## 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): May 8, 2018

### 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

follow	ing pro	ovisions (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))
	Indica	tte 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

Emerging growth company ⊠

chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

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.  $\boxtimes$ 

#### Item 2.02 Results of Operations and Financial Condition.

On May 8, 2018, Enanta Pharmaceuticals, Inc. announced via press release its results for the fiscal quarter ended March 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

Exhibit No.	<u>Description</u>
99.1	<u>Press Release of Enanta Pharmaceuticals, Inc., dated May 8, 2018, reporting Enanta's financial results for the fiscal quarter ended March 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: May 8, 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 Second Quarter Ended March 31, 2018

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

- Royalty revenue for the quarter increased to \$44.0 million due to increase in AbbVie's MAVYRET™ sales
- Net income for the quarter was \$12.6 million, or \$0.61 per diluted common share
- Fast Track designation granted to EDP-938 for Respiratory Syncytial Virus (RSV) Infection
- Cash and marketable securities totaled \$288.9 million at March 31, 2018

WATERTOWN, Mass., May 8, 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 second quarter ended March 31, 2018.

Enanta's results for the quarter benefited from \$44 million of royalty revenue on AbbVie's \$919 million in sales of its HCV regimens that contain either of the two protease inhibitor products developed through Enanta's collaboration with AbbVie. Enanta earns its annually tiered, per product royalties on a portion of AbbVie's net sales allocated to Enanta's protease inhibitor product in each HCV regimen. In the case of MAVYRET<sup>TM</sup> (U.S.)/ MAVIRET<sup>TM</sup> (ex-U.S.) (glecaprevir/pibrentasvir), Enanta's royalty is based on 50% of AbbVie's net sales of that combination.

"Our strong financial results this quarter were driven by royalty revenue earned on AbbVie's sales of MAVYRET, which reached \$850 million in sales in the quarter," commented Jay R. Luly. Ph.D., President and Chief Executive Officer, Enanta. "This royalty revenue supports our three clinical-stage programs in NASH, PBC and RSV, all of which have now been granted Fast Track designation by the U.S. FDA. We are looking forward to having preliminary data from our Phase 1 study of EDP-938 next quarter and initiating our planned Phase 2 RSV challenge study of EDP-938 in the last quarter of calendar 2018. We also plan to designate a candidate compound for HBV later this year."

Enanta's cash, cash equivalents and short-term and long-term marketable securities totaled \$288.9 million at March 31, 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, will be sufficient to meet the anticipated cash requirements of its existing business and development programs for the foreseeable future.

#### Fiscal Second Quarter Ended March 31, 2018 Financial Results

Total revenue for the three months ended March 31, 2018 was \$44.0 million, compared to \$9.0 million for the three months ended March 31, 2017. The increase in revenue was due to an increase in royalties earned on AbbVie's worldwide net sales of HCV regimens as a result of the launch of MAVYRET<sup>TM</sup>/MAVIRET<sup>TM</sup> in major markets in the second half of 2017. For the three months ended March 31, 2017, revenue consisted exclusively of royalties earned on AbbVie's worldwide net sales of HCV regimens containing paritaprevir. Royalties have varied significantly from period to period, and that variability may continue in the future.

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Research and development expenses totaled \$21.5 million for the three months ended March 31, 2018, compared to \$13.0 million for the three months ended March 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 non-alcoholic steatohepatitis (NASH), primary biliary cholangitis (PBC), respiratory syncytial virus (RSV) and hepatitis B virus (HBV).

General and administrative expenses totaled \$5.7 million for the three months ended March 31, 2018, which was consistent with the \$5.5 million of such expenses for the three months ended March 31, 2017.

Enanta recorded income tax expense of \$5.4 million for the three months ended March 31, 2018, compared to an income tax benefit of \$3.6 million for the three months ended March 31, 2017. During the three months ended March 31, 2018, income tax expense reflected the significant increase in pre-tax income during the quarter as well as an increase in Enanta's estimated annual effective tax rate for fiscal 2018. Enanta's estimated annual effective tax rate for fiscal 2018 of 27.1 percent includes the impact of a non-cash revaluation charge against deferred tax assets to reflect the reduced federal corporate income tax rate as a result of the enactment of the U.S. Tax Cuts and Jobs Act.

Net income for the three months ended March 31, 2018 was \$12.6 million, or \$0.61 per diluted common share, compared to a net loss of \$5.4 million, or \$(0.28) per diluted common share, for the corresponding period in 2017.

#### **Development Programs and Business Review**

#### **Respiratory Syncytial Virus**

- The U.S. Food and Drug administration has granted EDP-938 Fast Track designation for respiratory syncytial virus (RSV).
- A Phase 1 clinical study of EDP-938 is ongoing. In the third quarter of calendar 2018, topline Phase 1 data is expected to be announced and a Phase 2 proof-of-concept challenge study in RSV-infected humans is expected to begin in the following quarter.

#### **Hepatitis B Virus**

New data on EP-027367, one of several core inhibitors Enanta is evaluating for hepatitis B virus was presented at the International Liver Congress ™ (ILC) 2018 in April. The data demonstrated that in a chimeric SCID mouse model with human liver cells, EP-027367 reduced viral DNA and RNA levels by up to 3.0 logs from baseline with 4 weeks of treatment and demonstrated a favorable tolerability and pharmacokinetic profile. EP-027367 has also demonstrated potent, pan-genotypic, anti-HBV activity capable of preventing the establishment of cccDNA *in vitro*.

#### **NASH and PBC**

• Three posters on EDP-305, Enanta's FXR agonist currently in a Phase 2 study for NASH and a Phase 2 study for PBC, were presented at the ILC. Two posters focused on additional preclinical safety and efficacy data and a third presented data from Enanta's previously released Phase 1 study highlighting the pharmacokinetics, pharmacodynamics and safety of EDP-305 in healthy and presumptive NAFLD subjects.

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

- June 12, 2018 38th NASDAQ Investor Conference, London
- June 20-21, 2018 JMP Securities Life Sciences Conference, New York

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• Enanta plans to issue its fiscal third quarter financial results press release, and hold a conference call regarding those results, on August 7, 2018.

#### **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 May 8, 2018, through 11:59 p.m. ET on May 11, 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 3238478. 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 <a href="https://www.enanta.com">www.enanta.com</a>.

#### **About Enanta**

Enanta Pharmaceuticals has used its robust, chemistry-driven approach and drug discovery capabilities to become a leader in the discovery of small molecule drugs for the treatment of viral infections and liver diseases. Two protease inhibitors, glecaprevir and paritaprevir, discovered and developed through Enanta's collaboration with AbbVie, have now been approved in jurisdictions around the world as part of AbbVie's direct-acting antiviral (DAA) regimens for the treatment of hepatitis C virus (HCV) infection, including the regimens marketed as MAVYRET<sup>TM</sup> (U.S.) and MAVIRET<sup>TM</sup> (ex-U.S.) (glecaprevir/pibrentasvir) and VIEKIRA PAK® (paritaprevir/ritonavir/ombitasvir/dasabuvir) (U.S.) and VIEKIRAX® (paritaprevir/ritonavir/ombitasvir) (ex-U.S.).

Royalties from the AbbVie collaboration are helping to fund Enanta's research and development efforts, which 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). Please visit <a href="https://www.enanta.com">www.enanta.com</a> for more information.

#### **Forward Looking Statements**

This press release contains forward-looking statements, including statements with respect to the prospects for AbbVie's MAVYRET/MAVIRET regimen in HCV and the prospects for advancement of Enanta's earlier stage programs in NASH, PBC, RSV and HBV. 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 are dependent upon the success of AbbVie's continuing commercialization efforts for its HCV treatment regimens, primarily its new MAVYRET/MAVIRET regimen; competitive pricing, market acceptance and reimbursement rates for AbbVie's HCV treatment regimens compared to competitive HCV products on the market; 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-O for the quarter ended December 31. 2017 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 March 31,		Six Months Ended March 31,				
		2018	2017		2018		2017
Revenue	\$	44,049	\$ 8,959	\$	82,158	\$	19,376
Operating expenses							
Research and development		21,484	13,004		39,446		25,530
General and administrative		5,706	5,461		11,476		10,398
Total operating expenses		27,190	18,465		50,922		35,928
Income (loss) from operations		16,859	(9,506)		31,236		(16,552)
Other income, net		1,066	549		2,026		1,073
Income (loss) before income taxes		17,925	(8,957)		33,262		(15,479)
Income tax (expense) benefit		(5,370)	3,565		(9,014)		5,107
Net income (loss)		12,555	\$ (5,392)	\$	24,248	\$	(10,372)
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Net income (loss) per share							
Basic	\$	0.65	\$ (0.28)	\$	1.27	\$	(0.54)
Diluted	\$	0.61	\$ (0.28)	\$	1.20	\$	(0.54)
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Weighted average common shares outstanding							
Basic		19,206	19,047		19,167		19,042
Diluted		20,601	19,047		20,256		19,042

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

Assets	March 31, 2018		September 30, 2017	
Current assets				
	\$	66,926	\$	65,675
Cash and cash equivalents Short-term marketable securities	Þ	189,797	Э	157,994
Accounts receivable		44.049		10,614
		44,049		3,536
Prepaid expenses and other current assets				
Total current assets		305,677		237,819
Long-term marketable securities		32,186		70,038
Property and equipment, net		8,616		8,049
Deferred tax assets		7,567		10,123
Restricted cash		608		608
Total assets	\$	354,654	\$	326,637
Liabilities and Stockholders' Equity				
Current liabilities				
Accounts payable	\$	4,696	\$	3,714
Accrued expenses and other current liabilities		7,041		7,970
Income taxes payable		5,380		9,298
Total current liabilities		17,117		20,982
Warrant liability		-		807
Series 1 nonconvertible preferred stock		1,528		762
Other long-term liabilities		2,607		2,410
Total liabilities		21,252		24,961
Total stockholders' equity		333,402		301,676
Total liabilities and stockholders' equity	\$	354,654	\$	326,637

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