# **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 7, 2017

# 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)
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ck 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 rovisions (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))
cate 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 the Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

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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 7, 2017, Enanta Pharmaceuticals, Inc. announced via press release its results for the fiscal quarter ended June 30, 2017. 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	Press Release of Enanta Pharmaceuticals, Inc., dated August 7, 2017, reporting Enanta's financial results for the fiscal quarter ended June 30, 2017.

## **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 7, 2017 ENANTA PHARMACEUTICALS, INC.

By:/s/ Paul J. Mellett

Paul J. Mellett Senior Vice President, Finance and Administration and Chief Financial Officer

# EXHIBIT INDEX

# **Exhibit No. Description**

Press Release of Enanta Pharmaceuticals, Inc., dated August 7, 2017, reporting Enanta's financial results for the fiscal quarter ended June 30, 2017.



#### For Immediate Release

# Enanta Pharmaceuticals Reports Financial Results for its Fiscal Third Quarter Ended June 30, 2017

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

- Cash and marketable securities totaled \$235.3 million at June 30, 2017
- Royalty revenue for the quarter was \$7.5 million
- Milestone payments totaling \$65 million earned following AbbVie's EU approval of MAVIRET™ (glecaprevir/pibrentasvir) in July, and U.S. approval of MAVYRET™ (glecaprevir/pibrentasvir) in August
- RSV and NASH/PBC clinical programs continue to advance toward new stages next quarter

WATERTOWN, Mass., August 7, 2017 – 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, 2017.

Enanta's cash, cash equivalents and short-term and long-term marketable securities totaled \$235.3 million at June 30, 2017. This compares to a total of \$242.2 million in such accounts at September 30, 2016. Enanta expects that its current cash, cash equivalents and marketable securities will be sufficient to meet the anticipated cash requirements of its existing business and development programs for the foreseeable future.

#### Fiscal Third Quarter Ended June 30, 2017 Financial Results

Total revenue for the three months ended June 30, 2017 was \$7.5 million, compared to \$14.0 million for the three months ended June 30, 2016. For the nine months ended June 30, 2017, total revenue was \$26.9 million, compared to \$75.4 million for the same period in 2016. For the three and nine month periods ended June 30, 2017, revenue consisted exclusively of royalties earned on AbbVie's worldwide net sales of HCV regimens containing paritaprevir. For the 2016 nine month period, revenue consisted primarily of royalty revenues as well as a \$30.0 million milestone payment for the reimbursement approval of VIEKIRAX® in Japan in November 2015. Milestone payments and royalties have varied significantly from period to period, and we expect that variability to continue in the future.

Research and development expenses totaled \$15.4 million for the three months ended June 30, 2017, compared to \$10.8 million for the three months ended June 30, 2016. For the nine months ended June 30, 2017, research and development expenses totaled \$40.9 million compared to \$29.0 million for the same period in 2016. 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), respiratory syncytial virus (RSV) and hepatitis B virus (HBV).

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General and administrative expenses totaled \$5.2 million for the three months ended June 30, 2017, compared to \$4.3 million for the three months ended June 30, 2016. For the nine months ended June 30, 2017, general and administrative expenses totaled \$15.6 million, compared to \$12.5 million for the same period in 2016. For the three month period, the increase in general and administrative expenses was primarily due to increases in compensation expense driven substantially by increased headcount. For the nine month period, the increase was due to increased headcount as well as achievement of milestones under existing performance-based stock awards.

Enanta recorded an income tax benefit for the three months ended June 30, 2017 of \$4.1 million compared to an income tax expense of \$0.4 million for the same period in 2016. The Company's estimated annual effective tax rate for fiscal 2017 of approximately 33% was slightly below the statutory rate of 35% due to the availability of research and development tax credits.

The net loss for the three months ended June 30, 2017 was \$8.4 million, or \$(0.44) per diluted common share, compared to a net loss of \$1.1 million, or \$(0.06) per diluted common share, for the corresponding period in 2016. For the nine months ended June 30, 2017, net loss was \$18.8 million, or \$(0.99) per diluted common share, compared to net income of \$23.5 million, or \$1.22 per diluted common share, for the corresponding period in 2016.

"Enanta continues to make great progress from a research and development perspective," stated Jay R. Luly, Ph.D., President and Chief Executive Officer of Enanta. Our second commercialized protease inhibitor product, glecaprevir, is one of the two new DAAs in AbbVie's new pan-genotypic treatment regimen for HCV, which was recently approved in the EU and in the U.S. under the names MAVIRET<sup>TM</sup> and MAVYRET<sup>TM</sup>, respectively. Additionally, data from our Phase 1 clinical study for NASH will be available soon, and, with our strong cash resources of over \$235 million, we are well funded to continue to advance our clinical programs in NASH, PBC, RSV and HCV."

#### **Development Program and Business Review**

- On June 25 at the XIX International Symposium on Respiratory Viral Infections in Berlin, Germany, Enanta presented data on its respiratory syncytial virus inhibitor candidate EDP-938, which demonstrated a greater than 4-log reduction in viral load in an animal model challenged with RSV. Enanta expects to initiate a Phase 1 clinical study with EDP-938 during the fourth quarter of calendar 2017.
- On July 28, the European Commission granted AbbVie marketing authorization for MAVIRET (glecaprevir/pibrentasvir), and on August 3, the U.S. Food and Drug Administration (FDA) granted AbbVie marketing approval for MAVYRET (glecaprevir/pibrentasvir), sometimes referred to as the G/P regimen, AbbVie's new pan-genotypic treatment for patients with chronic hepatitis C virus (HCV) infection. Glecaprevir is Enanta's second protease inhibitor being developed and commercialized by AbbVie and is one of the two new direct-acting antivirals in G/P. Enanta earned a total of \$65 million in milestone payments following the EU and U.S. approvals. Enanta is eligible to earn the remaining \$15 million milestone payment upon G/P receiving commercial regulatory approval in Japan, which is anticipated next quarter. Additionally, Enanta is eligible to receive annually tiered, double digit, per product royalties on 50% of the net sales of G/P.
- Enanta expects to announce clinical data from its ongoing Phase 1 clinical study of EDP-305 in healthy volunteers and presumed NAFLD subjects¹ at the AASLD meeting in October and is conducting NASH-enabling studies during the second half of this year. A Phase 2 study in PBC is also expected to begin in the next quarter, and a Phase 2 study in NASH is expected to begin in early 2018.

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<sup>1</sup> Presumed NAFLD subjects in this study are obese subjects, with or without pre-diabetes or type-2 diabetes.

#### **Upcoming Events and Presentations**

- September 6, 2017 Baird 2017 Global Healthcare Conference, New York
- September 11-13, 2017 Morgan Stanley 15th Annual Global Healthcare Conference, New York
- September 25-27, 2017 Cantor Fitzgerald 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 20, 2017.

#### **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 7, 2017, through 11:59 p.m. ET on August 10, 2017 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 47670579. 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**

Enanta Pharmaceuticals is a research and development-focused biotechnology company that uses its robust chemistry-driven approach and drug discovery capabilities to create small molecule drugs for viral infections and liver diseases. Enanta's research and development efforts are currently focused on the following disease targets: non-alcoholic steatohepatitis (NASH)/ primary biliary cholangitis (PBC), respiratory syncytial virus (RSV) and hepatitis B virus (HBV). Enanta has also discovered novel protease inhibitors that have been developed as part of AbbVie's hepatitis C virus (HCV) treatment regimens under a collaboration that now provides Enanta a payment stream, which it is using to fund its research and development programs. Please visit www.enanta.com for more information on Enanta's programs and pipeline.

#### **Forward Looking Statements**

This press release contains forward-looking statements, including statements with respect to the prospects for AbbVie's G/P regimen in HCV and the prospects for advancement of Enanta's earlier stage programs in NASH/PBC and RSV. 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 regimens containing paritaprevir and its efforts to obtain additional regulatory approvals for G/P and commercialize that regimen; competitive pricing, market acceptance and reimbursement rates of AbbVie's treatment regimens containing paritaprevir or its G/P combination compared to competitive HCV products on the market and product candidates of other companies under development; the discovery and development risks of early stage discovery 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 scientific 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, 2016 and other periodic reports filed more recently wi

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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,				
	_	2017	2016		2017		2016	
Revenue	\$	7,511	\$	13,978	\$	26,887	\$	75,427
Operating expenses								
Research and development		15,407		10,785		40,937		28,961
General and administrative		5,233		4,282		15,631		12,526
Total operating expenses		20,640		15,067		56,568		41,487
Income (loss) from operations		(13,129)		(1,089)		(29,681)		33,940
Other income, net		600		447		1,673		1,248
Income (loss) before income taxes		(12,529)		(642)		(28,008)	·	35,188
Income tax (expense) benefit		4,103		(434)		9,210		(11,720)
Net income (loss)	\$	(8,426)	\$	(1,076)	\$	(18,798)	\$	23,468
Net income (loss) per share								
Basic	\$	(0.44)	\$	(0.06)	\$	(0.99)	\$	1.24
Diluted	\$	(0.44)	\$	(0.06)	\$	(0.99)	\$	1.22
Weighted average common shares outstanding								
Basic		19,081		18,983		19,055		18,893
Diluted		19,081		18,983		19,055		19,223

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# ENANTA PHARMACEUTICALS, INC. CONDENSED CONSOLIDATED BALANCE SHEETS UNAUDITED

(in	thousands)
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	June 30, 2017		September 30, 2016		
Assets					
Current assets					
Cash and cash equivalents	\$	22,263	\$	16,577	
Short-term marketable securities		169,752		193,507	
Accounts receivable		7,511		12,841	
Prepaid expenses and other current assets		6,589		9,231	
Total current assets	·	206,115	·	232,156	
Property and equipment, net		8,070		8,004	
Long-term marketable securities		43,321		32,119	
Deferred tax assets		17,723		8,390	
Restricted cash		608		608	
Total assets	\$	275,837	\$	281,277	
Liabilities and Stockholders' Equity					
Current liabilities					
Accounts payable	\$	5,488	\$	3,377	
Accrued expenses and other current liabilities		5,634		4,512	
Total current liabilities		11,122		7,889	
Warrant liability		1,291		1,251	
Series 1 nonconvertible preferred stock		164		159	
Other long-term liabilities		2,394		2,042	
Total liabilities		14,971		11,341	
Total stockholders' equity		260,866	_	269,936	
Total liabilities and stockholders' equity	\$	275,837	\$	281,277	

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#### **Investor Contact**

Carol Miceli 617-607-0710 cmiceli@enanta.com

#### **Media Contact**

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

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