Enanta Pharmaceuticals Reports Financial Results for its Fiscal First Quarter and Three Months Ended December 31, 2019

February 6, 2020
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Webcast and Conference Call Today at 4:30 p.m. ET

- *Positive results from part 1 of the Phase 1a/b clinical study of EDP-514 in healthy subjects - Part 2 initiated in nuc-suppressed chronic hepatitis B virus patients*
- *Research and development programs progressing well -- several milestones expected in 2020 from our RSV, NASH, and HBV programs*
- *Royalty revenue for the quarter was $52.6 million*
- *Cash and marketable securities totaled $414.7 million at December 31, 2019*

WATERTOWN, Mass.--(BUSINESS WIRE)-- Enanta Pharmaceuticals, Inc. (NASDAQ:ENTA), a research and development-focused 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, 2019.

“We achieved the first of our 2020 milestones with today’s announcement of positive data in healthy subjects with EDP-514, our core inhibitor for HBV. EDP-514 was found to be safe and well-tolerated in healthy adults, with a pharmacokinetic profile that demonstrated good blood levels to support once daily dosing. These results support further clinical evaluation, so we have initiated part 2 of the study in nuc-suppressed chronic HBV patients,” stated Jay R. Luly, Enanta President and CEO. “We look forward to reporting further clinical results and updates from our other wholly-owned clinical programs in RSV, NASH and PBC in 2020.”

Fiscal First Quarter Ended December 31, 2019 Financial Results

Total revenue for the three months ended December 31, 2019 was $52.6 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, 2018, total royalty revenue was $69.9 million.

Research and development expenses totaled $32.8 million for the three months ended December 31, 2019, compared to $34.9 million for the three months ended December 31, 2018. The decrease was primarily due to the timing of clinical trial costs associated with the progression of Enanta’s wholly owned clinical programs in respiratory syncytial virus (RSV), non-alcoholic steatohepatitis (NASH), primary biliary cholangitis (PBC), and hepatitis B virus (HBV).

General and administrative expenses totaled $6.9 million for the three months ended December 31, 2019 compared to $7.2 million for the three months ended December 31, 2018.

Enanta recorded income tax expense of $1.5 million for the three months ended December 31, 2019 compared to an income tax expense of $3.7 million for the same period in 2018. Enanta’s effective tax rate for the December 31, 2019 quarter was approximately 10 percent compared to approximately 12.5 percent for the corresponding period in 2018. The decrease quarter over quarter was due primarily to increased research and development tax credits and a federal income tax benefit from foreign-derived royalty income.

Net income for the three months ended December 31, 2019 was $13.4 million, or $0.65 per diluted common share, compared to net income of $26.0 million, or $1.25 per diluted common share, for the corresponding period in 2018.

Enanta’s cash, cash equivalents and short-term and long-term marketable securities totaled $414.7 million at December 31, 2019. This compares to a total of $400.2 million at September 30, 2019. 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.

Phase 1 data for core inhibitor EDP-514 for HBV

The Phase 1 randomized, double-blind, placebo-controlled, first-in-human study of EDP-514 was conducted to evaluate the safety, tolerability, and pharmacokinetics (PK) of single- and multiple- (14 days) ascending doses of EDP-514 in healthy subjects.

Overall, EDP-514 in healthy subjects dosed for up to 14 days was well tolerated with a favorable safety profile; treatment emergent adverse events were infrequent and mild in intensity; no one discontinued EDP-514 due to adverse events; and there were no significant individual lab data findings or pattern of lab abnormalities. Additionally, the pharmacokinetic (blood level) profile was fully supportive of once daily dosing.

Following these results, which support further clinical evaluation of EDP-514 in HBV patients, Enanta has initiated a study in patients with chronic HBV infection that is being suppressed with nucleos(t)ide-reverse-transcriptase treatment (nuc-suppressed patients). A further study is planned in patients with chronic HBV infection who are not on therapy and have high levels of virus in their blood (viremic patients).

Further details of results from this Phase 1a study will be presented at the International Liver Congress™, April 15-20, 2020.

Near-term Milestones

- **RSV: N-inhibitor EDP-938 and human metapneumovirus (hMPV) Inhibitor Leads**
  - Due to an apparent December peak in the RSV season in North America, continue enrollment in RSVP study of EDP-938 in adult RSV outpatients, including in the Southern Hemisphere, with the goal of having data in the first half of 2021.
  - Initiate Phase 2 dose ranging study in pediatric RSV patients in 4Q 2020
  - Initiate Phase 2 study in adult transplant patients with RSV in 4Q 2020
  - Perform optimization of Enanta's current nanomolar hMPV inhibitor leads

- **HBV: Core Inhibitor EDP-514**
  - Initiate Phase 1b in viremic HBV patients in 2Q 2020
  - Data from Phase 1b study in nuc-suppressed HBV patients in 1Q 2021

- **NASH / PBC: FXR Agonists EDP-305 and EDP-297**
  - Initiate ARGON-2 Phase 2b study of EDP-305 in NASH by early 2Q 2020
  - Phase 2 data from INTREPID study of EDP-305 in PBC by early 2Q 2020
  - Initiate Phase 1 study of EDP-297 (follow-on FXR) in mid-2020
  - Advance discovery of non-FXR compounds for NASH

Upcoming Events and Presentations

- Enanta Annual Shareholder Meeting, February 26, 2020, Cambridge, MA
- EDP-514, EDP-297, and EDP-305 abstracts at the International Liver Congress™, April 15-20, 2020
- Enanta plans to issue its fiscal second quarter financial results press release, and hold a conference call regarding those results, on May 6, 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 February 6, 2020, through 11:59 p.m. ET on February 8, 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 3972249. 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

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)/ primary biliary cholangitis (PBC), and hepatitis B virus (HBV). Enanta's research and development activities are funded by royalties from HCV products developed under its collaboration with AbbVie. Glecaprevir, a protease inhibitor discovered by Enanta, is now sold by AbbVie in numerous countries as part of its leading treatment for chronic hepatitis C virus (HCV) infection sold 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/PBC and HBV, as well as Enanta's 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 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, PBC and HBV; treatment rates, competitive pricing, and reimbursement rate actions affecting MAVYRET®/MAVIRET™ compared to competitive HCV products on the market; the discovery and development risks of Enanta's programs in RSV, NASH, PBC, 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; and other risk factors described or referred to in "Risk Factors" in Enanta's most recent Form 10-K for the year ended, 2019, 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 December 31,	
	2019	**2018**

Revenue	$ 52,570	$ 69,886
Operating expenses		
Research and development	32,778	34,878
General and administrative	6,921	7,152
Total operating expenses	39,699	42,030
Income from operations	12,871	27,856
Other income, net	2,076	1,885
Income before income taxes	14,947	29,741
Income tax expense	(1,504)	(3,730))
Net income	$ 13,443	$ 26,011
Net income per share		
Basic	$ 0.68	$ 1.34
Diluted	$ 0.65	$ 1.25
Weighted average common shares outstanding		
Basic	19,751	19,426
Diluted	20,773	20,810

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

	December 31, 2019	September 30, 2019
Assets		
Current assets		
Cash and cash equivalents	$ 27,558	$ 51,230
Short-term marketable securities	346,227	284,006
Accounts receivable	52,570	51,313
Prepaid expenses and other current assets	14,153	15,299
Total current assets	440,508	401,848
Long-term marketable securities	40,941	65,013
Property and equipment, net	10,407	10,927
Deferred tax assets	10,656	11,341
Operating lease, right-of-use assets	7,762	—
Restricted cash	608	608
Other long-term assets	92	92
Total assets	$ 510,974	$ 489,829
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 6,596	$ 6,689
Accrued expenses and other current liabilities	9,411	15,920
Operating lease liabilities	3,132	—
Total current liabilities	19,139	22,609
Operating lease liabilities, net of current portion	5,987	—
Series 1 nonconvertible preferred stock	1,628	1,628
Other long-term liabilities	1,933	3,100
Total liabilities	28,687	27,337
Total stockholders' equity	482,287	462,492
Total liabilities and stockholders' equity	$ 510,974	$ 489,829

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