

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 OR 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **March 15, 2022**

REVIVA PHARMACEUTICALS HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or Other Jurisdiction
of Incorporation)

001-38634

(Commission File Number)

85-4306526

(IRS Employer
Identification No.)

19925 Stevens Creek Blvd., Suite 100, Cupertino, CA

(Address of Principal Executive Offices)

95014

(Zip Code)

Registrant's telephone number, including area code: **(408) 501-8881**

Not Applicable

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered or to be registered pursuant to Section 12(b) of the Act.

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	RVPH	Nasdaq Capital Market
Warrants to purchase one share of Common Stock	RVPHW	Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02. Results of Operations and Financial Condition.

Reviva Pharmaceuticals Holdings, Inc. (the “Company”) issued a press release on March 15, 2022, disclosing financial information and operating metrics for its fiscal year ended December 31, 2021 and discussing its business outlook. A copy of the Company’s press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 7.01. Regulation FD Disclosure.

See “Item 2.02 Results of Operations and Financial Condition” above.

The information in this Current Report on Form 8-K under Items 2.02 and 7.01, including the information contained in Exhibit 99.1, is being furnished to the Securities and Exchange Commission, and shall not be deemed to be “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except as shall be expressly set forth by a specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) The following exhibit is furnished with this report:

Exhibit No.	Description
99.1	Press Release issued by Reviva Pharmaceuticals Holdings, Inc., dated March 15, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

REVIVA PHARMACEUTICALS HOLDINGS, INC.

Dated: March 15, 2022

By: /s/ Narayan Prabhu

Name: Narayan Prabhu

Title: Chief Financial Officer



**Reviva Pharmaceuticals Holdings, Inc. Reports Full Year 2021
Financial Results and Recent Business Highlights**

- Topline data for pivotal Phase 3 trial evaluating brilaroxazine for the treatment of schizophrenia anticipated in mid-2023

- \$29.7 Million in Cash as of December 31, 2021 -

Cupertino, Calif., March 15, 2022 – Reviva Pharmaceuticals Holdings, Inc. (NASDAQ: RVPH) (“Reviva” or the “Company”), a clinical-stage pharmaceutical company developing therapies that seek to address unmet medical needs in the areas of central nervous system (CNS), cardiovascular, metabolic, and inflammatory diseases, today reported financial results for the full year ended December 31, 2021 and summarized recent business highlights.

“2021 was a year of significant progress that capped off with initiation of our pivotal Phase 3 and long-term safety trials in January evaluating brilaroxazine in schizophrenia. We are highly encouraged by the differentiated pharmacology profile of brilaroxazine as a modulator of serotonin and dopamine signaling pathways that we believe is well-positioned for long-term use and the potential to address unmet needs in both neuropsychiatric and pulmonary indications,” said Laxminarayan Bhat, Ph.D., Founder, President, and CEO of Reviva. “In addition to schizophrenia, bipolar disorder, major depressive disorder, and attention deficit hyperactive disorder are also chronic neuropsychiatric conditions that arise from an underlying dysfunction in serotonin and dopamine signaling. We plan to prioritize our near-term efforts and may initiate Phase 2a studies in these indications, subject to the receipt of additional financing, potentially as early as 2H-2022.”

Full Year 2021 and Recent Business Highlights

- First patient dosed in pivotal Phase 3 study and long-term safety trial evaluating brilaroxazine for the treatment of schizophrenia (Jan 2022)
- Joined the Russell Microcap® Index as part of the Russell U.S. Indexes annual reconstitution (Jun 2021)
- Raised Gross Proceeds of \$34.5 Million in Public Offering of Common Stock and Warrants (May 2021)

Anticipated Milestones and Events

- May initiate Phase 2a studies in bipolar disorder, major depressive disorder, and attention deficit hyperactive disorder, subject to the receipt of additional financing, potentially as early as 2H-2022
 - Topline data for pivotal Phase 3 trial evaluating brilaroxazine for the treatment of schizophrenia anticipated in mid-2023
 - Pursue partnership opportunities for the development of our pipeline
 - Evaluate grant and other non-dilutive financing opportunities for our product candidates from Federal and State Healthcare Agencies and Foundations
-



Financial Results for 2021

For the year ended December 31, 2021, net loss was \$8.5 million, or \$0.58 per share, compared to \$3.8 million, or \$1.24 per share, for the year ended December 31, 2020.

As of December 31, 2021, the Company's cash totaled approximately \$29.7 million compared to approximately \$8.8 million as of December 31, 2020.

Reviva believes that based on the current operating plan and financial resources, the Company's cash as of December 31, 2021 will be sufficient to fund our current operating plans through at least December 2022.

About Reviva's Lead Drug Candidate Brilaroxazine

Brilaroxazine (RP5063) is a new chemical entity with potent affinity and selectivity against key serotonin and dopamine receptors implicated in schizophrenia and its comorbid symptoms. In a multinational, multicenter, double-blind Phase 2 study in 234 patients with acute schizophrenia or schizoaffective disorder, brilaroxazine met its primary endpoint, reducing Positive and Negative Syndrome Scale (PANSS) total score and demonstrating statistically significant improvements for secondary endpoints evaluating social functioning, and positive and negative symptoms, and directional improvements for depression and cognition. In this completed Phase 2 study, brilaroxazine met all safety endpoints with no weight gain, no increase in blood sugar and lipids, and no cardiac or endocrine adverse effects compared to placebo. A full battery of regulatory compliant toxicology and safety pharmacology studies has been completed for brilaroxazine. The U.S. Food and Drug Administration (FDA) has agreed to consider a potential 'Superior Safety' label claim if there is a positive outcome on a relevant endpoint in a pivotal Phase 3 study in patients with schizophrenia. Reviva intends to develop brilaroxazine for other neuropsychiatric indications including bipolar disorder, major depressive disorder (MDD) and attention-deficit/hyperactivity disorder (ADHD).

Additionally, brilaroxazine has shown promising efficacy for pulmonary arterial hypertension (PAH) and idiopathic pulmonary fibrosis (IPF) with mitigation of lung fibrosis and inflammation in translational animal models. Reviva believes brilaroxazine has the potential to delay disease progression in PAH and IPF and intends to develop brilaroxazine for these pulmonary indications. Brilaroxazine has already received Orphan Drug Designation by the U.S. FDA for the treatment of these conditions.

To learn more about the clinical and preclinical data available for brilaroxazine, please visit revivapharma.com/publications.

About Reviva

Reviva is a clinical-stage biopharmaceutical company that discovers, develops and seeks to commercialize next-generation therapeutics for diseases representing unmet medical needs and burdens to society, patients, and their families. Reviva's current pipeline focuses on the central nervous system, respiratory and metabolic diseases. Reviva's pipeline currently includes two drug candidates, RP5063 (brilaroxazine) and RP1208. Both are new chemical entities discovered in-house. Reviva has been granted composition of matter patents for both RP5063 and RP1208 in the United States (U.S.), Europe, and several other countries.



Forward-Looking Statements

This press release contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act, as amended, including those relating to the Company's RECOVER Phase 3 trial, product development, clinical and regulatory timelines and expenses, market opportunity, ability to raise sufficient funding, competitive position, possible or assumed future results of operations, business strategies, potential growth opportunities and other statements that are predictive in nature. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's current beliefs and assumptions.

These statements may be identified by the use of forward-looking expressions, including, but not limited to, "expect," "anticipate," "intend," "plan," "believe," "estimate," "potential," "predict," "project," "should," "would" and similar expressions and the negatives of those terms. These statements relate to future events or our financial performance and involve known and unknown risks, uncertainties, and other factors which may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such factors include those set forth in the Company's filings with the Securities and Exchange Commission. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this press release. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

Corporate Contact:

Reviva Pharmaceuticals Holdings, Inc.
Laxminarayan Bhat, PhD
www.revivapharma.com

Investor Relations Contact:

LifeSci Advisors, LLC
Bruce Mackle
bmackle@lifesciadvisors.com