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 4, 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 August 4, 2020, Enanta Pharmaceuticals, Inc. announced via press release its results for the fiscal quarter ended June 30, 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 August 4, 2020, reporting Enanta's financial results for the fiscal quarter ended June 30, 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: August 4, 2020

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, 2020 with Webcast and Conference Call Today at 4:30 p.m. ET

- *Initiated Phase 1b Study of EDP-514 in Viremic HBV Patients and Resumed Phase 1b Study of EDP-514 in NUC-Suppressed HBV Patients; Preliminary Data Expected in 1H 2021 and 2Q 2021, Respectively*
- *Plans to Initiate Two Phase 2 Studies of EDP-938 in Pediatric and Adult Transplant Patients with RSV in 4Q 2020*
- *Initiated ARGON-2 Phase 2b Study of EDP-305 in Patients with NASH, On Track to Initiate Phase 1 Study of EDP-297 for NASH in 3Q 2020*
- *Royalty Revenue for the Quarter was $18.7 Million*
- *Cash and Marketable Securities Totaled $435.4 Million at June 30, 2020*

WATERTOWN, Mass., August 4, 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 third quarter ended June 30, 2020.

“During the past quarter, Enanta made progress in our clinical development programs, laying the groundwork for several catalyst-rich quarters to come. Our virology programs, developed from years of antiviral drug discovery expertise, continue to advance with the initiation of our Phase 1b clinical trial in viremic HBV patients and the resumption of our Phase 1b study in HBV patients currently treated with nucleos(t)ide reverse transcriptase inhibitors, which was previously paused due to the COVID-19 pandemic,” said Jay R. Luly, Ph.D., President and Chief Executive Officer of Enanta Pharmaceuticals. “In addition, our Phase 2b RSVP trial in RSV is ongoing, and we are on schedule to initiate two additional studies for the condition, one in pediatric patients and a second in adult transplant patients, by year end. Finally, we are also excited about advancing our candidates in NASH this quarter, starting with the initiation of the ARGON-2 trial of EDP-305, our potent FXR agonist candidate, and the planned initiation later this quarter of the Phase 1 study of EDP-297, our highly potent and targeted follow-on FXR agonist.”

Fiscal Third Quarter Ended June 30, 2020 Financial Results

Total revenue of $18.7 million for the three months ended June 30, 2020 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, 2019, total revenue was $44.4 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 the three months ended June 30, 2020 was mainly driven by declining treated patient volumes due to the COVID-19 pandemic.

Research and development expenses increased slightly to $34.7 million for the three months ended June 30, 2020, compared to $34.5 million for the three months ended June 30, 2019.

General and administrative expenses totaled $6.8 million for the three months ended June 30, 2020, compared to $6.2 million for the three months ended June 30, 2019. The slight increase was due to an increase in compensation expense.

Enanta recorded an income tax benefit of $7.1 million for the three months ended June 30, 2020 compared to an income tax benefit of $0.9 million for the same period in 2019. The income tax benefit in 2020 was driven by the company's net loss for the period, federal research and development tax credits, and a federal net operating loss carry back.

Net loss for the three months ended June 30, 2020 was $14.3 million, or a loss of $0.71 per diluted common share, compared to net income of $7.0 million, or $0.33 per diluted common share, for the corresponding period in 2019.

Enanta's cash, cash equivalents and marketable securities totaled $435.4 million at June 30, 2020. This compares to a total of $400.2 million at September 30, 2019, its fiscal year end. Enanta expects that its current cash, cash equivalents and short-term and long-term marketable securities, as well as its continuing royalty revenue, will continue to 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

- **Virology**
  - **Respiratory Syncytial Virus (RSV): N-Protein Inhibitor EDP-938**
    - Phase 2b RSVP trial is ongoing at sites in the Southern Hemisphere and will expand to trial sites in Europe and North America for the fall and winter RSV season, with the goal of reporting data in 3Q 2021
    - Initiate Phase 2 dose-ranging study in pediatric patients with RSV in 4Q 2020
    - Initiate Phase 2 study in adult transplant patients with RSV in 4Q 2020
  - **Hepatitis B (HBV): Core Inhibitor EDP-514**
    - Initiated Phase 1b study in viremic HBV patients, with preliminary data expected in 1H 2021
    - Resumed Phase 1b study in NUC-suppressed HBV patients, with preliminary data expected in 2Q 2021
  - **Human Metapneumovirus (hMPV)**
    - Perform optimization of Enanta's current nanomolar hMPV inhibitor leads
  - **SARS-CoV-2 (COVID-19)**

Continue to advance efforts for discovery of direct-acting antiviral compounds for SARS-CoV-2

- **Non-Alcoholic Steatohepatitis (NASH)**
  - **Farnesoid X Receptor (FXR) Agonist EDP-305**
    Recruitment and dosing in ARGON-2 Phase 2b study of EDP-305 in NASH ongoing
  - **FXR Agonist EDP-297**
    Initiate Phase 1 study of EDP-297 in 3Q 2020, with data expected in 2Q 2021
  - **Advance efforts for discovery of non-FXR compounds for NASH**

- **Corporate**
  - Announced the appointment of Mark G. Foletta to Enanta's Board of Directors where he will serve as the Chair of the Audit Committee as well as a member of the Nominating and Corporate Governance Committee

Upcoming Events and Presentations
- August 10, 2020 – BTIG Virtual Biotechnology Conference 2020
- September 9-10, 2020 – Baird 2020 Global Healthcare Conference
- September 21-23, 2020 – Oppenheimer Fall Healthcare Life Sciences & MedTech Summit
- Enanta plans to issue its fiscal fourth quarter financial results press release, and hold a conference call regarding those results, on November 23, 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 August 4, 2020, through 11:59 p.m. ET on August 6, 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 7561838. A live audio webcast of the call and replay can be accessed by visiting the "Events and Presentations" 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 SARS-CoV-2 (COVID-19).

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, is sold by AbbVie in numerous countries as part of its leading treatment for chronic HCV infection 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 and HBV, as well as the prospects for advancing research in hMPV and SARS-CoV-2 and 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, HBV, hMPV and SARS-CoV-2; treatment rates, competitive pricing, and reimbursement rate actions affecting MAVYRET/MAVIRET compared to competitive HCV products on the market; the impact COVID-19 could have on number of patient treatments which could impact MAVYRET/MAVIRET sales; the discovery and development risks of Enanta's programs in RSV, NASH 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; the realizability of our deferred tax assets; 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, 2020, 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,	
	2020	**2019**	**2020**	**2019**
Revenue	$ 18,653	$ 44,367	$ 98,842	$ 153,884
Operating expenses				
Research and development	34,682	34,461	100,070	103,494
General and administrative	6,823	6,151	20,628	20,083
Total operating expenses	41,505	40,612	120,698	123,577
Income (loss) from operations	(22,852)	3,755	(21,856)	30,307
Other income, net	1,445	2,415	5,471	6,545
Income (loss) before income taxes	(21,407)	6,170	(16,385)	36,852
Income tax benefit	7,142	866	9,558	340
Net income (loss)	$ (14,265)	$ 7,036	$ (6,827)	$ 37,192
Net income (loss) per share				
Basic	$ (0.71)	$ 0.36	$ (0.34)	$ 1.90
Diluted	$ (0.71)	$ 0.33	$ (0.34)	$ 1.77
Weighted average common shares outstanding				
Basic	20,020	19,673	19,897	19,549
Diluted	20,020	21,105	19,897	20,999

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

	June 30, 2020	September 30, 2019
Assets		
Current assets		
Cash and cash equivalents	$ 99,855	$ 51,230
Short-term marketable securities	270,145	284,006
Accounts receivable	18,653	51,313
Prepaid expenses and other current assets	24,728	15,299
Total current assets	413,381	401,848
Long-term marketable securities	65,404	65,013
Property and equipment, net	9,285	10,927
Deferred tax assets	15,289	11,341
Operating lease, right of use assets	7,645	-
Restricted cash	608	608
Other long-term assets	92	92
Total assets	$ 511,704	$ 489,829
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 6,074	$ 6,689
Accrued expenses and other current liabilities	13,576	15,920
Operating lease liabilities	4,264	-
Total current liabilities	23,914	22,609
Operating lease liabilities, net of current portion	4,547	-
Series 1 nonconvertible preferred stock	1,628	1,628
Other long-term liabilities	1,058	3,100
Total liabilities	31,147	27,337
Total stockholders' equity	480,557	462,492
Total liabilities and stockholders' equity	$ 511,704	$ 489,829