
**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): February 6, 2019

ENANTA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-35839
(Commission
File Number)

04-3205099
(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 February 6, 2019, Enanta Pharmaceuticals, Inc. announced via press release its results for the fiscal quarter ended December 31, 2018. 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	<u>Press Release of Enanta Pharmaceuticals, Inc., dated February 6, 2019, reporting Enanta's financial results for the fiscal quarter ended December 31, 2018.</u>

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: February 6, 2019

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 First Quarter and Three Months Ended December 31, 2018****Webcast and Conference Call today at 4:30 p.m. ET**

- *Royalty revenue for the quarter increased to \$69.9 million*
- *Research and development programs progressing well with clinical milestones expected in 2019 in our RSV, NASH, and HBV programs*
- *Cash and marketable securities totaled \$357.3 million at December 31, 2018*

WATERTOWN, Mass., February 6, 2019 – 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 first quarter ended December 31, 2018.

“Enanta’s research and development programs are progressing well and we have many clinical goals that we expect to achieve this year,” said Jay R. Luly, Ph.D. President and CEO, Enanta Pharmaceuticals. “By mid-year, we expect to announce top-line data from our Phase 2a human challenge study of EDP-938 for RSV, followed by Phase 2a data from our NASH study. We also expect to initiate a Phase 1 study with our new HBV core inhibitor candidate EDP-514 in the second half of 2019.”

Fiscal First Quarter Ended December 31, 2018 Financial Results

Total revenue for the three months ended December 31, 2018 was \$69.9 million and consisted entirely of royalty revenue from worldwide net sales of AbbVie’s hepatitis C virus (HCV) regimens MAVYRET™/MAVIRET™, as well as its HCV regimens containing paritaprevir. For the three months ended December 31, 2017, total revenue was \$38.1 million which consisted of a \$15.0 million milestone payment for the reimbursement approval of MAVIRET™ in Japan and royalty revenue primarily earned on AbbVie’s global net sales from the launch of MAVYRET™/MAVIRET™ in major markets in the second half of 2017.

Research and development expenses totaled \$34.9 million for the three months ended December 31, 2018, compared to \$18.0 million for the three months ended December 31, 2017. The increase in research and development expenses was primarily due to increased preclinical and clinical costs associated with the progression of Enanta’s wholly-owned R&D programs in respiratory syncytial virus (RSV), non-alcoholic steatohepatitis (NASH) and primary biliary cholangitis (PBC), as well as research efforts in hepatitis B virus (HBV).

General and administrative expenses totaled \$7.2 million for the three months ended December 31, 2018, compared to \$5.8 million for the three months ended December 31, 2017. The increase in general and administrative expenses was primarily due to increases in compensation expense driven by increased headcount.

Enanta recorded income tax expense of \$3.7 million for the three months ended December 31, 2018 compared to an income tax expense of \$3.6 million for the same period in 2017. Enanta's effective tax rate for the December 31, 2018 quarter was approximately 13%.

Net income for the three months ended December 31, 2018 was \$26.0 million, or \$1.25 per diluted common share, compared to net income of \$11.7 million, or \$0.59 per diluted common share, for the corresponding period in 2017.

Enanta's cash, cash equivalents and short-term and long-term marketable securities totaled \$357.3 million at December 31, 2018. This compares to a total of \$325.1 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.

Development Programs and Business Review

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

- Dosing is ongoing in a Phase 2a human challenge study to evaluate the safety, pharmacokinetics and antiviral activity of multiple doses of EDP-938 orally administered to healthy subjects infected with a strain of respiratory syncytial virus. The trial is advancing well, and topline data is now expected mid-2019.

EDP-514, Core Inhibitor for Hepatitis B Virus:

- In January, Enanta announced positive preclinical data on EDP-514, a promising inhibitor of the HBV core protein. Data demonstrated potent inhibition of HBV replication *in vitro* accompanied by a greater than 4-log viral load reduction in a humanized liver mouse model after 12 weeks of dosing.
- A Phase 1 study of EDP-514, is planned to begin in the second half of 2019. The study will evaluate single and multiple doses of drug in healthy volunteers and will incorporate a Phase 1b arm in patients with chronic HBV infection.

EDP-305, FXR agonist for NASH:

- Enrollment in the 12-week Phase 2a NASH trial is expected to conclude in the first quarter of 2019, allowing Enanta to report preliminary top line data in the third quarter of calendar 2019.
- Enanta also expects to identify a follow-on FXR clinical candidate in calendar 2019.

Upcoming Events and Presentations

- 31st Annual Roth Conference, March 17-19, 2019, Dana Point, CA
- Oppenheimer's 29th Annual Healthcare Conference, March 19-20, 2019, New York
- Preclinical data presentations from our NASH and HBV programs at The International Liver Congress, Vienna, Austria, April 10-14, 2019

- Enanta plans to issue its fiscal second quarter financial results press release, and hold a conference call regarding those results, on May 7, 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 February 6, 2019, through 11:59 p.m. ET on February 8, 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 1190228. 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. Enanta’s research and development efforts 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).

Enanta’s research and development activities are currently 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 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). 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 and NASH/PBC and its preclinical program in HBV, as well as the prospects for future royalty revenue to Enanta 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: Enanta’s revenues in the short-term are dependent upon the continued success of AbbVie’s commercialization 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; competitive pricing, market acceptance 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-K for the fiscal year ended

September 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.

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

**Three Months Ended
December 31,**

	2018	2017
Revenue	\$ 69,886	\$ 38,109
Operating expenses		
Research and development	34,878	17,962
General and administrative	7,152	5,770
Total operating expenses	<u>42,030</u>	<u>23,732</u>
Income from operations	27,856	14,377
Other income, net	1,885	960
Income before income taxes	29,741	15,337
Income tax expense	<u>(3,730)</u>	<u>(3,644)</u>
Net income	<u>\$ 26,011</u>	<u>\$ 11,693</u>
Net income per share		
Basic	\$ 1.34	\$ 0.61
Diluted	\$ 1.25	\$ 0.59
Weighted average common shares outstanding		
Basic	19,426	19,130
Diluted	20,810	19,918

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

	<u>December 31,</u> <u>2018</u>	<u>September 30,</u> <u>2018</u>
Assets		
Current assets		
Cash and cash equivalents	\$ 74,365	\$ 63,902
Short-term marketable securities	271,423	244,828
Accounts receivable	69,886	67,205
Prepaid expenses and other current assets	7,636	4,454
Total current assets	423,310	380,389
Long-term marketable securities	11,465	16,389
Property and equipment, net	9,493	8,374
Deferred tax assets	9,248	8,375
Restricted cash	608	608
Other long-term assets	92	92
Total assets	\$ 454,216	\$ 414,227
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 5,622	\$ 4,745
Accrued expenses and other current liabilities	11,152	9,892
Income taxes payable	5,858	1,388
Total current liabilities	22,632	16,025
Series 1 nonconvertible preferred stock	1,628	1,628
Other long-term liabilities	3,121	2,895
Total liabilities	27,381	20,548
Total stockholders' equity	426,835	393,679
Total liabilities and stockholders' equity	\$ 454,216	\$ 414,227