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 6, 2020

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)

Registrant's Telephone Number, Including Area Code: (617) 607-0800

Not Applicable
(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:

☐ 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**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 May 6, 2020, Enanta Pharmaceuticals, Inc. announced via press release its results for the fiscal quarter ended March 31, 2020. 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 Number	Description
99.1	Press Release of Enanta Pharmaceuticals, Inc. dated May 6, 2020, reporting Enanta's financial results for the fiscal quarter ended March 31, 2020.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 thereunto duly authorized.

ENANTA PHARMACEUTICALS, INC.

Date: May 6, 2020

By: /s/ Paul J. Mellett
Paul J. Mellett
Senior Vice President, Finance and Administration and Chief Financial Officer

Exhibit 99.1

For Immediate Release

Enanta Pharmaceuticals Reports Financial Results for its Fiscal Second Quarter Ended March 31, 2020 with Webcast and Conference Call Today at 4:30 p.m. ET

- *On Track to Initiate Phase 1b Study of EDP-514 in Viremic Hepatitis B Patients in 2Q 2020 and Phase 1 Study of EDP-297 in 3Q 2020*

- *Royalty Revenue for the Quarter was $27.6 Million*
- *Cash and Marketable Securities Totaled $435.4 Million at March 31, 2020*

WATERTOWN, Mass., May 6, 2020 – Enanta Pharmaceuticals, Inc. (NASDAQ:ENTA), a clinical-stage 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, 2020.

“Enanta is fortunate to have advanced several of its programs in the recent quarter and it continues to have a strong balance sheet and ongoing royalty funding to support its business plans going forward,” said Jay R. Luly, President and Chief Executive Officer of Enanta Pharmaceuticals. “The current pandemic has underscored our commitment as a company to bring forth novel anti-viral therapies for respiratory viruses and liver infections, and we remain highly dedicated to the clinical advancement of our innovative small molecule pipeline. We are on schedule to initiate our Phase 1b study of EDP-514 in viremic hepatitis B patients this quarter, and we also expect to initiate a first-in-human study of our follow-on Farnesoid X receptor agonist, EDP-297, next quarter. Additionally, we have plans for two additional studies of EDP-938 for respiratory syncytial virus to start by year-end, one in pediatric patients and one in adult transplant patients. With these catalysts in mind, we continue to monitor any impact of COVID-19 on all of our clinical studies.”

Fiscal Second Quarter Ended March 31, 2020 Financial Results

Total revenue for the three months ended March 31, 2020 was $27.6 million and consisted of royalty revenue derived primarily from worldwide net sales of AbbVie’s hepatitis C virus (HCV) regimen MAVYRET®/MAVIRET® (glecaprevir/pibrentasvir). For the three months ended March 31, 2019, total revenue was $39.6 million, which consisted of royalty revenue earned on AbbVie’s global net sales of its HCV regimens. AbbVie has reported that the decrease in its first quarter 2020 HCV sales was due to lower patient volumes in select international markets where patients are treated in hospitals affected by COVID-19, as well as increased competition affecting pricing and market share within the U.S. Managed Medicaid segment.

Research and development expenses totaled $32.6 million for the three months ended March 31, 2020, compared to $34.2 million for the three months ended March 31, 2019. The decrease in research and development expenses was primarily due to a decrease in clinical trial expense due to timing of Phase 2

studies in non-alcoholic steatohepatitis (NASH)/primary biliary cholangitis (PBC) conducted in the prior year.

General and administrative expenses totaled $6.9 million for the three months ended March 31, 2020, compared to $6.8 million for the three months ended March 31, 2019.

Enanta recorded an income tax benefit of $3.9 million for the three months ended March 31, 2020 compared to an income tax benefit of $3.2 million for the same period of 2019. The income tax benefit for the three months ended March 31, 2020 was due to a pre-tax loss and increased research and development tax credits. In the prior year, Enanta recorded an income tax benefit despite reporting pre-tax income due to tax deductions from employee stock award-related activity during the quarter.

Net loss for the three months ended March 31, 2020 was $6.0 million, or a loss of $0.30 per diluted common share, compared to net income of $4.1 million, or $0.20 per diluted common share, for the corresponding period in 2019.

Enanta's cash, cash equivalents and short-term and long-term marketable securities totaled $435.4 million at March 31, 2020. This compares to a total of $400.3 million at September 30, 2019. 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.

Pipeline Programs and Near-term Milestones

- **Respiratory Syncytial Virus (RSV): N-Protein Inhibitor EDP-938, Human Metapneumovirus (hMPV) and SARS-CoV-2**
  - Continue with plans to broaden the RSVP study into the Southern Hemisphere, and to expand to trials sites in Europe and North America in the fall and winter RSV season, with the goal of having data in the third quarter of 2021
  - Plan to initiate Phase 2 dose ranging study in pediatric patients with RSV in 4Q 2020
  - Plan to initiate Phase 2 study in adult transplant patients with RSV in 4Q 2020
  - Perform optimization of Enanta's current nanomolar hMPV inhibitor leads
  - Advance efforts for discovery of direct-acting antiviral compounds for SARS-CoV-2

- **Hepatitis B (HBV): Core Inhibitor EDP-514**
  - Initiate Phase 1b study in viremic HBV patients in 2Q 2020
  - Resume recruitment in Phase 1b study in nuc-suppressed HBV patients, currently paused

- **Non-Alcoholic Steatohepatitis (NASH): Farnesoid X Receptor (FXR) Agonists EDP-305 and EDP-297**
  - Resume recruitment and dosing in ARGON-2 Phase 2b study of EDP-305 in NASH, currently paused
  - Plan to initiate Phase 1 study of EDP-297 (follow-on FXR for NASH) in 3Q 2020
  - Advance efforts for discovery of non-FXR compounds for NASH

- **Hepatitis C (HCV) Collaboration with AbbVie**

AbbVie announced that the European Commission approved a change to the marketing authorization for MAVIRET® (glecaprevir/pibrentasvir) to shorten once-daily treatment duration from 12 to 8 weeks in treatment-naïve, compensated cirrhotic, chronic HCV patients with genotype (GT) 3 infection. The decision makes MAVIRET the only pan-genotypic (GTs 1-6) 8-week treatment option for treatment-naïve, chronic HCV patients, without cirrhosis or with compensated cirrhosis.

Upcoming Events and Presentations

- May 19, 2020 – RBC Capital Markets Global Healthcare Conference, Virtual
- June 18, 2020 – Raymond James Healthcare Conference, Virtual
- Enanta plans to issue its fiscal third quarter financial results press release, and hold a conference call regarding those results, on August 4, 2020.

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 6, 2020, through 11:59 p.m. ET on May 8, 2020 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 4261269. 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 have produced clinical candidates for the following disease targets: respiratory syncytial virus (RSV), non-alcoholic steatohepatitis (NASH) and hepatitis B virus (HBV). Enanta is also conducting research in human metapneumovirus (hMPV) and emerging coronaviruses, including SARS-CoV-2.

Enanta's research and development activities are funded by royalties from hepatitis C virus (HCV) products developed under its collaboration with AbbVie. Glecaprevir, a protease inhibitor discovered by Enanta and now marketed by AbbVie as part of its leading treatment for chronic HCV infection, is sold under the brand names 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 and HBV, as well as discovery programs in hMPV and SARS-CoV-2, and prospects for future royalty revenue from sales of AbbVie's MAVYRET®/MAVIRET® HCV 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 level 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, 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, HBV, hMPV, SARS-CoV-2; 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 December 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 March 31,		Six Months Ended March 31,	
	2020	**2019**	**2020**	**2019**
Revenue	$ 27,619	$ 39,631	$ 80,189	$ 109,517
Operating expenses				
Research and development	32,610	34,155	65,388	69,033
General and administrative	6,884	6,780	13,805	13,932
Total operating expenses	39,494	40,935	79,193	82,965
Income (loss) from operations	(11,875)	(1,304)	996	26,552
Other income, net	1,950	2,245	4,026	4,130
Income (loss) before income taxes	(9,925)	941	5,022	30,682
Income tax (expense) benefit	3,920	3,204	2,416	(526)
Net income (loss)	$ (6,005)	$ 4,145	$ 7,438	$ 30,156
Net income (loss) per share				
Basic	$ (0.30)	$ 0.21	$ 0.37	$ 1.55
Diluted	$ (0.30)	$ 0.20	$ 0.36	$ 1.44
Weighted average common shares outstanding				
Basic	19,922	19,549	19,836	19,487
Diluted	19,922	21,084	20,692	20,946

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

	March 31, 2020	September 30, 2019
Assets		
Current assets		
Cash and cash equivalents	$ 74,338	$ 51,230
Short-term marketable securities	280,917	284,006
Accounts receivable	27,619	51,313
Prepaid expenses and other current assets	19,835	15,299
Total current assets	402,709	401,848
Long-term marketable securities	80,099	65,013
Property and equipment, net	9,738	10,927
Deferred tax assets	12,418	11,341
Operating lease, right-of-use assets	7,837	-
Restricted cash	608	608
Other long-term assets	92	92
Total assets	$ 513,501	$ 489,829
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 5,945	$ 6,689
Accrued expenses and other current liabilities	9,807	15,920
Operating lease liabilities	3,764	-
Total current liabilities	19,516	22,609
Operating lease liabilities, net of current portion	5,330	-
Series 1 nonconvertible preferred stock	1,628	1,628
Other long-term liabilities	1,036	3,100
Total liabilities	27,510	27,337
Total stockholders' equity	485,991	462,492
Total liabilities and stockholders' equity	$ 513,501	$ 489,829