18,467</b>	<b>20,625</b>	<b>21,000</b>	<b>19,640</b>	<b>21,250</b>	<b>25,000</b>

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

<sup>5</sup> Historical financial statement information presents data as originally reported.

## HISTORICAL STOCK PRICE

Reviva Pharmaceutical Holdings, Inc. – Share Price Chart<sup>6</sup>



<sup>6</sup> Source: Zacks Research System

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