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): February 07, 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 February 7, 2024, Enanta Pharmaceuticals, Inc. announced via press release its results for the fiscal quarter ended December 31, 2023. 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 February 7, 2024, reporting Enanta's financial results for the fiscal quarter ended December 31, 2023
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: February 7, 2024

By: /s/ Paul J. Mellett
Paul J. Mellett
Chief Financial and Administrative Officer

Enanta Pharmaceuticals Reports Financial Results for its Fiscal First Quarter Ended December 31, 2023 with Webcast and Conference Call Today at 4:30 p.m. ET

- *Enrollment Ongoing Across Three RSV Phase 2 Studies; Anticipates Announcing Topline Data for RSVPEDs and EDP-323 Challenge Study in Q3 2024*
- *Expanded into Immunology with New Discovery Program of Oral KIT Inhibitors for First Indication in Chronic Spontaneous Urticaria; Development Candidate Selection Targeted for 2024*
- *Cash and Marketable Securities Totaled $337.2 Million at December 31, 2023*

WATERTOWN, Mass., February 7, 2024 – Enanta Pharmaceuticals, Inc. (NASDAQ:ENTA), a clinical-stage biotechnology company dedicated to creating small molecule drugs in virology and immunology , today reported financial results for its fiscal first quarter ended December 31, 2023.

“In 2024, Enanta began a year which will be marked by execution and value creation across the company. We are preparing for multiple catalysts across our pipeline in 2024, starting with RSV, where we anticipate reporting topline data from the RSVPEDs Phase 2 study of zelicapavir, pending the continuation of a normal Northern Hemisphere RSV season, and the Phase 2a challenge study of EDP-323, in the third quarter of this year,” said Jay R. Luly, Ph.D., President and Chief Executive Officer at Enanta Pharmaceuticals. “Beyond RSV, we are excited to leverage our experience in virology and expertise in small molecule drug discovery to develop a robust immunology program, starting with our first program of KIT inhibitors for the treatment of chronic spontaneous urticaria (CSU), a severely debilitating chronic inflammatory skin disease. We are driven to help the millions of patients impacted by CSU and potentially other mast-cell-driven indications. Furthermore, we plan to expand more broadly into immune-mediated chronic diseases with high unmet need, with the announcement of a second program in 2024. To that end, we will continue to innovate and strengthen our pipeline, sustained by a solid cash position that will support the company well beyond a catalyst-rich 2024.”

Fiscal First Quarter Ended December 31, 2023 Financial Results

Total revenue for the three months ended December 31, 2023 was $18.0 million and consisted of royalty revenue from worldwide net sales of MAVYRET®/MAVIRET®, AbbVie’s eight-week treatment for chronic hepatitis C virus (HCV). For the three months ended December 31, 2022, total revenue was $23.6 million and was primarily related to royalties on AbbVie’s sales of MAVYRET®/MAVIRET®.

Beginning with the quarter ended September 30, 2023, 54.5% of Enanta’s ongoing royalties from AbbVie’s net sales of MAVYRET®/MAVIRET® are being paid to OMERS, one of Canada’s largest defined benefit pension plans, pursuant to a royalty sale transaction in April 2023. For financial reporting purposes, the transaction was treated as debt, with the upfront purchase payment of $200.0 million recorded as a liability. Enanta will continue to record 100% of the royalty earned as revenue and will

then amortize the debt liability proportionally as 54.5% of the cash royalty payments are paid to OMERS, until a cap of 1.42 times the purchase payment is met, after which point 100% of the cash royalty payments will be retained by Enanta. Interest expense from the royalty sale was $3.4 million for the three months ended December 31, 2023.

Research and development expenses totaled $36.4 million for the three months ended December 31, 2023, compared to $40.9 million for the three months ended December 31, 2022. 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.

General and administrative expenses totaled $16.5 million for the three months ended December 31, 2023, compared to $12.7 million for the three months ended December 31, 2022. This increase was due to an increase in stock compensation expense and an increase in legal fees related to the company's patent infringement suit against Pfizer.

Enanta recorded an income tax benefit of $0.6 million for the three months ended December 31, 2023, for interest earned on a pending $28 million federal income tax refund, compared to an income tax benefit of less than $0.1 million for the three months ended December 31, 2022.

Net loss for the three months ended December 31, 2023 was $33.4 million, or a loss of $1.58 per diluted common share, compared to a net loss of $29.0 million, or a loss of $1.39 per diluted common share, for the corresponding period in 2022.

Enanta's cash, cash equivalents and short-term marketable securities totaled $337.2 million at December 31, 2023. 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 fiscal year 2027.

Virology

Respiratory Syncytial Virus (RSV)

- Enanta aims to develop a first and leading RSV antiviral treatment portfolio to help all populations at high risk for severe outcomes from RSV. This currently includes zelicapavir, Enanta's lead, oral, N-protein inhibitor (formerly known as EDP-938), which is being evaluated in two ongoing Phase 2 studies, RSVPEDs and RSVHR and EDP-323, an oral, L-protein inhibitor.
    - RSVPEDs is a Phase 2, randomized, double-blind, placebo-controlled study of zelicapavir in hospitalized and non-hospitalized pediatric RSV patients.
    - 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.
    - Based on current enrollment trends, Enanta anticipates reporting data from RSVPEDs in the third quarter of 2024, if this winter continues to be a more normal RSV season in the

Northern Hemisphere. The Company will provide additional guidance on the RSVHR study as the season continues.

- Enanta's second RSV candidate EDP-323 is on track to report topline data from its ongoing Phase 2a challenge study in the third quarter of 2024. In this randomized, double-blind, placebo-controlled, human challenge study the safety, pharmacokinetics (PK), and changes in viral load measurements and symptoms will be evaluated in up to 114 healthy adult subjects who will be infected with RSV. EDP-323 is supported by Phase 1 data which demonstrated favorable safety, tolerability, and PK indicative of once-daily dosing, with high exposure multiples.

Immunology

Chronic Spontaneous Urticaria (CSU)

- In January, Enanta announced its expansion into immunology with a first program focused on KIT inhibitors for the treatment of CSU, a severely debilitating, chronic inflammatory skin disease characterized by hives, with limited effective oral treatment options. The company aims to address the significant unmet need in CSU by developing a best-in-disease, oral KIT inhibitor treatment to reduce the number of mast cells, which are the primary driver of the disease. As mast cells are implicated in multiple allergic diseases, this approach will allow for follow-on programs in other immunology indications.
- Enanta's prototype oral inhibitors exhibit potent inhibition of KIT in binding and cellular functional assays, are highly selective for KIT versus other kinases and demonstrate good *in vitro* and *in vivo* ADME properties. Preclinical optimization of Enanta's potent and selective oral KIT inhibitors is ongoing and the company is targeting a development candidate selection in late 2024, as well as plans to introduce a second immunology program in 2024.

Upcoming Events

- Oppenheimer 34th Annual Healthcare Life Sciences Conference, February 13, 2024
- Leerink Global Biopharma Conference 2024, March 13, 2024
- Enanta plans to issue its fiscal second quarter financial results press release, and hold a conference call regarding those results, on May 6, 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 under "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 RSV and CSU; 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 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.

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

		Three Months Ended December 31,	
		2023	**2022**
Revenue		$ 18,003	$ 23,585
Operating expenses			
Research and development		36,371	40,902
General and administrative		16,518	12,696
Total operating expenses		52,889	53,598
Loss from operations		(34,886)	(30,013)
Interest expense		(3,441)	—
Interest and investment income, net		4,298	993
Loss before income taxes		(34,029)	(29,020)
Income tax benefit		622	34
Net loss		$ (33,407)	$ (28,986)
Net loss per share			
	Basic	$ (1.58)	$ (1.39)
	Diluted	$ (1.58)	$ (1.39)
Weighted average common shares outstanding			
	Basic	21,088	20,816
	Diluted	21,088	20,816

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

	December 31, 2023	September 30, 2023
Assets		
Current assets		
Cash and cash equivalents	$ 39,933	$ 85,388
Short-term marketable securities	297,218	284,522
Accounts receivable	8,173	8,614
Prepaid expenses and other current assets	13,245	13,263
Income tax receivable	31,734	31,004
Total current assets	390,303	422,791
Property and equipment, net	12,119	11,919
Operating lease, right-of-use assets	21,344	22,794
Restricted cash	3,968	3,968
Other long-term assets	765	803
Total assets	$ 428,499	$ 462,275
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 9,326	$ 4,097
Accrued expenses and other current liabilities	11,603	18,339
Liability related to the sale of future royalties	36,512	35,076
Operating lease liabilities	4,966	5,275
Total current liabilities	62,407	62,787
Liability related to the sale of future royalties, net of current portion	151,612	159,429
Operating lease liabilities, net of current portion	20,524	21,238
Series 1 nonconvertible preferred stock	1,423	1,423
Other long-term liabilities	649	663
Total liabilities	236,615	245,540
Total stockholders' equity	191,884	216,735
Total liabilities and stockholders' equity	$ 428,499	$ 462,275