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): August 05, 2024

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)		**(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, par value $0.01 per share	ENTA	Nasdaq Global Select Market

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 August 5, 2024, Enanta Pharmaceuticals, Inc. announced via press release its results for the fiscal quarter ended June 30, 2024. 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.

Exhibit Number	Description
99.1	Press Release of Enanta Pharmaceuticals, Inc. dated August 5, 2024, reporting Enanta's financial results for the fiscal quarter ended June 30, 2024
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: August 5, 2024

By: /s/ Paul J. Mellett

Paul J. Mellett
Chief Financial and Administrative Officer

Exhibit 99.1

Enanta Pharmaceuticals Reports Financial Results for its Fiscal Third Quarter

- *Announces Completion of Enrollment of RSVPEDs, a Phase 2 Study of Zelicapavir in Pediatric Respiratory Syncytial Virus (RSV) Patients; On Track to Report Topline Data in Q4 2024*
- *Announces Completion of EDP-323 Phase 2a Challenge Study in RSV; On Track to Report Topline Data in Late Q3 2024*
- *Operations Supported by Cash and Marketable Securities Totaling $272.6 Million at June 30, 2024, as well as Continuing Retained Royalties*

WATERTOWN, Mass., August 5, 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 third quarter ended June 30, 2024.

“We are thrilled to announce that we have completed enrollment of RSVPEDs, our first-in-pediatrics study of zelicapavir, an N-protein inhibitor, and anticipate reporting topline data next quarter. We thank all the patients, caregivers and investigators involved in this important study for pediatric health,” said Jay R. Luly, Ph.D., President and Chief Executive Officer at Enanta Pharmaceuticals. “This is a key milestone in the ongoing advancement of our robust clinical RSV portfolio, aimed at addressing the significant unmet need in populations at high risk for severe outcomes from RSV. As we advance two potentially first-in-class oral antiviral replication inhibitors with differentiated mechanisms of action, our potent L-protein inhibitor, EDP-323, has completed the Phase 2a human challenge study and we remain on track to announce topline data this quarter.”

Fiscal Third Quarter Ended June 30, 2024 Financial Results
Total revenue for the three months ended June 30, 2024 was $18.0 million and consisted of royalty revenue from worldwide net sales of AbbVie’s hepatitis C virus (HCV) regimen MAVYRET®/MAVIRET® (glecaprevir/pibrentasvir), compared to $18.9 million for the three months ended June 30, 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 $2.4 million for the three months ended June 30, 2024.

Research and development expenses totaled $28.7 million for the three months ended June 30, 2024, compared to $43.0 million for the three months ended June 30, 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 immunology programs.

General and administrative expenses totaled $13.4 million for the three months ended June 30, 2024, compared to $12.6 million for the three months ended June 30, 2023. The increase was primarily due to an increase in legal expenses related to the company's patent infringement lawsuit against Pfizer.

Enanta recorded income tax benefit of $0.4 million for the three months ended June 30, 2024, due to interest earned on a pending $28.0 million federal income tax refund, compared to an income tax expense of $4.2 million for the three months ended June 30, 2023, driven by the receipt of the $200.0 million from the royalty sale agreement in April 2023 which was taxable for federal and state purposes.

Net loss for the three months ended June 30, 2024 was $22.7 million, or a loss of $1.07 per diluted common share, compared to a net loss of $39.1 million, or a loss of $1.86 per diluted common share, for the corresponding period in 2023.

Enanta's cash, cash equivalents and short-term and long-term marketable securities totaled $272.6 million at June 30, 2024. Enanta expects that its current cash, cash equivalents and marketable securities and its continuing portion of cash from future royalty revenue, should 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 progressing multiple clinical programs comprising a robust antiviral portfolio aimed at treating 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 Phase 2 clinical trials in high-risk pediatric and adult populations.
        - Enrollment is now complete in RSVPEDs, 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. Enanta anticipates reporting topline data in the fourth quarter 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 is targeting enrollment completion in the upcoming Northern Hemisphere RSV season.

- Enanta completed its Phase 2a challenge study of EDP-323 and is on track to announce topline data in late third quarter. This randomized, double-blind, placebo-controlled, human challenge study evaluated the safety, pharmacokinetics, and changes in viral load measurements and symptoms in healthy adult subjects who were infected with RSV.

Immunology

- Enanta continues to advance its initial immunology program aimed at developing KIT inhibitors to treat chronic spontaneous urticaria (CSU), a highly debilitating inflammatory skin disease characterized by severe and recurrent hives that can last for years. Enanta's goal is to address the significant unmet need in CSU treatment by developing an oral KIT inhibitor therapy that targets mast cells, which play a crucial role in the disease, and potentially other mast cell driven diseases.
  - Preclinical optimization of Enanta’s potent and selective oral KIT inhibitors is ongoing. The company continues to evaluate multiple compounds with the goal of nominating a best-in-class clinical candidate in the fourth quarter of 2024.
- Enanta plans to expand its presence in immunology with the introduction of a second program in the fourth quarter of 2024.

Corporate

- Enanta will not be holding a conference call with today’s quarterly update. The company will provide its next update with the release of the EDP-323 challenge study results, expected in late third quarter of 2024.

Upcoming Events and Presentations

- H.C. Wainwright Annual Global Investment Conference, September 10, 2024
- Baird Global Healthcare Conference, September 11, 2024
- Cantor Global Healthcare Conference, September 17, 2024
- Enanta plans to issue its full year and fiscal fourth quarter financial results press release on November 25, 2024.

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.

Media and Investors Contact:
Jennifer Viera
jviera@enanta.com

#

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

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
Revenue	$ 17,971	$ 18,892	$ 53,028	$ 60,272
Operating expenses				
Research and development	28,742	42,987	100,698	127,357
General and administrative	13,414	12,618	44,167	39,092
Total operating expenses	42,156	55,605	144,865	166,449
Loss from operations	(24,185)	(36,713)	(91,837)	(106,177)
Interest expense	(2,355)	(1,997)	(8,359)	(1,997)
Interest and investment income, net	3,487	3,866	11,594	6,696
Loss before income taxes	(23,053)	(34,844)	(88,602)	(101,478)
Income tax benefit (expense)	395	(4,221)	1,380	(4,231)
Net loss	$ (22,658)	$ (39,065)	$ (87,222)	$ (105,709)
Net loss per share				
Basic	$ (1.07)	$ (1.86)	$ (4.12)	$ (5.05)
Diluted	$ (1.07)	$ (1.86)	$ (4.12)	$ (5.05)
Weighted average common shares outstanding				
Basic	21,180	21,054	21,145	20,939
Diluted	21,180	21,054	21,145	20,939

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

	June 30, 2024	September 30, 2023
Assets		
Current assets		
Cash and cash equivalents	$ 35,775	$ 85,388
Short-term marketable securities	194,310	284,522
Accounts receivable	8,176	8,614
Prepaid expenses and other current assets	15,260	13,263
Income tax receivable	32,455	31,004
Short-term restricted cash	608	—
Total current assets	286,584	422,791
Long-term marketable securities	42,510	-
Property and equipment, net	25,051	11,919
Operating lease, right-of-use assets	41,211	22,794
Long-term restricted cash	3,360	3,968
Other long-term assets	105	803
Total assets	$ 398,821	$ 462,275
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 10,675	$ 4,097
Accrued expenses and other current liabilities	12,830	18,339
Liability related to the sale of future royalties	32,295	35,076
Operating lease liabilities	2,431	5,275
Total current liabilities	58,231	62,787
Liability related to the sale of future royalties, net of current portion	141,889	159,429
Operating lease liabilities, net of current portion	48,136	21,238
Series 1 nonconvertible preferred stock	1,423	1,423
Other long-term liabilities	227	663
Total liabilities	249,906	245,540
Total stockholders' equity	148,915	216,735
Total liabilities and stockholders' equity	$ 398,821	$ 462,275