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 23, 2020

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, including 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	ENTA	NASDAQ

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 23, 2020, Enanta Pharmaceuticals, Inc. announced via press release its results for the fiscal quarter and year ended September 30, 2020. 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.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release of Enanta Pharmaceuticals, Inc. dated November 23, 2020, reporting Enanta's financial results for the fiscal quarter and year ended September 30, 2020
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 23, 2020

By: /s/ Paul J. Mellett
Paul J. Mellett
Senior Vice President, Finance and Administration and Chief Financial Officer

For Immediate Release

Enanta Pharmaceuticals Reports Financial Results for its Fiscal Fourth Quarter and Year Ended September 30, 2020
Webcast and Conference Call Today at 4:30 p.m. ET

- *On track to initiate a Phase 2b study in adult transplant patients with respiratory syncytial virus by year-end and a Phase 2 study in pediatric patients with respiratory syncytial virus in early 2021*
- *Readouts from two clinical trials in hepatitis B virus program expected in the second quarter of 2021*
- *Initiated Phase 1 study of EDP-297, a highly potent and targeted follow-on farnesoid X receptor agonist for the treatment of non-alcoholic steatohepatitis; initial clinical data expected in the second quarter of 2021*
- *Royalty revenue for the quarter was $23.6 million*
- *Cash and marketable securities totaled approximately $419 million at September 30, 2020*

WATERTOWN, Mass., November 23, 2020 – Enanta Pharmaceuticals, Inc. (NASDAQ:ENTA), a clinical stage biotechnology company dedicated to creating small molecule drugs for viral infections and liver diseases, today reported financial results for its fiscal fourth quarter and year ended September 30, 2020.

“2020 was marked by significant progress for Enanta. We initiated four clinical trials between our hepatitis B and non-alcoholic steatohepatitis programs, and we announced two new discovery programs for respiratory viruses – SARS-CoV-2 and human metapneumovirus. Additionally, we remain on schedule to initiate our adult transplant Phase 2b study in RSV by year-end 2020, which will be followed shortly thereafter with the initiation of our pediatric Phase 2 study in RSV in early 2021,” commented Jay R. Luly, Ph.D., President and Chief Executive Officer of Enanta. “I am grateful to the entire Enanta team for rising to the challenges presented by the COVID-19 pandemic and advancing our existing pipeline. Our commitment has laid the groundwork for a strong 2021, with multiple catalysts anticipated next year, including clinical data in our lead disease areas. If positive, these data will strengthen Enanta as a leader in the discovery and development of small molecule drugs for viral infections and liver diseases, and position us well to progress further our wholly-owned pipeline of clinical and preclinical programs to bring meaningful new treatments to patients.”

FISCAL FOURTH QUARTER AND YEAR ENDED SEPTEMBER 30, 2020 FINANCIAL RESULTS

Total revenue of $23.6 million for the three months ended September 30, 2020 consisted of royalty revenue derived primarily from worldwide net sales of AbbVie's hepatitis C virus (HCV) regimen MAVYRET®/MAVIRET® (glecaprevir/pibrentasvir). Total revenue for the three months ended September 30, 2019, was $51.3 million. For the twelve months ended September 30, 2020, total revenue was $122.5 million compared to $205.2 million for the same period in 2019. The decrease in royalty revenue quarter over quarter was driven by lower HCV product sales as treated patient volumes have remained below pre-COVID levels, as reported by AbbVie.

Research and development expenses were $36.7 million for the three months ended September 30, 2020, compared to $38.7 million for the three months ended September 30, 2019. For the twelve months ended September 30, 2020, research and development costs were $136.8 million compared to $142.2 million in 2019. The decrease in research and development expenses was primarily due to the timing of the company's clinical studies year over year and COVID-19-related delays in two clinical studies that are now ongoing.

General and administrative expenses totaled $6.7 million for the three months ended September 30, 2020, compared to $6.2 million for the three months ended September 30, 2019. For the twelve months ended September 30, 2020, general and administrative costs were $27.4 million compared to $26.2 million in 2019.

Enanta recorded income tax expense of $10.7 million for the three months ended September 30, 2020, despite a net operating loss, compared to an income tax benefit of $0.5 million for the same period in 2019. For the twelve months ended September 30, 2020, Enanta recorded income tax expense of $1.1 million, compared to an income tax benefit of $0.8 million for the twelve months ended September 30, 2019. The income tax expense in 2020 was due to a tax valuation allowance charge of $18.3 million recorded against the company's deferred tax assets in the three months ended September 30, 2020. This is a non-cash charge based on an assessment that it is more likely than not that Enanta's deferred tax assets will not be fully realized. The tax valuation allowance charge, which is recorded in income tax expense, was partially offset by a federal net operating loss carryback under the CARES Act, research and development credits generated during the year, and a release of an uncertain tax position reserve related to the close of a Massachusetts Department of Revenue Audit. In 2019, the company's income tax benefit was the result of a federal tax benefit on foreign derived royalty income and tax deductions from employee stock-award-related activity during 2019.

Net loss for the three months ended September 30, 2020 was $29.3 million, or a loss of $1.46 per diluted common share, compared to net income of $9.2 million, or $0.44 per diluted common share, for the corresponding period in 2019. For the twelve months ended September 30, 2020, net loss was $36.2 million, or a loss of $1.81 per diluted common share, compared to net income of $46.4 million, or $2.21 per diluted common share for the twelve months ended September 30, 2019. The decrease in net income in both 2020 periods was due to a decrease in HCV royalties earned under the AbbVie agreement and a non-cash tax valuation allowance charge of $18.3 million recorded in the three months ended September 30, 2020.

Enanta's cash, cash equivalents and marketable securities totaled approximately $419 million at September 30, 2020. This compares to a total of approximately $400 million at September 30, 2019. Enanta expects that its current cash, cash equivalents and marketable securities, as well as its continuing royalty revenue, will be sufficient to meet the anticipated cash requirements of its existing business and development programs for the foreseeable future.

FINANCIAL GUIDANCE FOR FISCAL YEAR 2021

- Research and Development Expense: $145 million to $165 million
- General and Administrative Expense: $27 million to $33 million

PIPELINE PROGRAMS AND BUSINESS REVIEW

Virology

Respiratory Syncytial Virus (RSV)

Enanta is evaluating EDP-938, its N-protein inhibitor, in a broad clinical development program, consisting of three planned or ongoing trials: RSVP, RSVTx and RSVPEDs. Together, these studies are designed to evaluate the effect of EDP-938 in a range of pediatric and adult patient populations:

- RSVP, an ongoing Phase 2b study in adult outpatients with community-acquired RSV infection, is anticipated to readout data in 3Q 2021, subject to the impact of the ongoing COVID-19 pandemic on levels of community RSV infection and activities at trial sites.
- RSVTx, a Phase 2b study in adult hematopoietic cell transplant recipients with acute RSV infection of the upper respiratory tract, is expected to initiate in 4Q 2020.
- RSVPEDs, a Phase 2 study in hospitalized and non-hospitalized pediatric patients with RSV, is expected to initiate in early 2021.

Human Metapneumovirus (hMPV)

In January, Enanta announced a new program to develop nanomolar inhibitors of hMPV, a pathogen that causes upper and lower respiratory tract infections in young children and the elderly, as well as in immunocompromised patients or those with COPD or asthma. Enanta's goal is to finalize a clinical candidate in 2021.

SARS-CoV-2 (COVID-19)

In March, Enanta initiated a program to discover direct-acting antiviral drug candidates, with a focus on polymerase and protease inhibitors, for the treatment of patients infected with the novel coronavirus COVID-19, also known as SARS-CoV-2. Enanta's goal is to finalize a clinical candidate in 2021.

Hepatitis B Virus (HBV)

EDP-514, Enanta's novel class II core inhibitor with Fast Track Designation from the FDA, is being developed in two Phase 1b studies for the treatment of HBV across different patient populations: subjects treated with a nucleos(t)ide reverse transcriptase inhibitor (NUC-suppressed patients), and chronic HBV subjects with high viral loads and not currently on therapy (viremic patients):

- In February, Enanta announced positive results from Part 1 of a Phase 1a/1b clinical study, informing the company's decision to initiate a Phase 1b study in NUC-suppressed patients in March. The Phase 1b study is currently ongoing with preliminary data expected in 2Q 2021.
- Subsequently, in July, Enanta initiated a randomized, double-blind, placebo-controlled Phase 1b study in viremic chronic HBV subjects not currently on therapy, with preliminary data expected in 2Q 2021.

Non-Alcoholic Steatohepatitis (NASH)

EDP-305, Enanta's lead farnesoid X receptor (FXR) agonist, is currently being evaluated for the treatment of NASH with fibrosis:

- In May, Enanta announced that it was no longer pursuing an indication for EDP-305 in primary biliary cholangitis and would remain focused on NASH for this compound.
- In August, Enanta began enrollment for ARGON-2, its Phase 2b randomized, double-blind, placebo-controlled 72-week study of EDP-305 in approximately 340 patients with biopsy-confirmed NASH with fibrosis, using doses of 1.5 mg and 2.0 mg.

EDP-297, Enanta's highly potent and targeted follow-on FXR agonist is currently being developed for the treatment of NASH with fibrosis:

- A Phase 1 randomized, double-blind, placebo-controlled, first-in-human clinical trial of EDP-297 is ongoing. Enanta expects to report safety, tolerability and pharmacokinetics data in 2Q 2021.

Around mid-year Enanta expects that the EDP-297 data, together with an interim analysis at 12 weeks of treatment on a subset of patients in ARGON-2, will enhance Enanta's ability to prioritize its FXR agonist compounds and seek opportunities for development of one or both of them in combinations with other mechanisms for NASH with fibrosis.

UPCOMING EVENTS AND PRESENTATIONS

- Piper Sandler 32nd Annual Virtual Healthcare Conference, November 30 - December 3, 2020
- **Evercore ISI 3rd Annual Virtual HealthCONx** Conference, December 1 - 3, 2020
- 39th Annual JP Morgan Virtual Healthcare Conference, January 11 - 14, 2021
- Enanta plans to issue its fiscal first quarter 2021 financial results press release, and hold a conference call regarding those results, on February 8, 2021.

CONFERENCE CALL AND WEBCAST INFORMATION

Enanta will host a conference call and webcast today at 4:30 p.m. ET. To participate in the live conference call, please dial (855) 840-0595 in the U.S. or (518) 444-4814 for international callers. A replay of the conference call will be available starting at approximately 7:30 p.m. ET on November 23, 2020, through 11:59 p.m. ET on November 25, 2020 by dialing (855) 859-2056 from the U.S. or (404) 537-3406 for international callers. The passcode for both the live call and the replay is 5436807. A live audio webcast of the call and replay can be accessed by visiting the "Events and Presentations" section on the "Investors" page of Enanta's website at www.enanta.com.

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 and liver diseases. Enanta's research and development efforts have produced clinical candidates for the following disease targets: respiratory syncytial virus (RSV), non-alcoholic steatohepatitis (NASH) and hepatitis B virus (HBV). Enanta is also conducting research in human metapneumovirus (hMPV) and SARS-CoV-2 (COVID-19).

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 sold by AbbVie in numerous countries as part of its leading treatment for chronic HCV infection 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, NASH and HBV, as well as Enanta's projections of its expenses in fiscal 2021, and its prospects for future royalty revenue from sales of AbbVie's MAVYRET®/MAVIRET® regimen for HCV. 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 dependence of Enanta's revenues in the short-term upon the continued success of AbbVie's sales of its MAVYRET/MAVIRET HCV regimen; the impact of development, regulatory and marketing efforts of others with respect to competitive treatments for RSV, NASH, HBV, hMPV and SARS-CoV-2; treatment rates, competitive pricing, and reimbursement rate actions affecting MAVYRET/MAVIRET compared to competitive HCV products on the market; the discovery and development risks of Enanta's programs in RSV, NASH, HBV, hMPV and SARS-CoV-2; the competitive impact of development, regulatory and marketing efforts of others in those disease areas; any continuing impact of the COVID-19 pandemic on Enanta's HCV royalties, 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 most recent Form 10-Q for the quarter ended June 30, 2020, and 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
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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,	
	2020	**2019**	**2020**	**2019**
Revenue	$ 23,631	$ 51,313	$ 122,473	$ 205,197
Operating expenses				
Research and development	36,686	38,719	136,756	142,213
General and administrative	6,728	6,163	27,356	26,246
Total operating expenses	43,414	44,882	164,112	168,459
Income (loss) from operations	(19,783)	6,431	(41,639)	36,738
Other income, net	1,149	2,274	6,620	8,819
Income (loss) before income taxes	(18,634)	8,705	(35,019)	45,557
Income tax (expense) benefit	(10,707)	486	(1,149)	826
Net income (loss)	$ (29,341)	$ 9,191	$ (36,168)	$ 46,383
Net income (loss) per share				
Basic	$ (1.46)	$ 0.47	$ (1.81)	$ 2.37
Diluted	$ (1.46)	$ 0.44	$ (1.81)	$ 2.21
Weighted average common shares outstanding				
Basic	20,074	19,686	19,940	19,584
Diluted	20,074	20,876	19,940	20,968

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

	September 30, 2020	September 30, 2019
Assets		
Current assets		
Cash and cash equivalents	$ 87,131	$ 51,230
Short-term marketable securities	299,518	284,006
Accounts receivable	23,492	51,313
Prepaid expenses and other current assets	26,696	15,299
Total current assets	436,837	401,848
Long-term marketable securities	32,634	65,013
Property and equipment, net	8,596	10,927
Deferred tax assets	345	11,341
Operating lease, right of use assets	7,020	-
Restricted cash	608	608
Other long-term assets	92	92
Total assets	$ 486,132	$ 489,829
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 5,737	$ 6,689
Accrued expenses and other current liabilities	14,159	15,920
Operating lease liabilities	4,261	-
Total current liabilities	24,157	22,609
Operating lease liabilities, net of current portion	3,838	-
Series 1 nonconvertible preferred stock	1,479	1,628
Other long-term liabilities	1,078	3,100
Total liabilities	30,552	27,337
Total stockholders' equity	455,580	462,492
Total liabilities and stockholders' equity	$ 486,132	$ 489,829