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, 2021

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, 2021, Enanta Pharmaceuticals, Inc. announced via press release its results for the fiscal quarter ended March 31, 2021. 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, 2021, reporting Enanta's financial results for the fiscal quarter ended March 31, 2021
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, 2021

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, 2021 with Webcast and Conference Call Today at 4:30 p.m. ET

- *Reported Positive Data from a Phase 1b Study of EDP-514 in NUC-Suppressed Chronic Hepatitis B Virus (HBV) Patients Supporting Once Daily Dosing and Combination Approach*
- *On Track to Report Preliminary Data from a Phase 1b Study of EDP-514 in Viremic Chronic HBV Patients in Q2 2021 and to Initiate a Phase 1 Study of EDP-721 in Mid-2021*
- *IND-Enabling Studies of a Lead Oral Protease Inhibitor Specifically Designed for SARS-CoV-2 Expected to Begin in Q2 2021*
- *Initiated RSVPEDs, a Phase 2 Study of EDP-938 in Pediatric Patients with Respiratory Syncytial Virus (RSV) Infection*
- *Royalty Revenue for the Quarter was $20 Million*
- *Cash and Marketable Securities Totaled $400 Million at March 31, 2021*

WATERTOWN, Mass., May 6, 2021 – 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, 2021.

“This quarter was marked by meaningful progress, particularly as we further our efforts to develop an all-oral regimen for chronic HBV patients,” said Jay R. Luly, Ph.D., President and Chief Executive Officer of Enanta Pharmaceuticals. “We are especially pleased with the safety, tolerability, pharmacokinetic, and HBV RNA data we announced today from our Phase 1b study in NUC-suppressed patients, which reinforces our belief in EDP-514’s potential to serve as the foundation of an oral combination treatment approach to achieve a functional cure in patients with HBV. We also remain on track for other key milestones in our HBV program later this quarter, including reporting preliminary data from our Phase 1b trial of EDP-514 in viremic chronic HBV patients and initiating a Phase 1 study of EDP-721, our novel HBV RNA destabilizer. Looking to the rest of our pipeline, we are excited to soon initiate IND-enabling studies of a lead oral protease inhibitor specifically designed to target SARS-CoV-2, with a goal of beginning a Phase 1 study in early 2022. Each milestone we achieve brings us closer to our vision of being a leader in the discovery and development of small molecule drugs for the treatment of viral infections and liver diseases.”

Fiscal Second Quarter Ended March 31, 2021 Financial Results

Total revenue for the three months ended March 31, 2021 was $20.1 million and consisted of royalty revenue derived primarily from worldwide net sales of AbbVie’s hepatitis C virus (HCV) regimen

MAVYRET®/MAVIRET® (glecaprevir/pibrentasvir), which continued to be adversely impacted by the pandemic. For the three months ended March 31, 2020, total revenue from royalties on AbbVie's net sales of HCV regimens was $27.6 million.

Research and development expenses totaled $41.5 million for the three months ended March 31, 2021, compared to $32.6 million for the three months ended March 31, 2020. The increase in research and development expenses was primarily due to the timing of the company's clinical trials year over year.

General and administrative expenses totaled $8.3 million for the three months ended March 31, 2021, compared to $6.9 million for the three months ended March 31, 2020. The increase in general and administrative expenses was due to increased headcount and compensation expense.

Enanta recorded an income tax benefit of $7.1 million for the three months ended March 31, 2021, compared to an income tax benefit of $3.9 million for the same period of 2020. The income tax benefit during the three months ended March 31, 2021 was due to the provision of the CARES Act of 2020, which enables the Company to carry back its projected current year tax loss to offset taxable income in prior years.

Net loss for the three months ended March 31, 2021 was $22.0 million, or a loss of $1.09 per diluted common share, compared to a net loss of $6.0 million, or a loss of $0.30 per diluted common share, for the corresponding period in 2020.

Enanta's cash, cash equivalents and short-term and long-term marketable securities totaled $400.4 million at March 31, 2021. 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

Virology

- **HBV: Core Inhibitor EDP-514 and RNA Destabilizer EDP-721**
  - Positive preliminary data announced today from the Phase 1b study of EDP-514 in NUC-suppressed chronic HBV patients. The 200 mg and 400 mg doses were safe and well-tolerated, with pharmacokinetics supportive of once daily dosing. The 800 mg cohort is ongoing and final study results will be presented at a future scientific conference.
  - Preliminary data expected from the ongoing Phase 1b study of EDP-514 in viremic chronic HBV patients in the second quarter of 2021.
  - On track to initiate a Phase 1 clinical study of EDP-721 in mid-2021. EDP-721 is an oral, potent and selective HBV RNA destabilizer being developed for use in combination with other mechanisms, with the goal of achieving an all-oral functional cure.
  - Presenting the discovery and preclinical characterization of EDP-721 in a poster at the International Liver Congress™, sponsored by the European Association for the Study of the Liver (EASL), in June.

- **RSV: N-Protein Inhibitor EDP-938**
  - Due to ongoing COVID-19 mitigation measures, RSV, like influenza, did not emerge during the usual late-fall and winter RSV season in the Northern Hemisphere in 2020-2021. Enanta continues its preparedness efforts to establish trial sites in North America, Europe, the Asia-Pacific region, and the Southern Hemisphere.

    Continuing extensive efforts to double the number of clinical sites globally for RSVP, a Phase 2b randomized, double-blind, placebo-controlled study in 70 adult outpatients with community-acquired RSV infection.

    Initiated RSVPEDs, a Phase 2 randomized, double-blind, placebo-controlled study in 90 pediatric RSV patients, in March 2021.

    Continuing to activate sites for RSVTx, a Phase 2b randomized, double-blind, placebo-controlled study in 200 adult hematopoietic cell transplant recipients with acute RSV infection and symptoms of upper respiratory tract infection.

- **Respiratory Virology Discovery Initiatives** – In 2021, Enanta expects to identify two clinical development candidates among its three discovery initiatives below:

  COVID-19

  IND-enabling studies of a lead oral protease inhibitor specifically designed for SARS-CoV-2 are expected to begin later this quarter, with the goal to have a candidate in a Phase 1 study in early 2022.

  RSV L-Protein Inhibitor

  - Optimization of leads with potent nanomolar activity against both RSV-A and RSV-B is ongoing, with potential for use alone or in combination with agents targeting other RSV mechanisms, such as EDP-938, to possibly broaden the addressable treatment window or patient population.

  Human Metapneumovirus (hMPV)

  - Lead optimization on potent nanomolar hMPV inhibitors is currently ongoing.

NASH

- **Farnesoid X Receptor (FXR) Agonist EDP-305**
  - Continuing recruitment and dosing in ARGON-2 Phase 2b study of EDP-305, with a blinded 12-week internal interim analysis on a subset of patients to inform next steps, is expected in the third quarter of 2021, rather than in mid-year.
- **EDP-297, a Highly Potent and Targeted FXR Agonist**
  - Continuing recruitment and dosing in a Phase 1 study of EDP-297, with data expected in mid-2021.

Upcoming Events and Presentations

- RBC Capital Markets Global Healthcare Conference (May 18-19, 2021)
- JMP Securities 2021 Life Sciences Conference (June 16-17, 2021)
- Raymond James Human Health Innovation Conference (June 21-23, 2021)
- The International Liver Congress™ 2021 sponsored by EASL (June 23-26, 2021)

- Enanta plans to issue its fiscal third quarter financial results press release, and hold a conference call regarding those results, on August 5, 2021.

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, 2021, through 11:59 p.m. ET on May 10, 2021 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 4283865. 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 initiatives in SARS-CoV-2, RSV and hMPV. 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 impact of development, regulatory and marketing efforts of others with respect to competitive treatments for RSV, HBV, HCV, COVID-19 and NASH; the discovery and development risks of Enanta's programs in RSV, HBV, NASH, hMPV and 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, 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 March 31,		Six Months Ended March 31,	
	2021	**2020**	**2021**	**2020**
Revenue	$ 20,132	$ 27,619	$ 51,875	$ 80,189
Operating expenses				
Research and development	41,506	32,610	78,171	65,388
General and administrative	8,326	6,884	15,703	13,805
Total operating expenses	49,832	39,494	93,874	79,193
Income (loss) from operations	(29,700)	(11,875)	(41,999)	996
Other income, net	545	1,950	1,222	4,026
Income (loss) before income taxes	(29,155)	(9,925)	(40,777)	5,022
Income tax benefit	7,110	3,920	10,404	2,416
Net income (loss)	$ (22,045)	$ (6,005)	$ (30,373)	$ 7,438
Net income (loss) per share				
Basic	$ (1.09)	$ (0.30)	$ (1.51)	$ 0.37
Diluted	$ (1.09)	$ (0.30)	$ (1.51)	$ 0.36
Weighted average common shares outstanding				
Basic	20,171	19,922	20,131	19,836
Diluted	20,171	19,922	20,131	20,692

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

	March 31, 2021	September 30, 2020
Assets		
Current assets		
Cash and cash equivalents	$ 77,126	$ 87,131
Short-term marketable securities	298,821	299,518
Accounts receivable	20,132	23,492
Prepaid expenses and other current assets	32,140	26,696
Total current assets	428,219	436,837
Long-term marketable securities	24,493	32,634
Property and equipment, net	7,038	8,596
Deferred tax assets	345	345
Operating lease, right of use assets	6,972	7,020
Restricted cash	608	608
Other long-term assets	92	92
Total assets	$ 467,767	$ 486,132
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 5,699	$ 5,737
Accrued expenses and other current liabilities	15,744	14,159
Operating lease liabilities	5,175	4,261
Total current liabilities	26,618	24,157
Operating lease liabilities, net of current portion	2,644	3,838
Series 1 nonconvertible preferred stock	1,479	1,479
Other long-term liabilities	994	1,078
Total liabilities	31,735	30,552
Total stockholders' equity	436,032	455,580
Total liabilities and stockholders' equity	$ 467,767	$ 486,132