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 26, 2018

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)

(617) 607-0800
(Registrant's telephone number, including area code)

(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 Instructions 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))

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 26, 2018, Enanta Pharmaceuticals, Inc. announced via press release its results for the fiscal fourth quarter and year ended September 30, 2018. A copy of Enanta's press release is hereby furnished to the Commission and incorporated herein by reference as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of Enanta Pharmaceuticals, Inc., dated November 26, 2018, reporting Enanta's financial results for the fiscal fourth quarter and year ended September 30, 2018.

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.

Date: November 26, 2018

ENANTA PHARMACEUTICALS, INC.

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, 2018

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

- *Royalty revenue for the quarter increased to $67.2 million*
- *Net income was $27.4 million, or $1.30 per diluted common share*
- *Cash and marketable securities totaled $325.1 million*
- *Phase 2a study initiated with EDP-938 against respiratory syncytial virus (RSV) infection in a human challenge study*
- *Hepatitis B virus (HBV) candidate EDP-514 selected for clinical development in 2019*

WATERTOWN, Mass., November 26, 2018 – Enanta Pharmaceuticals, Inc. (NASDAQ:ENTA), a research and development-focused 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, 2018.

“Enanta has never been in a stronger position from both a financial and clinical development perspective,” said Jay R. Luly, Ph.D. President and CEO, Enanta Pharmaceuticals. “With the recent start of our Phase 2a study in RSV, we now have three Phase 2 studies ongoing in our wholly-owned development programs. Our momentum will continue into 2019, when we plan to initiate clinical testing of EDP-514, our first candidate to treat hepatitis B virus, and we expect Phase 2 data readouts in our other programs, starting with NASH and RSV studies.”

Fiscal Fourth Quarter and Year Ended September 30, 2018 Financial Results

Total revenue for the three months ended September 30, 2018 consisted of $67.2 million of royalty revenue, compared to total revenue of $75.9 million for the three months ended September 30, 2017, which consisted of $10.9 million of royalty revenue and $65.0 million in milestone payment revenue for the approvals of MAVYRET™/MAVIRET™ (glecaprevir/pibrentasvir) in the U.S. and the EU. For the twelve months ended September 30, 2018, total revenue was $206.6 million, compared to $102.8 million for the same period in 2017.

The increase in royalty revenue for the recent quarter was due to an increase in royalties earned on AbbVie’s worldwide net sales of MAVYRET™/MAVIRET™. For the twelve months ended September 30, 2018, revenue consisted of $191.6 million in royalties earned on AbbVie’s worldwide net sales of HCV

regimens containing glecaprevir or paritaprevir, as well as the final $15.0 million milestone payment for glecaprevir, which we earned upon the November 2017 reimbursement approval of MAVIRET™ in Japan. For the 2017 twelve-month period, revenue consisted of the $65.0 million in milestone payments, as well as $37.8 million in royalties earned on AbbVie's worldwide net sales of HCV regimens containing paritaprevir or glecaprevir.

Research and development expenses totaled $26.9 million for the three months ended September 30, 2018, compared to $16.5 million for the three months ended September 30, 2017. For the twelve months ended September 30, 2018, research and development expenses totaled $94.9 million compared to $57.5 million for the same period in 2017. The increase in research and development expenses in both periods was primarily due to increased preclinical and clinical costs associated with the progression of Enanta's wholly-owned R&D programs in non-alcoholic steatohepatitis (NASH), primary biliary cholangitis (PBC), and respiratory syncytial virus (RSV), as well as research efforts in hepatitis B virus (HBV).

General and administrative expenses totaled $5.8 million for the three months ended September 30, 2018, compared to $5.1 million for the three months ended September 30, 2017. For the twelve months ended September 30, 2018, general and administrative expenses totaled $23.4 million, compared to $20.7 million for the same period in 2017. The increase in general and administrative expenses in both periods was primarily due to increases in compensation expense driven by increased headcount to support Enanta's wholly-owned R&D programs.

Enanta recorded income tax expense of $8.5 million for the three months ended September 30, 2018 compared to an income tax expense of $18.4 million for the same period in 2017. Enanta recorded income tax expense of $21.2 million for the year ended September 30, 2018 compared to income tax expense of $9.2 million for the same period in 2017. The Company's effective tax rate for fiscal 2018 was approximately 23% compared to approximately 34% in fiscal 2017. Enanta's effective tax rate for fiscal 2018 reflects the impact of 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, 2018 was $27.4 million, or $1.30 per diluted common share, compared to a net income of $36.5 million, or $1.86 per diluted common share, for the corresponding period in 2017. For the twelve months ended September 30, 2018, net income was $72.0 million, or $3.48 per diluted common share, compared to net income of $17.7 million, or $0.91 per diluted common share, for the corresponding period in 2017.

Enanta's cash, cash equivalents and short-term and long-term marketable securities totaled $325.1 million at September 30, 2018. This compares to a total of $293.7 million at September 30, 2017. 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 2019

- Research and Development Expense: $135 to $155 million
- General and Administrative Expense: $27 to $33 million

Development Programs and Business Review

Respiratory Syncytial Virus (RSV)

- Phase 1 results for EDP-938, Enanta's non-fusion N-inhibitor candidate, were presented at the 11th International Respiratory Syncytial Virus Symposium in Asheville, North Carolina on November 1. Additional preclinical results of EDP-938 were also presented in an oral presentation demonstrating that EDP-938 has a high barrier to resistance *in vitro.*
- Dosing began in October in a Phase 2a study to evaluate the safety, pharmacokinetics and antiviral activity of multiple doses of orally administered EDP-938 against respiratory syncytial virus infection in a human challenge study. Initial data is expected in the third quarter of calendar 2019.

Hepatitis B Virus (HBV)

- Enanta's HBV program continues to move ahead as Enanta announces that it has selected EDP-514, a promising inhibitor of the HBV core protein, as its first development candidate in this program. A Phase 1 study of EDP-514, consisting of evaluation of single and multiple doses of drug in healthy volunteers and incorporating a Phase 1b arm in chronic HBV patients, is planned to begin in 2019.

Non-Alcoholic Steatohepatitis (NASH) and Primary Biliary Cholangitis (PBC)

- Two preclinical posters titled *"The Farnesoid X Receptor (FXR) Agonist EDP-305 Reduces Ascites and Hepatocellular Carcinoma Development in a Rat Model of Cirrhosis"* and *"The Farnesoid X Receptor (FXR) Agonist EDP-305 Inhibits Fibrosis Progression in a Rat Model of Non-alcoholic Steatohepatitis Cirrhosis"* were presented at The Liver Meeting® 2018 in November.
- Enrollment continues in the ARGON-1 study for non-alcoholic steatohepatitis (NASH), and in the INTREPID study for primary biliary cholangitis (PBC) patients. Enrollment will continue through the remainder of 2018 and into 2019. Initial data is expected starting in mid-2019.

Hepatitis C Virus (HCV)

- Enanta's HCV collaboration partner, AbbVie, presented data for its pan-genotypic chronic HCV treatment, MAVYRET™(glecaprevir/pibrentasvir), in treatment-naïve patients with compensated cirrhosis, as a late-breaking oral presentation at The Liver Meeting® 2018 on November 13, 2018. Results from the Phase 3 EXPEDITION-8 study showed that with 8 weeks of MAVYRET, 100 percent (n=273/273) of genotypes 1, 2, 4, 5 and 6 patients achieved a sustained virologic response 12 weeks after treatment (SVR_{12}).

Upcoming Events and Presentations

- 37th Annual J.P. Morgan Healthcare Conference, January 7-10, 2019
- Enanta plans to issue its fiscal first quarter financial results press release, and hold a conference call regarding those results, on February 6, 2019.

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 26, 2018, through 11:59 p.m. ET on November 28, 2018 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 9952167. 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 Pharmaceuticals 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. Glecaprevir, a protease inhibitor discovered by Enanta, has been developed by AbbVie, and is now approved and sold in numerous countries as part of AbbVie's newest treatment for chronic hepatitis C virus (HCV) infection. This leading HCV regimen is sold under the tradenames MAVYRET™ (U.S.) and MAVIRET™ (ex-U.S.) (glecaprevir/pibrentasvir).

Royalties from the AbbVie collaboration are helping to fund Enanta's research and development efforts, which are currently focused on the following disease targets: respiratory syncytial virus (RSV), non-alcoholic steatohepatitis (NASH), primary biliary cholangitis (PBC), and hepatitis B virus (HBV). 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 NASH/PBC and RSV and its preclinical program in HBV, as well as Enanta's projections of its expenses in fiscal 2019 and the prospects for AbbVie's MAVYRET™/MAVIRET™ regimen for HCV and future royalty revenue to Enanta from sales of that regimen. 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: Enanta's revenues in the short-term are dependent upon the success of AbbVie's continuing commercialization efforts for its HCV treatment regimen MAVYRET™/MAVIRET™; competitive pricing, market acceptance and reimbursement rates for MAVYRET™/MAVIRET™ compared to competitive HCV products on the market; the discovery and development risks of early stage discovery and clinical efforts in other disease

areas such as NASH, PBC, RSV and HBV; potential competition from the development efforts of others in those other 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, 2018 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,		Year Ended September 30,	
	2018	2017	2018	2017
Revenue	$ 67,205	$ 75,927	$ 206,625	$ 102,814
Operating expenses				
Research and development	26,923	16,514	94,856	57,451
General and administrative	5,830	5,118	23,441	20,749
Total operating expenses	32,753	21,632	118,297	78,200
Income from operations	34,452	54,295	88,328	24,614
Other income, net	1,429	660	4,793	2,333
Income before income taxes	35,881	54,955	93,121	26,947
Income tax expense	(8,461)	(18,447)	(21,165)	(9,237)
Net income	$ 27,420	$ 36,508	$ 71,956	$ 17,710
Net income per share				
Basic	$ 1.41	$ 1.91	$ 3.74	$ 0.93
Diluted	$ 1.30	$ 1.86	$ 3.48	$ 0.91
Weighted average common shares outstanding				
Basic	19,380	19,097	19,255	19,066
Diluted	21,066	19,611	20,650	19,407

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

	September 30, 2018	September 30, 2017
Assets		
Current assets		
Cash and cash equivalents	$ 63,902	$ 65,675
Short-term marketable securities	244,828	157,994
Accounts receivable	67,205	10,614
Prepaid expenses and other current assets	4,454	3,536
Total current assets	380,389	237,819
Long-term marketable securities	16,389	70,038
Property and equipment, net	8,374	8,049
Deferred tax assets	8,375	10,123
Restricted cash	608	608
Other long-term assets	92	—
Total assets	$ 414,227	$ 326,637
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 4,745	$ 3,714
Accrued expenses and other current liabilities	9,892	7,970
Income taxes payable	1,388	9,298
Total current liabilities	16,025	20,982
Warrant liability	—	807
Series 1 nonconvertible preferred stock	1,628	762
Other long-term liabilities	2,895	2,410
Total liabilities	20,548	24,961
Total stockholders' equity	393,679	301,676
Total liabilities and stockholders' equity	$ 414,227	$ 326,637