
**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): August 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))

Title of Each Class	Trading Symbol	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 August 6, 2019, Enanta Pharmaceuticals, Inc. announced via press release its results for the fiscal quarter ended June 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**

<u>Exhibit No.</u>	<u>Description</u>
99.1	<u>Press Release of Enanta Pharmaceuticals, Inc., dated August 6, 2019, reporting Enanta's financial results for the fiscal quarter ended June 30, 2019.</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: August 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 Third Quarter Ended June 30, 2019****Webcast and Conference Call today at 4:30 p.m. ET**

- *Royalty revenue for the quarter was \$44.4 million*
- *Phase 2a NASH data expected by the end of the third calendar quarter*
- *Cash and marketable securities totaled \$389.2 million at June 30, 2019*

WATERTOWN, Mass., August 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 third quarter ended June 30, 2019.

“Enanta executed on key clinical milestones during the past few months, the most significant being the completion of a successful Phase 2a challenge study of EDP-938 for RSV. In addition, we recently initiated a Phase 1 study of EDP-514, our lead candidate for the treatment of HBV,” commented Jay R. Luly, Ph.D., Enanta President and CEO. “Our pipeline is maturing, and we now have clinical studies ongoing with three compounds, all of which have been granted Fast Track designation.”

Fiscal Third Quarter Ended June 30, 2019 Financial Results

Total revenue of \$44.4 million for the three months ended June 30, 2019 consisted of royalty revenue derived primarily from worldwide net sales of AbbVie’s hepatitis C virus (HCV) regimen MAVYRET™/MAVIRET™. For the three months ended June 30, 2018, total revenue was \$57.3 million, which consisted of royalty revenue earned on AbbVie’s global net sales of its HCV regimens. AbbVie has stated that the decrease in royalty revenue in 2019 was mainly driven by lower treated patient volumes in select international markets.

Research and development expenses increased to \$34.5 million for the three months ended June 30, 2019, compared to \$28.5 million for the three months ended June 30, 2018, 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 June 30, 2019, compared to \$6.1 million for the three months ended June 30, 2018.

Enanta recorded an income tax benefit of \$0.9 million for the three months ended June 30, 2019 compared to income tax expense of \$3.7 million for the same period in 2018. The income tax benefit was driven by a federal tax benefit associated with foreign derived royalty income from our AbbVie collaboration agreement.

Net income for the three months ended June 30, 2019 was \$7.0 million, or \$0.33 per diluted common share, compared to net income of \$20.3 million, or \$0.97 per diluted common share, for the corresponding period in 2018.

Enanta's cash, cash equivalents and marketable securities totaled \$389.2 million at June 30, 2019. 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 (RSV):

- In June, Enanta announced topline results from its Phase 2a human challenge study of EDP-938 in healthy adults infected with respiratory syncytial virus (RSV). Data demonstrated EDP-938 achieved highly statistically significant ($p < 0.001$) reductions in viral load and in resolution of clinical symptoms compared to placebo.
- Enanta's first Phase 2b study in adult outpatients with RSV infection is planned to begin by the end of calendar 2019.

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

- Topline data from the Phase 2a ARGON-1 study in NASH are expected by the end of the third quarter of calendar 2019.
- Enanta also expects to identify a follow-on FXR clinical candidate in calendar 2019.

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

- In July, Enanta announced that it had initiated part 1 of a Phase 1a/1b clinical study of EDP-514. Part 1 of the 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. Part 2 will then evaluate the antiviral activity of EDP-514 in nucleos(t)ide-reverse-transcriptase (NUC)-suppressed patients with chronic HBV infection.

Hepatitis C Virus (HCV) collaboration with AbbVie:

- AbbVie announced that the European Commission has granted marketing authorization to AbbVie for MAVIRET™ (glecaprevir/pibrentasvir) to shorten once-daily treatment duration from 12 to 8 weeks in treatment-naïve, chronic hepatitis C (HCV) patients with compensated cirrhosis and genotype (GT)1, 2, 4, 5, or 6 infection.

- Glecaprevir, is one of the two direct-acting antivirals (DAAs) in MAVIRET and is Enanta's second protease inhibitor developed and commercialized by AbbVie.

Upcoming Events and Presentations

- September 4, 2019 – Baird 2019 Global Healthcare Conference, New York
- Enanta plans to issue its fiscal fourth quarter financial results press release, and hold a conference call regarding those results, on November 21, 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 August 6, 2019, through 11:59 p.m. ET on August 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 6794018. 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 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 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, NASH/PBC and 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: 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 March 31, 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.

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

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2019	2018	2019	2018
Revenue	\$ 44,367	\$ 57,262	\$ 153,884	\$ 139,420
Operating expenses				
Research and development	34,461	28,487	103,494	67,933
General and administrative	6,151	6,135	20,083	17,611
Total operating expenses	40,612	34,622	123,577	85,544
Income from operations	3,755	22,640	30,307	53,876
Other income, net	2,415	1,338	6,545	3,364
Income before income taxes	6,170	23,978	36,852	57,240
Income tax (expense) benefit	866	(3,690)	340	(12,704)
Net income	<u>\$ 7,036</u>	<u>\$ 20,288</u>	<u>\$ 37,192</u>	<u>\$ 44,536</u>
Net income per share				
Basic	\$ 0.36	\$ 1.05	\$ 1.90	\$ 2.32
Diluted	\$ 0.33	\$ 0.97	\$ 1.77	\$ 2.17
Weighted average common shares outstanding				
Basic	19,673	19,303	19,549	19,212
Diluted	21,105	21,017	20,999	20,509

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

	June 30, 2019	September 30, 2018
Assets		
Current assets		
Cash and cash equivalents	\$ 94,206	\$ 63,902
Short-term marketable securities	295,042	244,828
Accounts receivable	44,367	67,205
Prepaid expenses and other current assets	17,647	4,454
Total current assets	451,262	380,389
Long-term marketable securities	—	16,389
Property and equipment, net	11,373	8,374
Deferred tax assets	10,149	8,375
Restricted cash	608	608
Other long-term assets	92	92
Total assets	<u>\$ 473,484</u>	<u>\$ 414,227</u>
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 6,504	\$ 4,745
Accrued expenses and other current liabilities	13,997	9,892
Income taxes payable	—	1,388
Total current liabilities	20,501	16,025
Series 1 nonconvertible preferred stock	1,628	1,628
Other long-term liabilities	3,258	2,895
Total liabilities	25,387	20,548
Total stockholders' equity	448,097	393,679
Total liabilities and stockholders' equity	<u>\$ 473,484</u>	<u>\$ 414,227</u>