# 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

February 8, 2021
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- *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.--(BUSINESS WIRE)-- 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 calendar 2021.

- Phase 1b study of EDP-514 in NUC-suppressed HBV patients is ongoing, with preliminary data expected in the second quarter of calendar 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-2021.

- **FXR Agonist EDP-297**

- Continue recruitment and dosing in a Phase 1 study of EDP-297, with data expected in mid-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.

**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 |

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