Enanta Pharmaceuticals Reports Financial Results for its Fiscal Second Quarter with Webcast and Conference Call Today at 4:30 p.m. ET

May 6, 2024

- *Anticipates Reporting Topline Data from EDP-323 Respiratory Syncytial Virus (RSV) Challenge Study in Q3 2024 and Phase 2 Study of Zelicapavir in Pediatric RSV Patients in 2H 2024*
- *Selection of Chronic Spontaneous Urticaria (CSU) Development Candidate Targeted for Q4 2024*
- *Operations Supported by Cash and Marketable Securities Totaling $300.3 Million at March 31, 2024, as well as Continuing Retained Royalties*

WATERTOWN, Mass.--(BUSINESS WIRE)--May 6, 2024-- Enanta Pharmaceuticals, Inc. (NASDAQ:ENTA), a clinical-stage biotechnology company dedicated to creating small molecule drugs for virology and immunology indications, today reported financial results for its fiscal second quarter ended March 31, 2024.

“At Enanta, we are committed to advancing the first antiviral treatment for RSV, and more broadly developing important medicines in virology and immunology. Our commitment is highlighted by our goal to deliver multiple RSV data readouts this year, including from our challenge study of EDP-323, an oral L-protein inhibitor, expected in the third quarter, and from RSVPEDs, our Phase 2 pediatric study of zelicapavir, an oral N-protein inhibitor. In RSVPEDs, we are nearing study completion and are now only enrolling patients aged 28 days to 6 months, which is the last age cohort in Part 2. As this narrows the eligible patient population, we will continue recruiting in the Southern Hemisphere and anticipate reporting data from this study in the second half of 2024,” said Jay R. Luly, Ph.D., President and Chief Executive Officer at Enanta Pharmaceuticals. “Pending positive data from these studies, we will be poised to deliver potential first-in-class antiviral replication inhibitors with differentiated mechanisms of action and advance our robust RSV portfolio. Beyond RSV, we are eager to help patients affected by CSU, a severely debilitating inflammatory skin disease, with our first immunology program focused on developing oral KIT inhibitors. We are on track to select a KIT inhibitor development candidate in the fourth quarter and look forward to expanding more broadly into immune-mediated chronic diseases with a second program this year.”

Fiscal Second Quarter Ended March 31, 2024 Financial Results

Total revenue for the three months ended March 31, 2024 was $17.1 million and consisted of royalty revenue from worldwide net sales of AbbVie’s hepatitis C virus (HCV) regimen MAVYRET®/MAVIRET® (glecaprevir/pibrentasvir), compared to $17.8 million for the three months ended March 31, 2023.

A portion (54.5%) of Enanta’s ongoing royalty revenue from AbbVie’s net sales of MAVYRET®/MAVIRET® is paid to OMERS, one of Canada’s largest defined benefit pension plans, pursuant to a royalty sale transaction affecting royalties earned after June 2023. For financial reporting purposes, the transaction was treated as debt, with the upfront purchase payment of $200.0 million recorded as a liability. Each quarter, Enanta records 100% of the royalty earned as revenue and then amortizes the debt liability proportionally as 54.5% of the cash royalty payments are paid to OMERS through June 30, 2032 subject to a cap of 1.42 times the purchase payment, after which point 100% of the cash royalty payments will be retained by Enanta. Interest expense from the royalty sale was $2.6 million for the three months ended March 31, 2024.

Research and development expenses totaled $35.6 million for the three months ended March 31, 2024, compared to $43.5 million for the three months ended March 31, 2023. The decrease was primarily due to a decrease in costs associated with Enanta’s COVID-19 program, as the company announced previously that plans to pursue any future COVID-19 efforts would be in the context of a collaboration. This decrease was partially offset by increased costs associated with Enanta’s RSV programs and its recently announced immunology programs.

General and administrative expenses totaled $14.2 million for the three months ended March 31, 2024, compared to $13.8 million for the three months ended March 31, 2023. The increase was primarily due to an increase in legal expenses related to the company’s patent infringement lawsuit against Pfizer.

Enanta recorded an income tax benefit of $0.4 million for the three months ended March 31, 2024, for interest earned on a pending $28.0 million federal income tax refund, compared to an income tax expense of less than $0.1 million for the three months ended March 31, 2023.

Net loss for the three months ended March 31, 2024 was $31.2 million, or a loss of $1.47 per diluted common share, compared to a net loss of $37.7 million, or a loss of $1.79 per diluted common share, for the corresponding period in 2023.

Enanta is updating its expense guidance at this fiscal year mid-point. Research and development expense is $125 million to $145 million. General and administrative expense is $50 million to $60 million. The research and development expense increase reflects the impact of the company’s new immunology programs as well as additional efforts to accelerate the RSV clinical studies. The general and administrative expense increase is due to additional stock compensation expense and costs associated with pursuing the company’s patent infringement lawsuit.

Enanta’s cash, cash equivalents and short-term marketable securities totaled $300.3 million at March 31, 2024. Enanta expects that its current cash, cash equivalents and marketable securities, as well as its retained portion of future royalty revenue, will be sufficient to meet the anticipated cash requirements of its existing business and development programs through the third quarter of fiscal 2027.

Virology

RSV

- Enanta is advancing multiple clinical programs through a robust antiviral treatment portfolio aimed at populations at high-risk for serious outcomes from RSV infection. This includes zelicapavir, Enanta's lead, oral N-protein inhibitor, and EDP-323, its oral L-protein inhibitor.
    - Zelicapavir is being evaluated in two ongoing Phase 2 clinical trials in high-risk pediatric and adult populations.
        - RSVPEDs is a first-in-pediatrics Phase 2, randomized, double-blind, placebo-controlled study of zelicapavir in hospitalized and non-hospitalized RSV patients that are 28 days to three years of age. The study is near completion and has fully enrolled Part 1, and the older age cohort of Part 2. The remaining younger age cohort of 20 patients in Part 2 is partially enrolled. Recruitment for this cohort will continue in the Southern Hemisphere and Enanta now anticipates reporting data from this study in the second half of 2024.
        - RSVHR is a Phase 2b, randomized, double-blind, placebo-controlled study of zelicapavir in adults with RSV infection who are at high risk of complications, including the elderly and/or those with congestive heart failure, chronic obstructive pulmonary disease or asthma. Enrollment in RSVHR is progressing and the company will provide additional guidance on the study as the Southern Hemisphere RSV season advances.
    - Enanta's second RSV program, EDP-323, is on track to announce data from its Phase 2a challenge study in the third quarter of 2024. This randomized, double-blind, placebo-controlled, human challenge study will evaluate the safety, pharmacokinetics, and changes in viral load measurements and symptoms in up to 114 healthy adult subjects who will be infected with RSV.

Immunology

- Enanta continues to progress its initial immunology program aimed at developing KIT inhibitors to treat CSU, a highly debilitating inflammatory skin disease characterized by recurrent hives that can last for years. CSU is estimated to affect up to 1% of the global population and represents a large market opportunity, as currently there are limited effective oral treatment options for the condition. Enanta's goal is to address the significant unmet need in CSU treatment by developing a best-in-disease, oral KIT inhibitor therapy that targets mast cells, which play a crucial role in the disease. As mast cells are involved in other allergic diseases, this approach may be leveraged for future programs in other immunology indications.
    - Preclinical optimization of Enanta's potent and selective oral KIT inhibitors for CSU is ongoing. The company anticipates selecting a CSU development candidate in the fourth quarter of 2024 and plans to move into the clinic shortly thereafter.
- Enanta plans to expand its presence in immunology and introduce a second program in 2024.

Corporate

- In April, Enanta announced the appointment of Matthew P. Kowalsky, J.D., as its Chief Legal Officer. Mr. Kowalsky brings more than 20 years of experience in the life sciences industry handling legal matters across a range of disciplines, including corporate governance, public company reporting, intellectual property, financing, business development and M&A activities. As Enanta's Chief Legal Officer, he will lead all legal and compliance activities for the company and provide strategic guidance and corporate governance oversight. Prior to joining Enanta, Mr. Kowalsky held legal and operational roles of increasing responsibility at Sigilon Therapeutics, Inc., until its acquisition by Eli Lilly.

Upcoming Events and Presentations

- JMP Securities Life Sciences Conference, May 14, 2024
- Jefferies Healthcare Conference, June 5, 2024
- Enanta plans to issue its fiscal third quarter financial results press release on August 5, 2024.

Conference Call and Webcast Information

Enanta will host a conference call and webcast today at 4:30 p.m. ET. The live webcast can be accessed at "Events & Presentations" in the investors section of Enanta's website. To participate by phone, please register for the call here. It is recommended that participants register a minimum of 15 minutes before the call. Once registered, participants will receive an email with the dial-in information. The archived webcast will be available on Enanta's website for approximately 30 days following the event.

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 with an emphasis on indications in virology and immunology. Enanta's research and development programs are currently focused on respiratory syncytial virus (RSV) and chronic spontaneous urticaria (CSU) and the company has previously advanced clinical-stage compounds for SARS-CoV-2 (COVID-19) and chronic hepatitis B virus (HBV) infection.

Glecaprevir, a protease inhibitor discovered by Enanta, is part of one of the leading treatment regimens for curing chronic hepatitis c virus (HCV) infection and is sold by AbbVie in numerous countries under the tradenames MAVYRET® (U.S.) and MAVIRET® (ex-U.S.) (glecaprevir/pibrentasvir). A portion of Enanta's royalties from HCV products developed under its collaboration with AbbVie contribute ongoing funding to Enanta's operations.

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 and its preclinical program in CSU. 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 vaccines and competitive treatments for RSV and CSU; the discovery and development risks of Enanta's programs in virology and immunology; 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 Form 10-K for the fiscal year ended September 30, 2023, 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.

Tables to Follow

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,	
	2024	2023	2024	2023
Revenue	$ 17,054	$ 17,795	$ 35,057	$ 41,380
Operating expenses				
Research and development	35,585	43,468	71,956	84,370
General and administrative	14,235	13,778	30,753	26,474
Total operating expenses	49,820	57,246	102,709	110,844
Loss from operations	(32,766)	(39,451)	(67,652)	(69,464)
Interest expense	(2,563)	—	(6,004)	—
Interest and investment income, net	3,809	1,837	8,107	2,830
Loss before income taxes	(31,520)	(37,614)	(65,549)	(66,634)
Income tax benefit (expense)	363	(44)	985	(10)
Net loss	$ (31,157)	$ (37,658)	$ (64,564)	$ (66,644)
Net loss per share				
Basic	$ (1.47)	$ (1.79)	$ (3.06)	$ (3.19)
Diluted	$ (1.47)	$ (1.79)	$ (3.06)	$ (3.19)
Weighted average common shares outstanding				
Basic	21,167	21,035	21,128	20,882
Diluted	21,167	21,035	21,128	20,882

CONDENSED CONSOLIDATED BALANCE SHEETS
UNAUDITED
(in thousands)

	March 31, 2024	September 30, 2023
Assets		
Current assets		
Cash and cash equivalents	$ 63,542	$ 85,388
Short-term marketable securities	236,768	284,522
Accounts receivable	7,756	8,614
Prepaid expenses and other current assets	10,932	13,263
Income tax receivable	32,031	31,004
Total current assets	351,029	422,791
Property and equipment, net	15,479	11,919
Operating lease, right-of-use assets	42,894	22,794

Restricted cash	3,968	3,968
Other long-term assets	187	803
Total assets	$ 413,557	$ 462,275
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 6,726	$ 4,097
Accrued expenses and other current liabilities	10,630	18,339
Liability related to the sale of future royalties	33,671	35,076
Operating lease liabilities	3,581	5,275
Total current liabilities	54,608	62,787
Liability related to the sale of future royalties, net of current portion	147,776	159,429
Operating lease liabilities, net of current portion	43,412	21,238
Series 1 nonconvertible preferred stock	1,423	1,423
Other long-term liabilities	224	663
Total liabilities	247,443	245,540
Total stockholders' equity	166,114	216,735
Total liabilities and stockholders' equity	$ 413,557	$ 462,275

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