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): February 8, 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 February 8, 2021, Enanta Pharmaceuticals, Inc. announced via press release its results for the fiscal quarter ended December 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 February 8, 2021, reporting Enanta's financial results for the fiscal quarter ended December 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: February 8, 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 First Quarter Ended December 31, 2020 with Webcast and Conference Call Today at 4:30 p.m. ET

- *Broadened Hepatitis B Virus (HBV) Program with EDP-721, a New Oral HBV RNA Destabilizer, as a Potential Component of a Functional HBV Cure Regimen; Plan to Initiate Phase 1 Study Mid-2021*
- *Initiated RSVTx, a Phase 2b Study of EDP-938 in Adult Hematopoietic Cell Transplant Recipients with Acute Respiratory Syncytial Virus (RSV) Infection*
- *Expanded RSV Program with a Discovery Initiative for Novel RSV L-Protein Inhibitors*
- *Royalty Revenue for the Quarter was $31.7 Million*
- *Cash and Marketable Securities Totaled $404.7 Million at December 31, 2020*

WATERTOWN, Mass., February 8, 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 first quarter ended December 31, 2020.

“Our first fiscal quarter of 2021 was an especially active time, as we advanced and expanded our wholly-owned pipeline. In HBV, not only did we advance our two ongoing Phase 1b trials of EDP-514, but we also broadened our program with the introduction of EDP-721, a novel HBV RNA destabilizer. We believe that an all-oral regimen of EDP-514, EDP-721 and a nucleos(t)ide reverse transcriptase inhibitor has the potential to lead to a functional cure. We anticipate having preliminary data in our two existing HBV trials in the second quarter of 2021, with a Phase 1 study of EDP-721 on track to initiate mid-year,” stated Jay R. Luly, Ph.D., President and Chief Executive Officer of Enanta Pharmaceuticals.

“We also made meaningful progress on our RSV franchise, initiating an RSV L-protein inhibitor discovery effort centered on potent nanomolar leads active against both RSV-A and RSV-B. Further, we initiated the Phase 2b RSVTx study evaluating EDP-938 in adult hematopoietic cell transplant recipients with RSV, and remain on track to initiate the Phase 2 RSVPEDs study of EDP-938 in pediatric patients with RSV this quarter. Meanwhile we are in the process of expanding clinical sites for RSVP in Europe and Asia Pacific, so that we are ready when RSV re-emerges. Additionally, we are making significant progress in our discovery efforts in human metapneumovirus (hMPV) and SARS-CoV-2 (COVID-19), with the goal of identifying two clinical candidates this year from among our hMPV, COVID-19 and RSV discovery

programs. Importantly, our strategy for COVID-19 involves targeting mechanisms that should be effective against emerging spike protein variants," continued Dr. Luly.

"Finally, our non-alcoholic steatohepatitis (NASH) program is progressing with the ARGON-2 trial of EDP-305 and the Phase 1 study of EDP-297 ongoing, and we look forward to having valuable insights around mid-year to inform next steps for our NASH program. Looking ahead, we believe the upcoming year will be important for Enanta as we progress through numerous milestones across our entire pipeline."

Fiscal First Quarter Ended December 31, 2020 Financial Results
Total revenue for the three months ended December 31, 2020 was $31.7 million and consisted entirely of royalty revenue from worldwide net sales of AbbVie's hepatitis C virus (HCV) regimens. For the three months ended December 31, 2019, total royalty revenue was $52.6 million on AbbVie's higher HCV sales. As reported by AbbVie, continued lower HCV product sales were due primarily to lower treated patient volumes during the COVID-19 pandemic.

Research and development expenses totaled $36.7 million for the three months ended December 31, 2020, compared to $32.8 million for the three months ended December 31, 2019. The increase was primarily due to the timing of the company's clinical trials year over year.

General and administrative expenses totaled $7.4 million for the three months ended December 31, 2020, compared to $6.9 million for the three months ended December 31, 2019. This increase was primarily due to increased headcount and compensation expense.

Enanta recorded an income tax benefit of $3.3 million for the three months ended December 31, 2020 compared to income tax expense of $1.5 million for the same period in 2019. Enanta recorded an income tax benefit during the three months ended December 31, 2020 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 December 31, 2020 was $8.3 million, or a loss of $0.41 per diluted common share, compared to net income of $13.4 million, or $0.65 per diluted common share, for the corresponding period in 2019.

Enanta's cash, cash equivalents and short-term and long-term marketable securities totaled $404.7 million at December 31, 2020. 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

- **RSV: N-Protein Inhibitor EDP-938**

RSVP, a Phase 2b randomized, double-blind, placebo-controlled study in 70 adult outpatients with community-acquired RSV infection, is ongoing, but to date the 2021 RSV season in the Northern Hemisphere has not yet begun due to COVID-19 mitigation measures. Enanta has made extensive efforts to more than double its clinical sites globally, including sites across Europe and Asia-Pacific, to be ready when RSV re-emerges.
Initiated 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.
On schedule to initiate RSVPEDs, a Phase 2 randomized, double-blind, placebo-controlled study in 90 hospitalized and non-hospitalized pediatric RSV patients in the first quarter of calendar 2021.

- **HBV: Core Inhibitor EDP-514 and RNA Destabilizer EDP-721**
  Introduced EDP-721, a potent and selective HBV RNA destabilizer, for use alone or in combination with other mechanisms, such as EDP-514, with the goal of achieving an all-oral functional cure. Enanta expects to initiate a Phase 1 clinical study of EDP-721 in mid-2021.
  Phase 1b study of EDP-514 in viremic HBV patients is ongoing, with preliminary data expected in the second quarter of 2021.
  Phase 1b study of EDP-514 in NUC-suppressed HBV patients is ongoing, with preliminary data expected in the second quarter of 2021.

- **Respiratory Virology Discovery Programs** – In 2021, Enanta expects to identify clinical development candidates for two of its three programs below:
  RSV L-Protein Inhibitor
  - Recently announced an RSV L-inhibitor discovery initiative with potent nanomolar leads active against both RSV-A and RSV-B, for potential use alone or in combination with agents targeting other RSV mechanisms, such as EDP-938.

  COVID-19
  - Urgently performing lead optimization on direct-acting antiviral leads targeting mechanisms that should be effective against emerging spike protein variants.

  hMPV
  - Continue performing lead optimization on current nanomolar hMPV inhibitor leads.

NASH

- **Farnesoid X Receptor (FXR) Agonist EDP-305**
  Continue recruitment and dosing in ARGON-2 Phase 2b study of EDP-305, with a blinded 12-week interim analysis on a subset of patients, for Enanta's internal use, expected in mid-year 2021.
- **FXR Agonist EDP-297**
  Continue recruitment and dosing in a Phase 1 study of EDP-297, with data expected in mid-year 2021.

Corporate

- Announced the appointment of several key new hires, including
  Tara Kieffer, Ph.D., Senior Vice President, New Product Strategy and Development;
  Brendan Luu, Senior Vice President, Business Development; and
  John DeVincenzo, M.D., Vice President, Translational Virology.

Upcoming Events and Presentations
- SVB Leerink Global Healthcare Conference (February 23-26, 2021, Virtual)
- Enanta Annual Shareholder Meeting (March 2, 2021, Virtual)
- H.C. Wainwright Global Life Sciences Conference (March 9-10, 2021, Virtual)
- ROTH Capital Partners Annual Conference (March 15-17, 2021, Virtual)
- Oppenheimer & Co. Annual Healthcare Conference (March 16-17, 2021, Virtual)
- Enanta Fiscal Second Quarter 2021 Financial Results Webcast and Conference Call (May 6, 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 February 8, 2021, through 11:59 p.m. ET on February 12, 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 2854627. 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
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), hepatitis B virus (HBV) and non-alcoholic steatohepatitis (NASH). 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, HBV and NASH, as well as its discovery programs in SARS-CoV-2 and hMPV and prospects for future royalty revenue 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 impact of development, regulatory and marketing efforts of others with respect to competitive treatments for RSV, HBV, NASH, SARS-CoV-2 and hMPV; the discovery and development risks of Enanta's programs in RSV, HBV, NASH, SARS-CoV-2 and hMPV; the competitive impact of development, regulatory and marketing efforts of others in those disease areas; the dependence of Enanta's revenues in the short-term upon AbbVie's sales of its MAVYRET®/MAVIRET® HCV regimen; any continuing impact of the COVID-19 pandemic on Enanta's royalty revenues, business operations and clinical trials; 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-K for the fiscal year ended September 30, 2020, and any 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 December 31,	
	2020	**2019**
Revenue	$ 31,743	$ 52,570
Operating expenses		
Research and development	36,665	32,778
General and administrative	7,377	6,921
Total operating expenses	44,042	39,699
Income (loss) from operations	(12,299)	12,871
Other income, net	677	2,076
Income (loss) before income taxes	(11,622)	14,947
Income tax (expense) benefit	3,294	(1,504)
Net income (loss)	$ (8,328)	$ 13,443
Net income (loss) per share		
Basic	$ (0.41)	$ 0.68
Diluted	$ (0.41)	$ 0.65
Weighted average common shares outstanding		
Basic	20,093	19,751
Diluted	20,093	20,773

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

	December 31, 2020	September 30, 2020
Assets		
Current assets		
Cash and cash equivalents	$ 55,095	$ 87,131
Short-term marketable securities	331,101	299,518
Accounts receivable	31,743	23,492
Prepaid expenses and other current assets	28,003	26,696
Total current assets	445,942	436,837
Long-term marketable securities	18,462	32,634
Property and equipment, net	7,788	8,596
Deferred tax assets	345	345
Operating lease, right of use assets	7,775	7,020
Restricted cash	608	608
Other long-term assets	92	92
Total assets	$ 481,012	$ 486,132
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 6,305	$ 5,737
Accrued expenses and other current liabilities	11,542	14,159
Operating lease liabilities	5,197	4,261
Total current liabilities	23,044	24,157
Operating lease liabilities, net of current portion	3,520	3,838
Series 1 nonconvertible preferred stock	1,479	1,479
Other long-term liabilities	974	1,078
Total liabilities	29,017	30,552
Total stockholders' equity	451,995	455,580
Total liabilities and stockholders' equity	$ 481,012	$ 486,132