

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): **November 15, 2021**

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 November 15, 2021, disclosing financial information and operating metrics for its fiscal quarter ended September 30, 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 November 15, 2021.
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: November 15, 2021

By: /s/ Laxminarayan Bhat

Name: Laxminarayan Bhat

Title: Chief Executive Officer



**Reviva Pharmaceuticals Holdings, Inc. Reports Third Quarter 2021
Financial Results and Recent Business Highlights**

- Initiation of a pivotal Phase 3 trial evaluating the efficacy and safety of brilaroxazine for the treatment of schizophrenia expected by year-end -

- Additional Phase 3 trial evaluating the long-term safety of brilaroxazine in adult patients with schizophrenia expected to begin by year-end -

- \$33.5 Million in Cash as of September 30, 2021 -

Cupertino, Calif., November 15, 2021 – 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 third quarter of 2021 and summarized recent business highlights.

“We look forward to initiating two Phase 3 trials evaluating both the efficacy and safety, as well as long-term safety of brilaroxazine in adults with schizophrenia by year-end,” said Laxminarayan Bhat, Ph.D., Founder, President, and CEO of Reviva. “We are highly encouraged by the therapeutic potential brilaroxazine demonstrated in our successful Phase 2 trial for the treatment of schizophrenia and expect to begin regulatory submissions to the FDA for pulmonary indications including IPF and PAH by the end of the first quarter of 2022.”

Recent Business Highlights, Anticipated Milestones and Events for 2021 and 2022

- Engaged a clinical research organization to lead recruitment and trial services of its pivotal Phase 3 trials in patients with schizophrenia
- Initiation of both a pivotal Phase 3 trial evaluating the efficacy and safety, and an additional long-term safety trial of brilaroxazine for the treatment of schizophrenia expected by year-end 2021
- Regulatory submissions to the U.S. Food and Drug Administration (FDA) for initiating Phase 2 studies in pulmonary arterial hypertension (PAH) and idiopathic pulmonary fibrosis (IPF) now expected by the end of Q1 2022
- Participation in H.C. Wainwright 23rd Annual Global Investment Conference and Benzinga Healthcare Small Cap Conference
- 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

Third Quarter 2021 Financial Results

The Company reported a net loss of approximately \$2.28 million, or \$0.12 per share, for the three months ended September 30, 2021, compared to a net loss of approximately \$0.66 million, or \$0.24 per share, for the same period in 2020.

As of September 30, 2021, the Company’s cash totaled approximately \$33.5 million compared to approximately \$0.35 million for the quarter ended September 30, 2020.



Reviva believes that based on the current operating plan and financial resources, the Company's cash and cash equivalents at the quarter ended September 30, 2021 will be sufficient to cover general operating expenses through the fourth quarter of 2022.

About Reviva's Lead Drug Candidate Brilaroxazine (RP5063)

Brilaroxazine (RP5063) is a novel serotonin and dopamine receptor modulator that is being evaluated in diseases characterized by dysfunctional serotonin signaling including neuropsychiatric (e.g. schizophrenia, bipolar disorder, depression and attention deficit hyperactivity disorder (ADHD)) and pulmonary indications (e.g. idiopathic pulmonary fibrosis (IPF) and pulmonary arterial hypertension (PAH)). In a successful 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. A full battery of regulatory compliant toxicology and safety pharmacology studies has been completed for brilaroxazine. Reviva believes that 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. 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.

The Company believes brilaroxazine has the potential to delay disease progression in PAH and IPF. 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 R1208 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 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