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, 2019

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 21, 2019, Enanta Pharmaceuticals, Inc. announced via press release its results for the fiscal quarter and year ended September 30, 2019. 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 21, 2019, reporting Enanta's financial results for the fiscal quarter and year ended September 30, 2019.
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, 2019

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, 2019

Webcast and Conference Call today at 4:30 p.m. ET

- *Initiation of RSVP, a Phase 2b study of EDP-938 in adult outpatients with RSV*
- *EDP-297 selected as follow-on FXR agonist with differentiated preclinical profile*
- *Royalty revenue for the quarter was $51.3 million*
- *Cash and marketable securities totaled approximately $400 million at September 30, 2019*

WATERTOWN, Mass., November 21, 2019 – 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, 2019.

“During 2019, we successfully advanced our lead RSV, NASH and HBV compounds in clinical trials,” commented Jay R. Luly, Ph.D., Enanta President and CEO. “EDP-938, the only RSV N-protein inhibitor in clinical development today, has shown highly statistically significant reductions in RSV viral load and total symptom score endpoints in a human challenge study, and we have initiated RSVP, our first Phase 2b study, which is in adult outpatients with community-acquired RSV. Following RSVP, we are planning additional studies in other patients such as the elderly, immune-compromised patients and pediatric populations. In NASH, we plan to further evaluate EDP-305 in a Phase 2b study, known as ARGON-2, in biopsy-proven NASH patients. This study will include an interim readout to enhance our ability to seek opportunities more quickly for development of EDP-305 in combinations with other mechanisms in NASH. Additionally, in NASH, Enanta has selected EDP-297 as its follow-on FXR development candidate. Preclinical data on EDP-297 reveal a differentiated profile that delivers high target-tissue distribution along with potency greater than that published on any FXR agonist in clinical development today. Finally, our Phase 1a study of EDP-514, our lead core inhibitor candidate for treatment of chronic HBV , is on track to have topline data from healthy volunteers in the first quarter of calendar 2020, after which we plan to proceed to study EDP-514 in ‘nuc-suppressed’ HBV patients and viremic HBV patients in the first and second quarters, respectively.”

Fiscal Fourth Quarter and Year Ended September 30, 2019 Financial Results

Total revenue of $51.3 million for the three months ended September 30, 2019 consisted of royalty revenue derived primarily from worldwide net sales of AbbVie's hepatitis C virus (HCV) regimen MAVYRET®/MAVIRET™. Total revenue for the three months ended September 30, 2018, was $67.2 million. For the twelve months ended September 30, 2019, total revenue was $205.2 million compared to $206.6 million in the same period in 2018.

The decrease in royalty revenue quarter over quarter was driven by lower HCV product sales as reported by AbbVie. Year over year, revenues decreased slightly due to the fact that the 2018 revenue included receipt of the final $15.0 million milestone payment for reimbursement approval of MAVIRET™ in Japan. The absence of any milestone payment in 2019 was substantially offset by increased royalty revenue due to the higher proportion of HCV product sales in 2019 being derived from MAVYRET®/MAVIRET™, for which Enanta earns a higher royalty allocation.

Research and development expenses increased to $38.7 million for the three months ended September 30, 2019, compared to $26.9 million for the three months ended September 30, 2018. For the twelve months ended September 30, 2019, research and development costs were $142.2 million compared to $94.9 million in 2018. The increase was primarily due to increased clinical costs associated with the progression of Enanta's wholly owned clinical programs in respiratory syncytial virus (RSV), non-alcoholic steatohepatitis (NASH), primary biliary cholangitis (PBC), and hepatitis B virus (HBV).

General and administrative expenses totaled $6.2 million for the three months ended September 30, 2019, compared to $5.8 million for the three months ended September 30, 2018. For the twelve months ended September 30, 2019, general and administrative costs were $26.2 million compared to $23.4 million in 2018. The increase in general and administrative expenses was primarily due to increases in compensation expense driven by increased headcount.

Enanta recorded an income tax benefit of $0.5 million for the three months ended September 30, 2019 compared to income tax expense of $8.5 million for the same period in 2018. For the twelve months ended September 30, 2019, Enanta recorded an income tax benefit $0.8 million at a tax rate benefit of approximately 2%, compared to income tax expense of $21.2 million at an effective tax rate of approximately 23%, for the twelve months ended September 30, 2018. The income tax benefit in 2019 was driven by lower income before taxes, a federal tax benefit from foreign derived royalty income, higher research and development tax credits due to higher research and development expenses, and tax deductions from employee stock-award related activity during the year. Income tax expense in 2018 was driven by higher income before taxes as well as a non-cash revaluation charge against deferred tax assets due to the reduced federal corporate income tax rate in the U.S. Tax Cuts and Jobs Act enacted in December 2017.

Net income for the three months ended September 30, 2019 was $9.2 million, or $0.44 per diluted common share, compared to net income of $27.4 million, or $1.30 per diluted common share, for the corresponding period in 2018. For the twelve months ended September 30, 2019, net income was $46.4 million, or $2.21 per diluted common share, compared to net income of $72.0 million, or $3.48 per diluted common share for the twelve months ended September 30, 2018.

Enanta's cash, cash equivalents and marketable securities totaled approximately $400 million at September 30, 2019. This compares to a total of approximately $325 million at September 30, 2018. 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 2020

- Research and Development Expense: $155 million to $175 million
- General and Administrative Expense: $27 million to $33 million

Development Programs and Business Review

EDP-938, N-Protein Inhibitor for Respiratory Syncytial Virus (RSV):

- Enanta has initiated a Phase 2b study of EDP-938. This study, named RSVP, will be in adult outpatients with community-acquired RSV infection. Future Phase 2b studies are planned to focus on pediatric populations, as well as immune-compromised and other adult populations where RSV morbidity is significant.
- Data from Enanta's Phase 2a human challenge study of EDP-938 in healthy adults infected with respiratory syncytial virus (RSV) was presented in October at IDWeek™ 2019 in Washington, DC. EDP-938 demonstrated highly statistically significant reductions ($p<0.001$) in RSV viral load as measured by RT-PCR assay and by plaque assay, as well as in total symptom score and mucus weight.

EDP-305, FXR Agonist for Non-Alcoholic Steatohepatitis (NASH):

- In September, Enanta announced topline data from the Phase 2a ARGON-1 study in NASH subjects. The primary endpoint, ALT reduction at week 12, and a key secondary endpoint, reduction in liver fat content as measured by MRI-PDFF at week 12, was met in the 2.5mg dosing group.
- Enanta expects to initiate a Phase 2b study, named ARGON-2, in the second quarter of calendar 2020. This study will be a randomized, double-blind, placebo-controlled 72-week study in approximately 340 subjects with biopsy-proven NASH. This study will include an early interim readout.
- The INTREPID study for primary biliary cholangitis (PBC) is continuing and topline data are expected in the second quarter of calendar 2020.

EDP-297, Follow-on FXR Agonist for NASH:

- Enanta has identified EDP-297 as its follow-on FXR candidate, for which it expects to initiate Phase 1 development in mid-calendar 2020.
- Preclinical data on EDP-297 reveal a differentiated profile that delivers high target-tissue distribution along with potency greater than that published on any FXR agonist in clinical development today. In preclinical models, EDP-297 delivered the drug preferentially to tissues with FXR receptors, namely liver and intestine, while minimizing drug levels in plasma and skin.

EDP-514, Core Inhibitor for Hepatitis B Virus (HBV):

- Part 1 of a Phase 1a/1b clinical study of EDP-514 is ongoing. Part 1 of this randomized, double-blind, placebo-controlled study is designed to evaluate the safety, tolerability and pharmacokinetics (PK) of single ascending doses (SAD) and multiple ascending doses (MAD) of EDP-514 in healthy subjects. Data from part 1 of this study is expected in the first quarter of calendar 2020.
- Part 2 of the study is expected to be initiated in the first quarter of calendar 2020 and will evaluate the antiviral activity of EDP-514 in nucleoside-analog-reverse-transcriptase (NUC)-suppressed patients with chronic HBV infection.
- A separate Phase 1b study in viremic HBV patients is expected to begin in the second quarter of calendar 2020.

Upcoming Events and Presentations

- 38th Annual JP Morgan Healthcare Conference, January 12-16, 2020.
- Enanta plans to issue its fiscal first quarter 2020 financial results press release, and hold a conference call regarding those results, on February 6, 2020.

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 21, 2019, through 11:59 p.m. ET on November 23, 2019 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 1983986. A live audio webcast of the call and replay can be accessed by visiting the “Events and Presentation” 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)/ primary biliary cholangitis (PBC), and hepatitis B virus (HBV).

Enanta’s research and development activities are funded by royalties from HCV products developed under its collaboration with AbbVie. Glecaprevir, a protease inhibitor discovered by Enanta, is now sold by AbbVie in numerous countries as part of its leading treatment for chronic hepatitis C virus (HCV) infection sold 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/PBC and HBV, as well as Enanta’s projections of its expenses in fiscal 2020, its potential results of operations, 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, PBC and HBV; 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, PBC, and HBV; the competitive impact of development, regulatory and marketing efforts of others in those disease areas; 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, 2019, 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.

Investor Contact:
Carol Miceli
617-607-0710
cmiceli@enanta.com

Media Contact:
Kari Watson
MacDougall Biomedical Communications
781-235-3060
kwatson@macbiocom.com

###

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,	
	2019	**2018**	**2019**	**2018**
Revenue	$ 51,313	$ 67,205	$ 205,197	$ 206,625
Operating expenses				
Research and development	38,719	26,923	142,213	94,856
General and administrative	6,163	5,830	26,246	23,441
Total operating expenses	44,882	32,753	168,459	118,297
Income from operations	6,431	34,452	36,738	88,328
Other income, net	2,274	1,429	8,819	4,793
Income before income taxes	8,705	35,881	45,557	93,121
Income tax benefit (expense)	486	(8,461)	826	(21,165)
Net income	$ 9,191	$ 27,420	$ 46,383	$ 71,956
Net income per share				
Basic	$ 0.47	$ 1.41	$ 2.37	$ 3.74
Diluted	$ 0.44	$ 1.30	$ 2.21	$ 3.48
Weighted average common shares outstanding				
Basic	19,686	19,380	19,584	19,255
Diluted	20,876	21,066	20,968	20,650

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

	September 30, 2019	September 30, 2018
Assets		
Current assets		
Cash and cash equivalents	$ 51,230	$ 63,902
Short-term marketable securities	284,006	244,828
Accounts receivable	51,313	67,205
Prepaid expenses and other current assets	15,299	4,454
Total current assets	401,848	380,389
Long-term marketable securities	65,013	16,389
Property and equipment, net	10,927	8,374
Deferred tax assets	11,341	8,375
Restricted cash	608	608
Other long-term assets	92	92
Total assets	$ 489,829	$ 414,227
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 6,689	$ 4,745
Accrued expenses and other current liabilities	15,920	9,892
Income taxes payable	-	1,388
Total current liabilities	22,609	16,025
Series 1 nonconvertible preferred stock	1,628	1,628
Other long-term liabilities	3,100	2,895
Total liabilities	27,337	20,548
Total stockholders' equity	462,492	393,679
Total liabilities and stockholders' equity	$ 489,829	$ 414,227