Enanta Pharmaceuticals Reports Financial Results for its Fiscal Fourth Quarter and Year Ended September 30, 2021 with Webcast and Conference Call Today at 4:30 p.m. ET

November 22, 2021
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- *Presented First Preclinical Data for EDP-235, an Oral Protease Inhibitor Specifically Designed for the Treatment of COVID-19; First-in-Human Study Planned for Early 2022*
- *Reported Positive Clinical Data from Two Phase 1b Studies of EDP-514, a Hepatitis B Virus (HBV) Core Inhibitor, in Viremic and NUC-Suppressed Chronic HBV Patients; Terminated Clinical Development of EDP-721, an Oral HBV RNA Destabilizer*
- *Announced Decision to Pursue Combination Approaches with Farnesoid X Receptor (FXR) Agonists for Non-Alcoholic Steatohepatitis (NASH) Through an Out-Licensing Strategy*
- *Royalty Revenue for the Quarter was $23.6 Million*

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 fourth quarter and year ended September 30, 2021.

“We ended fiscal 2021 achieving multiple milestones including presenting positive Phase 1b data of EDP-514 in two major HBV patient populations,” stated Jay R. Luly, Ph.D., President and Chief Executive Officer of Enanta Pharmaceuticals. “We were also excited to present the first preclinical data for EDP-235, our oral protease inhibitor specifically designed to target SARS-CoV-2, and we are making meaningful progress with our Phase 2b RSVP study in RSV. Looking ahead, we expect to make significant advancements across our pipeline and are on schedule to select a new clinical development candidate from our RSV L-inhibitor program by year-end and to report initial data from RSVP in the first half of 2022.”

Fiscal Fourth Quarter and Year Ended September 30, 2021 Financial Results

Total revenue of $23.6 million for the three months ended September 30, 2021 consisted of royalty revenue derived almost entirely from worldwide net sales of AbbVie’s hepatitis C virus (HCV) regimen MAVYRET®/MAVIRET®, which was unchanged from the royalty revenue of $23.6 million for the three months ended September 30, 2020. For the twelve months ended September 30, 2021, total revenue was $97.1 million compared to $122.5 million for the same period in 2020. Royalty revenue for these periods reflect that treated patient volumes remain suppressed compared to pre-COVID levels, as reported by AbbVie.

Research and development expenses were $48.9 million for the three months ended September 30, 2021, compared to $36.7 million for the three months ended September 30, 2020. For the twelve months ended September 30, 2021, research and development expenses were $174.1 million compared to $136.8 million in 2020. The increases in both periods were due to the timing of clinical trials in the company's virology programs.

General and administrative expenses totaled $8.4 million for the three months ended September 30, 2021, compared to $6.7 million for the three months ended September 30, 2020. For the twelve months ended September 30, 2021, general and administrative expenses were $32.5 million compared to $27.4 million in 2020. The increase was due to additional headcount and related compensation expense.

Enanta recorded an income tax benefit of $8.8 million for the three months ended September 30, 2021 compared to an income tax expense of $10.7 million for the same period in 2020. For the twelve months ended September 30, 2021, Enanta recorded an income tax benefit of $28.6 million, compared to income tax expense of $1.1 million for the twelve months ended September 30, 2020. The income tax expense in 2020 was due to a tax valuation allowance charge of $18.3 million recorded against the company’s deferred tax assets in the three months ended September 30, 2020. The income tax benefit in the current period was due to the provision of the CARES Act of 2020, which enables the company to carry back its current year tax loss to offset taxable income in prior years. This provision will not apply to periods ending after September 30, 2021.

Net loss for the three months ended September 30, 2021 was $24.6 million, or a loss of $1.22 per diluted common share, compared to a net loss of $29.3 million, or a loss of $1.46 per diluted common share, for the corresponding period in 2020. For the twelve months ended September 30, 2021, net loss was $79.0 million, or a loss of $3.92 per diluted common share, compared to a net loss of $36.2 million, or loss of $1.81 per diluted common share for corresponding period in 2020.

Enanta’s cash, cash equivalents and marketable securities totaled $352.4 million at September 30, 2021. 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 at least the next two years.

Financial Guidance for Fiscal Year 2022

- Research and Development Expense: $150 million to $170 million
- General and Administrative Expense: $35 million to $41 million

Pipeline Programs – Recent Events and Near-Term Milestones

Virology

- **Respiratory Syncytial Virus (RSV): N-Protein Inhibitor EDP-938**
  - Evaluating EDP-938, an N-protein inhibitor, in a broad clinical development program, consisting of three ongoing Phase 2 trials: RSVP, RSVTx and RSVPEDs.
  - Continued to establish additional trial sites worldwide for RSVP, which is designed to study the effect of EDP-938 on community-acquired RSV infection in an adult population. While RSV, like influenza, was significantly suppressed while there were mitigation measures in place to control COVID-19, more recently there has been evidence of increased RSV activity in various regions of the world, including parts of the United States and Europe. Enanta expects that enrollment in the RSVP study will be complete during the Northern Hemisphere winter season, if there is no further significant increase in COVID-19 or mitigation measures in those regions. Assuming this enrollment occurs, the company expects data in the first half of 2022.
  - For RSVTx and RSVPEDs, which were initiated more recently, enrollment is expected to require more than one global RSV season, subject to the uncertainties of the continuing pandemic.

- **COVID-19 (SARS-CoV-2): Protease Inhibitor EDP-235**
  - Presented preclinical data during the International Society for Influenza and Other Respiratory Virus Diseases (ISIRV)–World Health Organization (WHO) Virtual Conference 2021 demonstrating that oral EDP-235 selectively blocked replication of SARS-CoV-2 in multiple cellular models with nanomolar potency. Further, antiviral activity was maintained against multiple SARS-CoV-2 variants. Good distribution to lung cells was observed with optimized pharmacokinetic properties supporting once-daily, oral dosing without ritonavir boosting. Enanta plans to move EDP-235 into the clinic in early 2022.

- **HBV: Core Inhibitor EDP-514 and HBV RNA Destabilizer EDP-721**
  - Announced positive final data from both Phase 1b studies of EDP-514 in viremic and NUC-suppressed chronic HBV patients. These data demonstrated that the 200 mg, 400 mg, and 800 mg doses were safe and well-tolerated through 28 days of treatment and displayed pharmacokinetics supportive of once-daily dosing. In viremic patients, treatment with EDP-514 resulted in mean HBV DNA reductions of 2.9, 3.3, and 3.5 logs at 28 days for the 200 mg, 400 mg, and 800 mg cohorts, respectively, compared to a 0.2 log reduction in the placebo group.
  - Terminated development of EDP-721, an oral HBV RNA destabilizer due to adverse safety signals in a Phase 1 healthy volunteer study.

- **Respiratory Virology Discovery Initiatives:** Enanta's goal in the second half of 2021 is to identify one more clinical development candidate among the two discovery initiatives below:
  - **RSV L-Protein Inhibitor**
    - On schedule to select a clinical candidate with potent nanomolar activity against both RSV-A and RSV-B by year-end.
  - **Human Metapneumovirus (hMPV)**
    - Continuing lead optimization on potent nanomolar hMPV inhibitors.

Non-Alcoholic Steatohepatitis (NASH)

- Announced a strategic decision to discontinue internal development of FXR agonists EDP-305 and EDP-297, to prioritize combination approaches for NASH through out-licensing.

Corporate

- Announced the election of Yujiro S. Hata to Enanta's Board of Directors.

Upcoming Events and Presentations

- Evercore HealthCONx, November 30 – December 2, 2021
- Piper Sandler 33rd Annual Healthcare Conference, November 30 – December 2, 2021
- 40th Annual JP Morgan Healthcare Conference, January 10 – 13, 2022
- Enanta plans to issue its fiscal 2022 first quarter results press release, and hold a conference call regarding those results, on February 8, 2022.

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 844-467-7101 in the U.S. or 270-215-9353 for international callers. A replay of the conference call will be available starting at approximately 7:30 p.m. ET on November 22, 2021, through 11:59 p.m. ET on November 29, 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 **1973737**. 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 currently in development for the following disease targets: respiratory syncytial virus (RSV), hepatitis B virus (HBV) and SARS-CoV-2 (COVID-19). Enanta is also conducting research in human metapneumovirus (hMPV).

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 part of AbbVie's leading treatment for chronic HCV infection that it sells in numerous countries 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 research and development programs in RSV, HBV, SARS-CoV-2 and hMPV, as well as 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 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, HBV, SARS-CoV-2 and hMPV; treatment rates, competitive pricing, and reimbursement rate actions affecting MAVYRET/MAVIRET compared to competitive HCV products on the market; any continuing impact of COVID-19 on AbbVie's MAVYRET/MAVIRET sales; the discovery and development risks of Enanta's research and development programs in RSV, HBV, SARS-CoV-2 and hMPV; 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 June 30, 2021, 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.

ENANTA PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
UNAUDITED
(in thousands, except per share amounts)

	Three Months Ended September 30,		Twelve Months Ended September 30,	
	2021	2020	2021	2020
Revenue	$ 23,575	$ 23,631	$ 97,074	$ 122,473
Operating expenses				
Research and development	48,946	36,686	174,111	136,756
General and administrative	8,356	6,728	32,536	27,356
Total operating expenses	57,302	43,414	206,647	164,112
Loss from operations	(33,727)	(19,783)	(109,573)	(41,639)
Other income, net	333	1,149	1,994	6,620
Loss before income taxes	(33,394)	(18,634)	(107,579)	(35,019)
Income tax (expense) benefit	8,795	(10,707)	28,583	(1,149)
Net loss	$ (24,599)	$ (29,341)	$ (78,996)	$ (36,168)
Net loss per share				
Basic	$ (1.22)	$ (1.46)	$ (3.92)	$ (1.81)
Diluted	$ (1.22)	$ (1.46)	$ (3.92)	$ (1.81)
Weighted average common shares outstanding				
Basic	20,221	20,074	20,171	19,940
Diluted	20,221	20,074	20,171	19,940

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

	September 30,	September 30,

	2021	2020
Assets		
Current assets		
Cash and cash equivalents	$ 57,206	$ 87,131
Short-term marketable securities	186,796	299,518
Accounts receivable	23,576	23,492
Prepaid expenses and other current assets	14,188	13,655
Income tax receivable	37,255	13,041
Total current assets	319,021	436,837
Long-term marketable securities	108,416	32,634
Property and equipment, net	5,943	8,596
Deferred tax assets	—	345
Operating lease, right-of-use assets	4,711	7,020
Restricted cash	608	608
Other long-term assets	92	92
Total assets	$ 438,791	$ 486,132
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 9,540	$ 5,737
Accrued expenses and other current liabilities	22,429	14,159
Operating lease liabilities	4,203	4,261
Total current liabilities	36,172	24,157
Operating lease liabilities, net of current portion	1,126	3,838
Series 1 nonconvertible preferred stock	1,506	1,479
Other long-term liabilities	558	1,078
Total liabilities	39,362	30,552
Total stockholders' equity	399,429	455,580
Total liabilities and stockholders' equity	$ 438,791	$ 486,132

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Source: Enanta Pharmaceuticals, Inc.