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 21, 2022

ENANTA PHARMACEUTICALS, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-35839**	**04-3205099**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

500 Arsenal Street **Watertown, Massachusetts**	**02472**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (617) 607-0800

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:

☐ 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 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 $0.01 per share	ENTA	NASDAQ Global Select Market

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

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.

On November 21, 2022, Enanta Pharmaceuticals, Inc. announced via press release its results for the fiscal quarter and year ended September 30, 2022. A copy of Enanta's press release is hereby furnished to the Commission and incorporated by reference herein as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

Exhibit Number	Description
99.1	Press Release of Enanta Pharmaceuticals, Inc. dated November 21, 2022, reporting Enanta's financial results for the fiscal quarter and year ended September 30, 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 thereunto duly authorized.

ENANTA PHARMACEUTICALS, INC.

Date: November 21, 2022

By: /s/ Paul J. Mellett

Paul J. Mellett
Senior Vice President, Finance and Administration and Chief Financial Officer

Enanta Pharmaceuticals Reports Financial Results for its Fiscal Fourth Quarter and Year Ended September 30, 2022 With Webcast and Conference Call Today at 4:30 p.m. ET

- *Initiated SPRINT (**S**ARS-Cov-2 **PR**otease **IN**hibitor **T**reatment), a Phase 2 Study of EDP-235, an Oral, 3CL Protease Inhibitor, in Non-Hospitalized, Symptomatic Patients With Mild to Moderate COVID-19*
- *Initiated RSVHR, a Phase 2 Study of EDP-938, an Oral N-Protein Inhibitor, in Adults at High Risk for Complications from Respiratory Syncytial Virus (RSV)*
- *Began Dosing in a Phase 1 Study of EDP-323, a Novel, Oral L-Protein Inhibitor Designed for the Treatment of RSV*
- *Royalty Revenue for the Quarter was $20.3 Million*

WATERTOWN, Mass., Nov. 21, 2022 – Enanta Pharmaceuticals, Inc. (NASDAQ:ENTA), a clinical-stage biotechnology company dedicated to creating small molecule drugs for viral infections, today reported financial results for its fiscal fourth quarter and year ended September 30, 2022.

“Our fiscal 2022 was a year of progress toward our vision of transforming the lives of patients with curative therapies, and in the past two months alone we began three new clinical trials to advance our pipeline,” said Jay R. Luly, Ph.D., President and Chief Executive Officer of Enanta Pharmaceuticals. “Most recently, the initiation of SPRINT, a Phase 2 study of EDP-235, our lead 3CL protease inhibitor, moves us further in developing a best-in-class treatment for COVID-19 without ritonavir boosting and associated drug-drug interactions. As new variants emerge that can evade immunity arising from vaccination or previous infection, EDP-235 has the potential to fill the need for rapid treatment of COVID infection as a once-daily, oral treatment. This quarter, we also expanded our RSV clinical program with the initiation of RSVHR, a Phase 2 study of EDP-938 in patients who are at high risk of complications, a population where we believe that treatment with EDP-938 has significant potential to show optimal efficacy and clinical benefit. Additionally, we dosed our first subject with EDP-323, our novel, oral therapeutic targeting the RSV L-protein RNA polymerase. The further progression of our clinical studies and expansion of our pipeline continues to enhance our robust position in respiratory virology.”

Fiscal Fourth Quarter and Year Ended September 30, 2022 Financial Results
Total revenue of $20.3 million for the three months ended September 30, 2022, consisted of royalty revenue derived from worldwide net sales of AbbVie’s hepatitis C virus (HCV) regimen MAVYRET®/MAVIRET®, compared to royalty revenue of $23.6 million for the three months ended September 30, 2021. For the twelve months ended September 30, 2022, total revenue was $86.2 million compared to $97.1 million for the same period in 2021.

Research and development expenses were $34.8 million for the three months ended September 30, 2022, compared to $48.9 million for the three months ended September 30, 2021. For the twelve months ended

September 30, 2022, research and development expenses were $164.5 million compared to $174.1 million in 2021. The decreases in both periods were due to the timing and scope of the company's clinical trials.

General and administrative expenses totaled $12.6 million for the three months ended September 30, 2022, compared to $8.4 million for the three months ended September 30, 2021. For the twelve months ended September 30, 2022, general and administrative expenses were $45.5 million compared to $32.5 million in 2021. The increases in both periods were due primarily to additional headcount and stock compensation expense.

Enanta recorded an income tax expense of $0.01 million for the three months ended September 30, 2022, and an income tax benefit of $0.4 million for the twelve months ended September 30, 2022, which are due primarily to the release of a state tax reserve. Enanta recorded an income tax benefit of $8.8 million and $28.6 million for the three and twelve months ended September 30, 2021, respectively, due primarily to a federal net loss carryback available in fiscal 2021 under the CARES Act of 2020. Enanta is still due a refund of $28.7 million for the tax losses carried back in 2021 to offset taxable income in prior years.

Net loss for the three months ended September 30, 2022, was $26.3 million, or a loss of $1.27 per diluted common share, compared to a net loss of $24.6 million, or a loss of $1.22 per diluted common share, for the corresponding period in 2021. For the twelve months ended September 30, 2022, net loss was $121.8 million, or a loss of $5.91 per diluted common share, compared to a net loss of $79.0 million, or loss of $3.92 per diluted common share for the corresponding period in 2021.

Enanta's cash, cash equivalents and marketable securities totaled $278.5 million at September 30, 2022. Enanta expects that its current cash, cash equivalents and short-term and long-term marketable securities, as well as its continuing royalty revenue, will continue to be sufficient to meet the anticipated cash requirements of its existing business and development programs into the fourth quarter of fiscal 2024.

Financial Guidance for Fiscal Year 2023

- Research and Development Expense: $210 million to $230 million
- General and Administrative Expense: $46 million to $52 million

Pipeline Programs

COVID-19 (SARS-CoV-2)

- Enanta announced the initiation of SPRINT, a Phase 2 clinical study of EDP-235, an oral, 3CL protease inhibitor, which has Fast Track designation from the U.S. Food and Drug Administration (FDA). The randomized, double-blind, placebo-controlled study is designed to evaluate the safety, tolerability and antiviral activity of once-daily doses of EDP-235 compared to placebo. SPRINT will enroll approximately 200 non-hospitalized, symptomatic patients with mild to moderate COVID-19, who are not at increased risk for developing severe disease. During the study, patients will receive EDP-235 orally at a dose of 200 mg or 400 mg or placebo, once daily for five days, and will be assessed for a further 28 days. The primary objective of the study includes evaluation of safety and tolerability, and key secondary objectives include analysis of pharmacokinetics (PK) and multiple virology measures to guide dose selection for other trials.

- EDP-235 is supported by positive topline data from a Phase 1 study which assessed the safety, tolerability, and PK of orally administered single and multiple ascending doses of EDP-235 in healthy adult subjects.
    - Data from the Phase 1 study demonstrated EDP-235 was generally safe and well-tolerated up to 400 mg for seven days, with strong exposure multiples over the EC_{90}, which is a measure of potency, specifically the concentration of drug that results in 90% inhibition of viral replication *in vitro.* EDP-235 200 mg taken once daily with food resulted in mean trough plasma levels at steady state that were 3-fold and 7-fold over the plasma-protein-adjusted EC_{90} for the Alpha variant and Omicron variant, respectively, while the 400 mg dose resulted in levels that were 6-fold and 13-fold over the plasma-protein-adjusted EC_{90} for the respective variants. These target exposure multiples were achieved without the need for ritonavir boosting and its associated drug-drug interactions. EDP-235 has good tissue distribution and is expected to drive these multiples four times higher in lung tissue.

RSV

- EDP-938, an N-protein inhibitor with Fast Track designation from the FDA, is being evaluated in a broad clinical development program in multiple patient groups, including pediatric and high-risk adult populations.
    - In October 2022, Enanta announced the initiation of RSVHR, a Phase 2b randomized, double-blind, placebo-controlled, multi-center, global study in adults with acute RSV infection who are at high risk of complications, including the elderly and/or those with congestive heart failure, chronic obstructive pulmonary disease (COPD) or asthma. The study is designed to evaluate the effect of EDP-938 compared with placebo on the progression of RSV infection by assessment of clinical symptoms in non-hospitalized adult subjects with up to 72 hours of respiratory tract infection symptoms who test positive for RSV and negative for influenza and SARS-CoV-2. Approximately 180 patients will be treated with 800 mg of EDP-938 or placebo for five days and evaluated over a 28-day period thereafter.
    - Other ongoing studies include RSVPEDs, a Phase 2 randomized, double-blind, placebo-controlled study in hospitalized and non-hospitalized pediatric RSV patients, and RSVTx, a Phase 2b, randomized, double-blind, placebo-controlled study in adult hematopoietic cell transplant recipients with acute RSV infection and symptoms of upper respiratory tract infection.
    - Enanta will continue to monitor RSV infection trends during the Northern Hemisphere season to evaluate timing for data readouts in its ongoing RSV studies.
- Enanta is also evaluating EDP-323, a novel, oral, direct-acting antiviral selectively targeting the RSV L-protein, for the treatment of RSV.
    - In October 2022, Enanta announced the first subject was dosed in a Phase 1 study of EDP-323. This double-blind, placebo-controlled, first-in-human study will enroll approximately 80 healthy subjects to evaluate the safety, tolerability, and PK of EDP-323 with a single-ascending dose phase, including a two-part food-effect cohort, and a multiple-ascending dose phase.
    - EDP-323 has shown sub-nanomolar potency against RSV-A and RSV-B *in vitro* and is not expected to have cross-resistance to other classes of inhibitors. EDP-323 could be used as a monotherapy or in combination with other RSV mechanisms, such as EDP-938, to potentially broaden the addressable patient populations or the treatment window.

- EDP-323 is also supported by promising preclinical data presented this quarter at the 12th International RSV Symposium, which showed that EDP-323 inhibited polymerase activity *in vitro* and inhibited the virus-induced cytopathic effect of both RSV-A and RSV-B strains. In a rodent RSV infection model, treatment with EDP-323 was associated with improved lung histopathology and dose-dependent reductions in pro-inflammatory cytokines.

Human Metapneumovirus (hMPV)

- hMPV is a pathogen that causes upper and lower respiratory tract infections similar to RSV in young children and the elderly, as well as in immunocompromised patients or those with COPD or asthma.
- This quarter, Enanta presented new data at the 12th International RSV Symposium, which highlighted several advances in virus detection, quantification and growth methods for the generation of an improved toolkit for *in vitro* characterization of multiple hMPV strains across each of the four hMPV genetic subgroups. This expanded *in vitro* characterization of genetically distinct hMPV strains catalyzes the advancement of hMPV virology and the development of direct-acting antivirals.
- Enanta's goal is to select a development candidate for hMPV in 2023.

Hepatitis B Virus (HBV)

- Enanta remains committed to developing a cure for HBV patients and is currently focused on identifying additional compounds with different mechanisms of action to combine with EDP-514, its potent core inhibitor, and a nucleoside reverse transcriptase inhibitor. EDP-514, which has Fast Track designation from the FDA, has displayed a good safety profile and robust antiviral activity in multiple HBV patient populations, with declines in HBV DNA among the best published to date for core inhibitors.

Upcoming Events and Presentations

- Piper Sandler Healthcare Conference, November 29, 2022
- Evercore Healthcare Conference, November 30, 2022
- 41st Annual JP Morgan Healthcare Conference, January 10, 2023
- Enanta plans to issue its fiscal first quarter financial results press release, and hold a conference call regarding those results, on February 7, 2023.

Conference Call and Webcast Information

Enanta will host a conference call and webcast today at 4:30 p.m. ET. The live webcast can be accessed under "Events & Presentations" in the investors section of Enanta's website https://ir.enanta.com/events-presentations or by clicking here. To participate by phone, please register for the call here. It is recommended that participants register a day in advance or at a minimum of 15 minutes before the call. Once registered, participants will receive the dial-in information. The archived webcast will be available on Enanta's website for approximately 30 days following the event.

About Enanta Pharmaceuticals, Inc.

Enanta is using its robust, chemistry-driven approach and drug discovery capabilities to become a leader in the discovery and development of small molecule drugs for the treatment of viral infections. Enanta's research and development programs include clinical candidates in development for the following disease targets: respiratory

syncytial virus (RSV), SARS-CoV-2 (COVID-19) and hepatitis B virus (HBV). Enanta is also conducting research in human metapneumovirus (hMPV).

Enanta's research and development activities are funded by royalties from hepatitis C virus (HCV) products developed under its collaboration with AbbVie. Glecaprevir, a protease inhibitor discovered by Enanta, is part of one of the leading treatment regimens for curing chronic HCV infection and is sold by AbbVie in numerous countries under the tradenames MAVYRET® (U.S.) and MAVIRET® (ex-U.S.) (glecaprevir/pibrentasvir). Please visit www.enanta.com for more information.

Forward Looking Statements
This press release contains forward-looking statements, including statements with respect to the prospects for advancement of Enanta's clinical programs in RSV, SARS-CoV-2 and HBV and its preclinical program in hMPV. Statements that are not historical facts are based on management's current expectations, estimates, forecasts and projections about Enanta's business and the industry in which it operates and management's beliefs and assumptions. The statements contained in this release are not guarantees of future performance and involve certain risks, uncertainties and assumptions, which are difficult to predict. Therefore, actual outcomes and results may differ materially from what is expressed in such forward-looking statements. Important factors and risks that may affect actual results include: the impact of development, regulatory and marketing efforts of others with respect to vaccines and competitive treatments for RSV, SARS-CoV-2 and HBV; the discovery and development risks of Enanta's programs in RSV, SARS-CoV-2, HBV and hMPV; the competitive impact of development, regulatory and marketing efforts of others in those disease areas; any continuing impact of the COVID-19 pandemic on business operations and clinical trials; Enanta's lack of clinical development experience; Enanta's need to attract and retain senior management and key research and development personnel; Enanta's need to obtain and maintain patent protection for its product candidates and avoid potential infringement of the intellectual property rights of others; and other risk factors described or referred to in "Risk Factors" in Enanta's Form 10-Q for the fiscal quarter ended June 30, 2022, and any other periodic reports filed more recently with the Securities and Exchange Commission. Enanta cautions investors not to place undue reliance on the forward-looking statements contained in this release. These statements speak only as of the date of this release, and Enanta undertakes no obligation to update or revise these statements, except as may be required by law.

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Tables to Follow

ENANTA PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
UNAUDITED
(in thousands, except per share amounts)

	Three Months Ended September 30,		Twelve Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Revenue	$ 20,317	$ 23,575	$ 86,160	$ 97,074
Operating expenses				
Research and development	34,796	48,946	164,522	174,111
General and administrative	12,569	8,356	45,482	32,536
Total operating expenses	47,365	57,302	210,004	206,647
Loss from operations	(27,048)	(33,727)	(123,844)	(109,573)
Other income, net	714	333	1,656	1,994
Loss before income taxes	(26,334)	(33,394)	(122,188)	(107,579)
Income tax benefit (expense)	(14)	8,795	433	28,583
Net loss	$ (26,348)	$ (24,599)	$ (121,755)	$ (78,996)
Net loss per share				
Basic	$ (1.27)	$ (1.22)	$ (5.91)	$ (3.92)
Diluted	$ (1.27)	$ (1.22)	$ (5.91)	$ (3.92)
Weighted average common shares outstanding				
Basic	20,755	20,221	20,603	20,171
Diluted	20,755	20,221	20,603	20,171

ENANTA PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
UNAUDITED
(in thousands)

	September 30, 2022	September 30, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 43,994	$ 57,206
Short-term marketable securities	205,238	186,796
Accounts receivable	20,318	23,576
Prepaid expenses and other current assets	13,445	14,188
Income tax receivable	28,718	37,255
Total current assets	311,713	319,021
Long-term marketable securities	29,285	108,416
Property and equipment, net	6,173	5,943
Operating lease, right-of-use assets	23,575	4,711
Restricted cash	3,968	608
Other long-term assets	696	92
Total assets	$ 375,410	$ 438,791
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 6,000	$ 9,540
Accrued expenses and other current liabilities	20,936	22,429
Operating lease liabilities	2,891	4,203
Total current liabilities	29,827	36,172
Operating lease liabilities, net of current portion	22,372	1,126
Series 1 nonconvertible preferred stock	1,423	1,506
Other long-term liabilities	454	558
Total liabilities	54,076	39,362
Total stockholders' equity	321,334	399,429
Total liabilities and stockholders' equity	$ 375,410	$ 438,791