UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2024

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission File Number 001-35839

ENANTA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

DELAWARE	**04-3205099**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
500 Arsenal Street Watertown, Massachusetts	**02472**
(Address of principal executive offices)	**(Zip Code)**

(Registrants telephone number, including area code:) (617) 607-0800

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☒
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. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of August 5, 2024, the registrant had 21,188,571 shares of common stock, $0.01 par value per share, outstanding.

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NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q ("Quarterly Report") contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act") about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this Quarterly Report, including statements regarding our future results of operations and financial condition, business strategy and plans and objectives of management for future operations, are forward-looking statements. In some cases, forward-looking statements may be identified by words such as "anticipate," "believe," "continue," "could," "design," "estimate," "expect," "intend," "may," "plan," "potentially," "predict," "project," "should," "will" or the negative of these terms or other similar expressions. We caution you that the foregoing list may not encompass all of the forward-looking statements made in this Quarterly Report.

Forward-looking statements are based on our management's beliefs and assumptions and on information currently available. These forward-looking statements are subject to a number of known and unknown risks, uncertainties and assumptions, including risks described in the section titled "Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended September 30, 2023, our subsequently filed Quarterly Reports on Form 10-Q and as updated in Item 1A herein.

PART I—UNAUDITED FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

ENANTA PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)
(in thousands, except per share data)

	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
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Common stock; $0.01 par value per share, 100,000 shares authorized; 21,182 and 21,059 shares issued and outstanding at June 30, 2024 and September 30, 2023, respectively	212	211
Additional paid-in capital	443,573	424,693
Accumulated other comprehensive loss	(653)	(1,174)
Accumulated deficit	(294,217)	(206,995)
Total stockholders' equity	148,915	216,735
Total liabilities and stockholders' equity	$ 398,821	$ 462,275

The accompanying notes are an integral part of these condensed consolidated financial statements.

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

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2024	2023	2024	2023
Revenue				
Royalty revenue	$ 17,971	$ 18,892	$ 53,028	$ 59,272
License revenue	—	—	—	1,000
Total 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)
Other income (expense):				
Interest expense	(2,355)	(1,997)	(8,359)	(1,997)
Interest and investment income, net	3,487	3,866	11,594	6,696
Total other income, net	1,132	1,869	3,235	4,699
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 and diluted	$ (1.07)	$ (1.86)	$ (4.12)	$ (5.05)
Weighted average common shares outstanding, basic and diluted	21,180	21,054	21,145	20,939

The accompanying notes are an integral part of these condensed consolidated financial statements.

ENANTA PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(unaudited)
(in thousands)

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2024	2023	2024	2023
Net loss	$ (22,658)	$ (39,065)	$ (87,222)	$ (105,709)
Other comprehensive income:				
Net unrealized gain on marketable securities	14	311	521	2,220
Total other comprehensive income	14	311	521	2,220
Comprehensive loss	$ (22,644)	$ (38,754)	$ (86,701)	$ (103,489)

The accompanying notes are an integral part of these condensed consolidated financial statements.

ENANTA PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(unaudited)
(in thousands)

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Loss	Deficit	Equity
Balances, September 30, 2023	21,059	$ 211	$ 424,693	$ (1,174)	$ (206,995)	$ 216,735
Vesting of restricted stock units, net of withholding	97	1	(184)	—	—	(183)
Stock-based compensation expense	—	—	8,099	—	—	8,099
Other comprehensive income	—	—	—	640	—	640
Net loss	—	—	—	—	(33,407)	(33,407)
Balances, December 31, 2023	21,156	$ 212	$ 432,608	$ (534)	$ (240,402)	$ 191,884
Exercise of stock options	6	—	51	—	—	$ 51
Vesting of restricted stock units, net of withholding	17	—	(92)	—	—	(92)
Stock-based compensation expense	—	—	5,561	—	—	5,561
Other comprehensive loss	—	—	—	(133)	—	(133)
Net loss	—	—	—	—	(31,157)	(31,157)
Balances, March 31, 2024	21,179	$ 212	$ 438,128	$ (667)	$ (271,559)	$ 166,114
Exercise of stock options	3	—	28	—	—	28
Stock-based compensation expense	—	—	5,417	—	—	5,417
Other comprehensive income	—	—	—	14	—	14
Net loss	—	—	—	—	(22,658)	(22,658)
Balances, June, 2024	21,182	$ 212	$ 443,573	$ (653)	$ (294,217)	$ 148,915

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Loss	Deficit	Equity
Balances, September 30, 2022	20,791	$ 208	$ 398,029	$ (3,724)	$ (73,179)	$ 321,334
Exercise of stock options	56	1	1,125	—	—	1,126
Vesting of restricted stock units, net of withholding	37	—	(825)	—	—	(825)
Stock-based compensation expense	—	—	7,139	—	—	7,139
Other comprehensive income	—	—	—	1,049	—	1,049
Net loss	—	—	—	—	(28,986)	(28,986)
Balances, December 31, 2022	20,884	$ 209	$ 405,468	$ (2,675)	$ (102,165)	300,837
Exercise of stock options	61	1	881	—	—	882
Vesting of restricted stock units, net of withholding	104	—	(2,909)	—	—	(2,909)
Stock-based compensation expense	—	—	7,363	—	—	7,363
Other comprehensive income	—	—	—	860	—	860
Net loss	—	—	—	—	(37,658)	(37,658)
Balances, March 31, 2023	21,049	$ 210	$ 410,803	$ (1,815)	$ (139,823)	269,375
Exercise of stock options	7	—	200	—	—	200
Stock-based compensation expense	—	—	6,998	—	—	6,998
Other comprehensive income	—	—	—	311	—	311
Net loss	—	—	—	—	(39,065)	(39,065)
Balances, June 30, 2023	21,056	$ 210	$ 418,001	$ (1,504)	$ (178,888)	$ 237,819

The accompanying notes are an integral part of these condensed consolidated financial statements.

ENANTA PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)
(in thousands)

	Nine Months Ended June 30,	
	2024	**2023**
Cash flows from operating activities		
Net loss	$ (87,222)	$ (105,709)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	19,077	21,500
Depreciation and amortization expense	1,857	1,702
Non-cash interest expense associated with the sale of future royalties	(620)	1,997
Non-cash royalty revenue	514	—
Premium paid on marketable securities	—	(73)
Amortization (accretion) of premiums (discounts) on marketable securities	64	(2,792)
Loss on disposal of property and equipment	—	7
Change in operating assets and liabilities:		
Accounts receivable	438	1,426
Prepaid expenses and other current assets	(1,997)	(3,626)
Income tax receivable	(1,451)	2,801
Operating lease, right-of-use assets	4,558	3,187
Other long-term assets	698	(134)
Accounts payable	1,124	2,682
Accrued expenses	(6,047)	(3,350)
Operating lease liabilities	1,079	(1,142)
Other long-term liabilities	(436)	(28)
Net cash used in operating activities	(68,364)	(81,552)
Cash flows from investing activities		
Purchase of marketable securities	(307,283)	(267,274)
Proceeds from maturities and sale of marketable securities	355,442	209,550
Purchase of property and equipment	(8,997)	(7,690)
Net cash provided by (used in) investing activities	39,162	(65,414)
Cash flows from financing activities		
Payments on royalty sale liability, net of imputed interest	(20,215)	—
Proceeds from the sale of future royalties	—	200,000
Payments for debt issuance costs	—	(325)
Payments for settlement of share-based awards	(275)	(3,734)
Proceeds from the exercise of stock options	79	2,208
Net cash provided by (used in) financing activities	(20,411)	198,149
Net increase (decrease) in cash, cash equivalents and restricted cash	(49,613)	51,183
Cash, cash equivalents and restricted cash at beginning of period	89,356	47,962
Cash, cash equivalents and restricted cash at end of period	$ 39,743	$ 99,145
Supplemental disclosure of non-cash information:		
Purchases of fixed assets included in accounts payable and accrued expenses	$ 6,416	$ 1,075
Operating lease liabilities arising from obtaining right-of-use assets	$ 22,975	$ 3,580
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 9,187	$ —
Cash received from tenant improvement allowances	$ 4,622	$ 1,994

The accompanying notes are an integral part of these condensed consolidated financial statements.

ENANTA PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)
(amounts in thousands, except per share data)

1. Nature of the Business and Basis of Presentation

Enanta Pharmaceuticals, Inc. (collectively with its subsidiary, the "Company"), incorporated in Delaware in 1995, is a biotechnology company that uses its robust, chemistry-driven approach and drug discovery capabilities to discover and develop small molecule drugs with an emphasis on virology and immunology indications. The Company discovered glecaprevir, the second of two protease inhibitors discovered and developed through its collaboration with AbbVie for the treatment of chronic infection with hepatitis C virus ("HCV"). Glecaprevir is co-formulated as part of AbbVie's leading direct-acting antiviral ("DAA") combination treatment for HCV, which is marketed under the tradenames MAVYRET® (U.S.) and MAVIRET®(ex-U.S.) (glecaprevir/pibrentasvir). The Company's existing financial resources, as well as the retained portion of its royalties from the AbbVie collaboration, provide funding to support the Company's wholly-owned research and development programs, which have been primarily focused on the following disease targets: respiratory syncytial virus ("RSV"), SARS-CoV-2, hepatitis B virus ("HBV") and chronic spontaneous urticaria ("CSU").

The Company is subject to many of the risks common to companies in the biotechnology industry, including but not limited to, the uncertainties of research and development, competition from technological innovations of others, dependence on collaborative arrangements, protection of proprietary technology, dependence on key personnel and compliance with government regulation. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approvals, prior to commercialization. These efforts require significant amounts of capital, adequate personnel and infrastructure, and extensive compliance reporting capabilities.

Unaudited Interim Financial Information

The condensed consolidated balance sheet as of September 30, 2023 was derived from audited financial statements but does not include all disclosures required by accounting principles generally accepted in the United States of America ("GAAP"). The accompanying unaudited condensed consolidated financial statements as of June 30, 2024 and for the three and nine months ended June 30, 2024 and 2023 have been prepared by the Company pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC") for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. These condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and the notes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2023.

In the opinion of management, all adjustments, consisting of normal recurring adjustments necessary for a fair statement of the Company's financial position as of June 30, 2024 and results of operations for the three and nine months ended June 30, 2024 and 2023 and cash flows for the nine months ended June 30, 2024 and 2023 have been made. The results of operations for the three and nine months ended June 30, 2024 are not necessarily indicative of the results of operations that may be expected for subsequent quarters or the year ending September 30, 2024.

The accompanying condensed consolidated financial statements have been prepared in conformity with GAAP. All amounts in the condensed consolidated financial statements and in the notes to the condensed consolidated financial statements, except per share amounts, are in thousands unless otherwise indicated.

The accompanying condensed consolidated financial statements have been prepared based on continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the ordinary course of business. The Company began reporting a net loss in fiscal 2020 and reported a net loss of $87,222 for the nine months ended June 30, 2024 and $133,816 for the year ended September 30, 2023. As of June 30, 2024, the Company had an accumulated deficit of $294,217. The Company expects to continue to generate operating losses for the foreseeable future as the Company continues to advance its wholly-owned programs. As of June 30, 2024, the Company had $272,595 in cash, cash equivalents and short-term and long-term marketable securities. The Company expects that its cash, cash equivalents and short-term and long-term marketable securities will be sufficient to fund its operating expenses and capital expenditure requirements for at least 12 months from the issuance date of the interim condensed consolidated financial statements. The Company may seek additional funding through equity offerings, non-dilutive financings, collaborations, strategic alliances or licensing agreements. The Company may not be able to obtain sufficient financing on acceptable terms, or at all, and the Company may not be able to enter into collaborations or other arrangements. The terms of any financing may adversely affect the holdings or the rights of the Company's stockholders. If the Company is unable to obtain funding, the Company could be forced to delay, reduce or eliminate some or all of its research and development programs, product expansion or commercialization efforts, or the Company may be unable to continue operations.

2. Summary of Significant Accounting Policies

For the Company's Significant Accounting Policies, please refer to its Annual Report on Form 10-K for the fiscal year ended September 30, 2023. Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements, and the reported amounts of revenues and expenses during the reporting period. Significant estimates and assumptions reflected in these condensed consolidated financial statements include, but are not limited to, management's judgments with respect to its revenue arrangements; liability related to the sale of future royalties; valuation of stock-based awards and the accrual of research and development expenses. Estimates are periodically reviewed in light of changes in circumstances, facts and experience.

Net Loss per Share

Basic net loss per common share is computed by dividing the net loss by the weighted average number of shares of common stock outstanding for the period. In periods in which the Company has reported a net loss, diluted net loss per common share is the same as basic net loss per common share since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. Therefore, the Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss as its effect would have been anti-dilutive:

	As of June 30,	
	2024	2023
	(in thousands)	
Options to purchase common stock	5,236	4,455
Unvested rTSRUs	92	81
Unvested PSUs	92	81
Unvested restricted stock units	436	423

Recently Issued Accounting Pronouncements

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which requires public entities to disclose information about their reportable segments' significant expenses and other segment items on an interim and annual basis. Public entities with a single reportable segment are required to apply the disclosure requirements in ASU 2023-07, as well as all existing segment disclosures and reconciliation requirements in ASC 280 on an interim and annual basis. This amendment is effective for the Company in the fiscal year beginning October 1, 2024, and interim periods within the fiscal year beginning October 1, 2025, on a retrospective basis with early adoption permitted. The Company is currently evaluating the potential impact that ASU 2023-07 may have on its financial statement disclosures.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which requires public entities, on an annual basis, to provide disclosure of specific categories in the rate reconciliation, as well as disclosure of income taxes paid disaggregated by jurisdiction. ASU 2023-09 is effective for the Company in the fiscal year beginning October 1, 2025, with early adoption permitted. The Company is currently evaluating the potential impact that ASU 2023-09 may have on its financial statement disclosures.

3. Fair Value of Financial Assets and Liabilities

The following tables present information about the Company's financial assets and liabilities that were subject to fair value measurement on a recurring basis as of June 30, 2024 and September 30, 2023, and indicate the fair value hierarchy of the valuation inputs utilized to determine such fair value:

	Fair Value Measurements as of June 30, 2024 Using:			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets:				
Cash equivalents:				
Money market funds	$ 35,519	$ —	$ —	$ 35,519
Marketable securities:				
U.S. Treasury notes	233,824	—	—	233,824
Corporate bonds	—	2,996	—	2,996
	$ 269,343	$ 2,996	$ —	$ 272,339
Liabilities:				
Series 1 nonconvertible preferred stock	$ —	$ —	$ 1,423	$ 1,423
	$ —	$ —	$ 1,423	$ 1,423

	Fair Value Measurements as of September 30, 2023 Using:			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets:				
Cash equivalents:				
Money market funds	$ 55,357	$ —	$ —	$ 55,357
U.S. Treasury notes	29,755	—	—	29,755
Marketable securities:				
U.S. Treasury notes	236,782	—	—	236,782
Corporate bonds	—	26,435	—	26,435
Commercial paper	—	21,305	—	21,305
	$ 321,894	$ 47,740	$ —	$ 369,634
Liabilities:				
Series 1 nonconvertible preferred stock	$ —	$ —	$ 1,423	$ 1,423
	$ —	$ —	$ 1,423	$ 1,423

During the three and nine months ended June 30, 2024 and 2023 there were no transfers between Level 1, Level 2 and Level 3.

The fair value of Level 2 instruments classified as marketable securities were determined through third-party pricing services. The pricing services use many observable market inputs to determine value, including reportable trades, benchmark yields, credit spreads, broker/dealer quotes, bids, offers, and current spot rates.

The outstanding shares of Series 1 nonconvertible preferred stock as of June 30, 2024 and September 30, 2023 are measured at fair value. These outstanding shares are financial instruments that might require a transfer of assets because of the liquidation features in the contract and are therefore recorded as liabilities and measured at fair value. The fair value of the outstanding shares is based on significant inputs not observable in the market, which represent a Level 3 measurement within the fair value hierarchy. The Company utilizes a probability-weighted valuation model which takes into consideration various outcomes that may require the Company to transfer assets upon liquidation. Changes in the fair values of the Series 1 nonconvertible preferred stock are recognized in other income (expense) in the condensed consolidated statements of operations.

The recurring Level 3 fair value measurements of the Company's outstanding Series 1 nonconvertible preferred stock using probability-weighted discounted cash flow include the following significant unobservable inputs:

	Range	
Unobservable Input	June 30, 2024	September 30, 2023
Probabilities of payout	0%-65%	0%-65%
Discount rate	7.25%	7.25%

There were no changes in the fair value of nonconvertible preferred stock during the three and nine months ended June 30, 2024 and 2023.

In April 2023, the Company entered into a royalty sale agreement with an affiliate of OMERS, pursuant to which the Company was paid a $200,000 cash purchase price in exchange for 54.5% of future quarterly royalty payments on net sales of MAVYRET/MAVIRET, after June 30, 2023, through June 30, 2032, subject to a cap on aggregate payments equal to 1.42 times the purchase price. The Company accounted for the upfront payment as a liability related to the sale of future royalties. The carrying value of the liability related to the sale of future royalties approximates fair value as of June 30, 2024 and is based on current estimates of future royalties expected to be paid to OMERS over the next 8 years, which are considered Level 3 inputs. See Note 8 for a rollforward of the liability.

4. Marketable Securities

As of June 30, 2024 and September 30, 2023, the fair value of available-for-sale marketable securities, by type of security, was as follows:

	June 30, 2024				
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Credit Losses	Fair Value
	(in thousands)				
U.S. Treasury notes	$ 234,092	$ 11	$ (279)	$ —	$ 233,824
Corporate bonds	2,997	—	(1)	—	2,996
	$ 237,089	$ 11	$ (280)	$ —	$ 236,820

	September 30, 2023				
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Credit Losses	Fair Value
	(in thousands)				
U.S. Treasury notes	$ 236,880	$ 12	$ (110)	$ —	$ 236,782
Corporate bonds	27,127	—	(692)	—	26,435
Commercial paper	21,305	—	—	—	21,305
	$ 285,312	$ 12	$ (802)	$ —	$ 284,522

As of June 30, 2024, marketable securities consisted of investments that mature within one year, with the exception of certain U.S. Treasury notes, which have maturities between one and two years and an aggregate fair value of $42,510. As of September 30, 2023, marketable securities consisted of investments that mature within one year.

5. Property and Equipment, Net

Property and equipment, net consisted of the following as of June 30, 2024 and September 30, 2023:

	June 30, 2024	September 30, 2023
	(in thousands)	
Laboratory and office equipment	$ 15,849	$ 15,891
Leasehold improvements	13,975	13,804
Purchased software	1,444	1,444
Furniture	3,117	2,290
Computer equipment	1,083	962
Construction in progress	14,795	1,273
	50,263	35,664
Less: Accumulated depreciation and amortization	(25,212)	(23,745)
	$ 25,051	$ 11,919

As of June 30, 2024, construction in progress related primarily to leasehold improvements for the new laboratory and office space located at 4 Kingsbury Avenue in Watertown, Massachusetts.

6. Accrued Expenses

Accrued expenses and other current liabilities consisted of the following as of June 30, 2024 and September 30, 2023:

	June 30, 2024	September 30, 2023
	(in thousands)	
Accrued professional fees	$ 2,006	$ 1,632
Accrued payroll and related expenses	4,793	7,037
Accrued research and development expenses	2,711	6,120
Accrued pharmaceutical drug manufacturing	1,581	3,083
Accrued other	1,739	467
	$ 12,830	$ 18,339

7. AbbVie Collaboration

The Company has a Collaborative Development and License Agreement (as amended, the "AbbVie Agreement"), with AbbVie to identify, develop and commercialize HCV NS3 and NS3/4A protease inhibitor compounds, including paritaprevir and glecaprevir, under which the Company has received license payments, proceeds from a sale of preferred stock, research funding payments, milestone payments and royalties totaling approximately $1,312,000 through June 30, 2024. Since the Company satisfied all of its performance obligations under the AbbVie Agreement by the end of fiscal 2011, all milestone payments received since then have been recognized as revenue when the milestones were achieved by AbbVie.

The Company is receiving annually tiered royalties per Company protease product ranging from ten percent up to twenty percent, or on a blended basis from ten percent up to the high teens, on the portion of AbbVie's calendar year net sales of each HCV regimen that is allocated to the protease inhibitor in the regimen. Beginning with each January 1, the cumulative net sales of a given royalty-bearing protease inhibitor product start at zero for purposes of calculating the tiered royalties on a product-by-product basis.

8. Liability Related to the Sale of Future Royalties

In April 2023, the Company entered into a royalty sale agreement with an affiliate of OMERS, pursuant to which the Company was paid a $200,000 cash purchase price in exchange for 54.5% of future quarterly royalty payments on net sales of MAVYRET/MAVIRET, after June 30, 2023, through June 30, 2032, subject to a cap on aggregate payments equal to 1.42 times the purchase price.

Because the royalty sale agreement will be paid back to OMERS up to a capped amount as well as the Company's significant continuing involvement in the generation of future cash flows under its AbbVie Agreement, the Company recorded the proceeds from the transaction as a liability on its condensed consolidated balance sheets which will be amortized as interest expense in the condensed consolidated statements of operations under the effective interest rate method over the life of the royalty sale agreement. The Company will continue to record the full amount of royalties earned on MAVYRET/MAVIRET sales as royalty revenue in the condensed consolidated statements of operations.

The Company's liability related to the sale of future royalties is estimated based on forecasted worldwide MAVYRET/MAVYRET royalties to be paid to OMERS over the course of the royalty sale agreement. This estimate requires significant judgment, including the amount and timing of royalty payments up until the end of the royalty sale agreement, which is estimated to be the stated term of June 30, 2032. As royalties are earned by OMERS, the liability is reduced on the Company's condensed consolidated balance sheets.

At June 30, 2024, the estimated future cash flows resulted in an effective annual imputed interest rate of approximately 5.6%.

The following table summarizes the activity of the liability related to the sale of future royalties:

	Liability related to the sale of future royalties
	(in thousands)
Balance - September 30, 2023	$ 194,505
Royalty payable to purchaser	(9,796)
Payments on royalty sale liability	(19,120)
Interest expense, net of capitalized interest	8,595
Balance - June 30, 2024	$ 174,184

9. Series 1 Nonconvertible Preferred Stock

As of June 30, 2024, 1,930 shares of Series 1 nonconvertible preferred stock were issued and outstanding. The outstanding shares are financial instruments that might require a transfer of assets because of the liquidation features in the contract and are carried at fair value as a liability on the Company's condensed consolidated balance sheets.

10. Stock-Based Awards

The Company grants stock-based awards, including stock options, restricted stock units and other unit awards under its 2019 Equity Incentive Plan (the "2019 Plan"), which was approved by its stockholders on February 28, 2019 and amended in March 2021, March 2022, March 2023 and March 2024, and its 2024 Inducement Stock Incentive Plan, which was adopted by the Board of Directors in April 2024 for awards to new employees. The Company also has outstanding stock option awards under its 2012 Equity Incentive Plan (the "2012 Plan") but is no longer granting awards under this plan.

The following table summarizes stock option activity, including performance-based options, for the year-to-date period ending June 30, 2024:

	Shares Issuable Under Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
	(in thousands)		(in years)	(in thousands)
Outstanding as of September 30, 2023	4,365	$ 52.68	5.9	$ —
Granted	1,357	9.98		
Exercised	(9)	8.99		
Forfeited	(477)	40.30		
Outstanding as of June 30, 2024	5,236	$ 42.82	6.5	$ 4,189
Options vested and expected to vest as of June 30, 2024	5,236	$ 42.82	6.5	$ 4,189
Options exercisable as of June 30, 2024	3,229	$ 51.79	5.1	$ 498

Market and Performance-Based Stock Unit Awards

The Company awards both performance share units, or PSUs, and relative total stockholder return units, or rTSRUs, to its executive officers. The number of units granted represents the target number of shares of common stock that may be earned; however, the actual number of shares that may be earned ranges from 0% to 150% of the target number. The number of shares cancelled represents the target number of shares, less any shares that vested. The following table summarizes PSU and rTSRU activity for the year-to-date period ending June 30, 2024:

	PSUs		rTSRUs	
	Shares	Weighted Average Grant Date Fair Value	Shares	Weighted Average Grant Date Fair Value
	(in thousands)		(in thousands)	
Unvested as of September 30, 2023	81	$ 58.58	81	$ 45.82
Granted	55	9.69	52	9.89
Vested	(25)	68.67	—	—
Cancelled	(19)	51.14	(41)	47.25
Unvested as of June 30, 2024	92	$ 27.98	92	$ 25.09

Restricted Stock Units

The following table summarizes the restricted stock unit activity for the year-to-date period ending June 30, 2024:

	Restricted Stock Units	Weighted Average Grant Date Fair Value
	(in thousands)	
Unvested as of September 30, 2023	411	$ 51.78
Granted	172	9.20
Vested	(116)	52.00
Cancelled	(31)	24.75
Unvested as of June 30, 2024	436	$ 36.81

Stock-Based Compensation Expense

During the three and nine months ended June 30, 2024 and 2023, the Company recognized the following stock-based compensation expense:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2024	2023	2024	2023
	(in thousands)			
Research and development	$ 1,738	$ 2,385	$ 5,587	$ 7,437
General and administrative	3,679	4,613	13,490	14,063
	$ 5,417	$ 6,998	$ 19,077	$ 21,500

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2024	2023	2024	2023
	(in thousands)			
Stock options	$ 3,632	$ 4,963	$ 11,805	$ 15,020
Restricted stock units	1,525	1,595	4,597	4,491
rTSRUs	260	440	963	1,447
Performance stock units	—	—	1,712	542
	$ 5,417	$ 6,998	$ 19,077	$ 21,500

During the nine months ended June 30, 2024 and 2023, the Company recognized stock-based compensation expense for performance-based stock units for which vesting became probable upon achievement of performance-based targets that occurred during the performance period.

As of June 30, 2024, the Company had an aggregate of $40,045 of unrecognized stock-based compensation cost, which is expected to be recognized over a weighted average period of 2.1 years.

11. Income Taxes

For the three and nine months ended June 30, 2024, the Company recorded an income tax benefit of $395 and $1,380, respectively, due to interest recorded on a pending federal income tax refund as compared to income tax expense of $4,221 and $4,231 during the three and nine months ended June 30, 2023, due to $200,000 received in April 2023 from the royalty sale agreement with OMERS which was taxable for federal and state purposes.

12. Commitments and Contingencies

Litigation and Contingencies Related to Use of Intellectual Property

From time to time, the Company may become subject to legal proceedings, claims and litigation arising in the ordinary course of business. Except as described below, the Company currently is not a party to any material threatened or pending litigation. However, third parties might allege that the Company or its collaborators are infringing their patent rights or that the Company is otherwise violating their intellectual property rights. Such third parties may resort to litigation against the Company or its collaborators, which the Company has agreed to indemnify. With respect to some of these patents, the Company expects that it will be required to obtain licenses and could be required to pay license fees or royalties, or both. These licenses may not be available on acceptable terms, or at all. A costly license, or inability to obtain a necessary license, would have a material adverse effect on the Company's financial condition, results of operations or cash flows. The Company accrues contingent liabilities when it is probable that future expenditures will be made and such expenditures can be reasonably estimated.

In June 2022, the Company announced that it filed suit in the United States District Court for the District of Massachusetts on June 21, 2022, against Pfizer, Inc. seeking damages for infringement of U.S. Patent No. 11,358,953 (the ’953 Patent) in the manufacture, use and sale of Pfizer’s COVID-19 antiviral, Paxlovid™ (nirmatrelvir tablets; ritonavir tablets). The United States Patent and Trademark Office awarded the '953 Patent to the Company in June 2022 based on the Company's July 2020 patent application describing coronavirus protease inhibitors invented by the Company. The Company is seeking fair compensation for Pfizer’s use of a coronavirus protease inhibitor claimed in the ‘953 patent. On May 28, 2024, the Company and Pfizer each filed motions for summary judgment and a hearing on the motions was held on July 31, 2024. The timing for a ruling on each of the motions for summary judgment is currently uncertain. The Company records all legal expenses associated with the patent infringement suit as incurred in the condensed consolidated statements of operations.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnifications of varying scope and terms to customers, vendors, lessors, business partners, and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from services to be provided to the Company, or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and its executive officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. In addition, the Company maintains directors’ and officers’ insurance coverage. The Company does not believe that the outcome of any claims under indemnification arrangements will have a material effect on its financial position, results of operations or cash flows, and has not accrued any liabilities related to such obligations in its condensed consolidated financial statements as of June 30, 2024.

Leases

The Company leases laboratory and office space under various non-cancelable operating leases.

In May 2022, the Company entered into a new ten-year lease agreement with its existing landlord for laboratory and office space in Watertown, Massachusetts, adjacent to its 400 Talcott Avenue premises. The new laboratory and office space is located at Arsenal on the Charles in Watertown, Massachusetts at 4 Kingsbury Avenue. Construction of the facility shell was completed by the landlord and the Company gained access to the building to construct tenant improvements during the three months ended March 31, 2024. The estimated minimum lease payments for the 4 Kingsbury Avenue facility total $76,470 over the ten-year term. The lease also contains a tenant improvement allowance of $15,205. The Company recorded a right-of-use asset of $32,499 and lease liability of $31,939 upon commencement of the lease during the three months ended March 31, 2024.

In conjunction with the new lease agreement at 4 Kingsbury Avenue, the Company amended its 500 Arsenal Street lease to shorten the term of the lease from September 2027 to the date the 4 Kingsbury Avenue facility is ready for the Company’s occupancy which is expected to be by the end of November 2024. The Company remeasured the lease term and remaining lease payments for the 500 Arsenal Street facility during the three months ended March 31, 2024 when the Company gained access to the 4 Kingsbury Avenue building. The Company recorded an adjustment to the right-of-use asset and lease liability for 500 Arsenal Street of $9,322 during the three months ended March 31, 2024.

The non-cash change arising from the new 4 Kingsbury Avenue lease, net of the remeasurement of the 500 Arsenal lease liability totaled $22,617 during the nine months ended June 30, 2024.

Future annual minimum facility and equipment lease payments, net of the tenant improvement allowance under the Company’s 4 Kingsbury Avenue lease, as of June 30, 2024, are as follows:

Years ended September 30,	(in thousands)
Remainder of fiscal 2024	$ 1,753
2025	8,223
2026	8,467
2027	8,721
2028	8,983
Thereafter	59,191
Total future minimum lease payments	95,338
Less: imputed interest	(33,786)
Less: tenant improvement allowance	(10,985)
Total operating lease liabilities	$ 50,567

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the unaudited condensed consolidated financial statements and notes thereto included elsewhere in this Quarterly Report on Form 10-Q, or Form 10-Q, and the audited consolidated financial statements and notes thereto for our fiscal year ended September 30, 2023 included in our Annual Report on Form 10-K for that fiscal year, which is referred to as our 2023 Form 10-K. Please refer to our note regarding forward-looking statements on page 2 of this Form 10-Q, which is incorporated herein by this reference.

The Enanta name and logo are our trademarks. This Form 10-Q also includes trademarks, trade names and service marks of other persons. All other trademarks, trade names and service marks appearing in this Form 10-Q are the property of their respective owners.

Overview

We are a biotechnology company that uses our robust, chemistry-driven approach and drug discovery capabilities to discover and develop small molecule drugs with an emphasis on virology and immunology indications. We discovered glecaprevir, the second of two protease inhibitors discovered and developed through our collaboration with AbbVie for the treatment of chronic infection with hepatitis C virus, or HCV. Glecaprevir is co-formulated as part of AbbVie's leading brand of direct-acting antiviral, or DAA, combination treatment for HCV, which is marketed under the tradenames MAVYRET® (U.S.) and MAVIRET® (ex-U.S.) (glecaprevir/pibrentasvir). The ongoing royalties from our AbbVie collaboration, combined with the proceeds from our 2023 royalty sale transaction, have provided us funding to support our wholly-owned research and development programs primarily focused on the following disease targets:

Virology:

- Respiratory syncytial virus, or RSV, the most common cause of bronchiolitis and pneumonia in young children and a significant cause of respiratory illness in older adults, with estimates suggesting that on average each year RSV leads to 3 million hospitalizations globally in children under 5 years old and 177,000 hospitalizations in the U.S. in adults over the age of 65;
- SARS-CoV-2, the virus that causes COVID-19, with estimates suggesting that COVID-19 continues to have a disease burden greater than influenza, including persistent cases of infection often referred to as long COVID and hospitalization and death among the elderly and those with comorbidities, while new variants continue to emerge on a regular basis; and
- Hepatitis B virus, or HBV, the most prevalent chronic hepatitis, which is estimated by the World Health Organization to affect close to 300 million individuals worldwide.

Immunology:

- Chronic spontaneous urticaria (CSU) is a severely debilitating, chronic inflammatory skin disease with no identified triggers. Clinical manifestations include hives, angioedema, or both. Patients with CSU also experience symptoms beyond the skin manifestations, including sleep disturbances, fatigue, irritability, anxiety and depression. The estimated global prevalence is between 0.5% – 1% of the population, which means that at any given time in the U.S. alone approximately 1.75-3.5 million people are experiencing this condition. Standard of care treatment for CSU is antihistamines, however in approximately half the patients, symptom alleviation is not adequate. There is a substantial unmet need for an efficacious oral agent as only a minority of these uncontrolled cases are treated with one indicated biologic (<28%).

As of June 30, 2024, we had $272.6 million in cash, cash equivalents and short-term and long-term marketable securities. We expect that our existing cash, cash equivalents, short-term and long-term marketable securities, as well as the cash flows from our retained portion of future HCV royalties will enable us to fund our operating expenses and capital expenditure requirements through the third quarter of fiscal 2027.

Our Wholly-Owned Programs

Our primary wholly-owned research and development programs are in virology and immunology. Our virology programs have been focused on RSV, SARS-CoV-2 and HBV and our immunology program is focused on oral inhibitors of the receptor tyrosine kinase

known as KIT for the treatment of CSU, and potentially other mast-cell-driven diseases. The programs currently in active development are in RSV and CSU.

Virology Programs:

- RSV: We have two clinical stage programs for RSV – zelicapavir (formerly EDP-938) and EDP-323. Both of these compounds are replication inhibitors that work by shutting down replication and the production of new virions, as opposed to the other mechanism in development of fusion inhibition that only blocks viral entry. Zelicapivir, which has Fast Track designation from the U.S. Food and Drug Administration, or FDA, is a potent inhibitor of the RSV N-protein being studied in two ongoing Phase 2 studies, each in a different patient population. EDP-323, which also has a Fast Track designation from the FDA is an inhibitor of the RSV L-protein that is currently in a Phase 2 challenge study.

    - *Zelicapavir - N-protein Inhibitor Candidate:* We have studied zelicapavir in two Phase 2 studies that were designed to be proof-of-concept and exploratory studies to understand the viral response in the context of RSV infection. With these studies, zelicapavir has demonstrated a favorable safety profile, consistent with that observed in over 500 subjects exposed to zelicapavir to date. These studies were conducted in otherwise healthy young adults (not at high-risk for serious outcomes with RSV) infected with RSV. The first study was a challenge study, in which healthy adults were infected with RSV in a clinical setting and statistically significant effects on viral load and symptoms were observed. The second study, known as RSVP, was in an otherwise healthy young adult outpatient population with community-acquired RSV infection and showed that this population resolves quickly from infection and is not in need of treatment. We believe that zelicapavir has the greatest potential to show optimal efficacy in high-risk populations since these patients have reduced RSV immunity, which manifests in a higher and longer duration of viral load and greater disease severity, allowing a bigger window to realize the full potential of zelicapavir. Based on its growing safety profile, we are continuing to evaluate zelicapavir in high-risk populations in the following ongoing clinical studies, including pediatric patients and high-risk adults, all of which have significant unmet need:

        - *RSVPEDs:* RSVPEDs is a Phase 2 study in approximately 90 pediatric patients, aged >28 days to <36 months. This dose-ranging, randomized, double-blind, placebo-controlled study, is evaluating multiple ascending doses for five days in two age cohorts to determine safety, tolerability, and pharmacokinetics, as well as a second part evaluating antiviral activity at the selected dose. In August 2024, we announced completion of enrollment of the RSVPEDs study. We anticipate reporting topline data in the fourth quarter of calendar 2024.

        - *RSVHR:* RSVHR is a Phase 2b study in high-risk adults, including those who are older than 65 years of age and those who have asthma, chronic obstructive pulmonary disease, or COPD, or congestive heart failure. Approximately 180 patients will be treated with zelicapavir or placebo for five days with a primary endpoint of time to resolution of RSV lower respiratory tract disease symptoms. Enrollment is progressing and the Company is targeting enrollment completion in the upcoming Northern Hemisphere RSV season.

    - *EDP-323 - L-protein Inhibitor Candidate:* Our second clinical RSV candidate, EDP-323, is a novel oral, direct-acting antiviral selectively targeting the RSV L-protein, a viral RNA-dependent RNA polymerase enzyme that contains multiple enzymatic activities required for RSV replication. EDP-323 has sub-nanomolar potency against RSV-A and RSV-B *in vitro* and protected mice in a dose-dependent manner from RSV infection as demonstrated by both virological and pathological endpoints. EDP-323 is not expected to have cross-resistance to other classes of inhibitors and has the potential to be used alone, or in combination with other RSV mechanisms, to broaden the treatment window or addressable patient populations. In June 2023, we completed a Phase 1 clinical study and reported positive topline results, which demonstrated that EDP-323 was safe and well-tolerated with pharmacokinetics supportive of once-daily dosing and target exposures achieved with no food effect. Based on these positive data, we initiated a Phase 2a challenge study of EDP-323 in the fourth quarter of calendar 2023. We completed our Phase 2a challenge study and are on track to announce topline data in late third quarter of calendar 2024.

- COVID-19: We leveraged our expertise in developing protease inhibitors to discover compounds specifically designed to target the SARS-CoV-2 virus and potentially other coronaviruses. We selected EDP-235, an oral inhibitor of the coronavirus 3CL protease, also referred to as 3CLpro or the main coronavirus protease, or Mpro, for clinical development. In addition to nanomolar activity against all SARS-CoV-2 variants tested to date, EDP-235 has potent antiviral activity against other human coronaviruses, enabling the potential for a pan-coronavirus treatment, including possibly coronaviruses that may infect human populations in the future. Furthermore, EDP-235 has good tissue distribution, and is projected to have four times higher drug levels in lung tissue compared to plasma. A robust treatment effect and

prevention of transmission was observed in a ferret model. A Phase 1 study demonstrated EDP-235 was generally safe and well-tolerated in doses up to 400 mg for seven days, adverse events were infrequent and mild, and pharmacokinetics were supportive of once-daily dosing without ritonavir and without regard to food and achieved target exposure levels of up to 13-fold over the plasma protein-adjusted EC_{90}. In May 2023, we reported topline results from a Phase 2 clinical trial of EDP-235 in non-hospitalized, symptomatic patients with mild to moderate COVID-19 who were not at increased risk for developing severe disease. EDP-235 met the primary endpoint of the trial and was generally safe and well-tolerated. A dose-dependent improvement in total symptom score was observed with EDP-235 treatment compared to placebo, which achieved statistical significance ($p<0.05$) in the 400 mg treatment group at multiple time points, starting as early as one day after the first dose. An analysis of a subset of six symptoms showed a two-day shorter time (5 days to 3 days) to improvement in patients receiving EDP-235 400 mg who were enrolled within three days of symptom onset ($p<0.01$). No effect on virologic endpoints as measured in the nose was detected due to the rapid viral decline in the placebo arm of this highly immunologically-experienced, standard risk population. However, in the subset of patients who were nucleocapsid seronegative (indicating no recent natural infection with SARS-CoV-2), a viral load decline was observed at day five in the 400 mg group of 0.8 log overall and 1 log in the patients with symptom onset within three days before treatment with EDP-235. We will continue to focus on potential collaborations to progress EDP-235, as we will not advance this candidate into Phase 3 studies on our own.

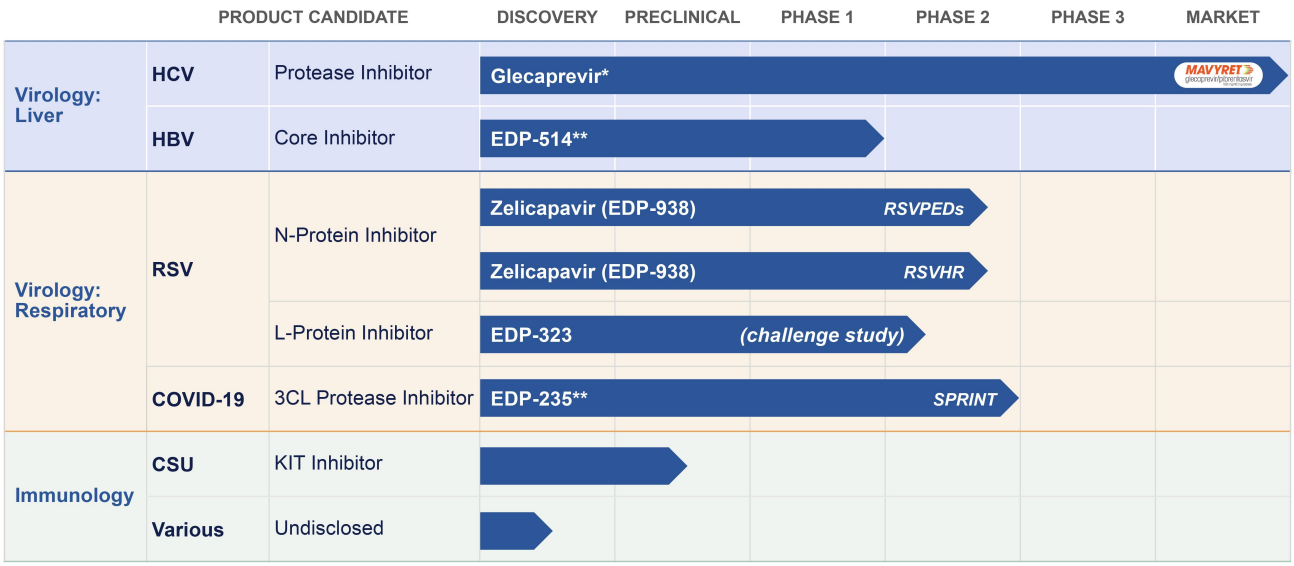
- HBV: Our lead clinical candidate for the treatment of chronic infection with hepatitis B virus, or HBV, is EDP-514, a core inhibitor that displays potent anti-HBV activity *in vitro* at multiple points in the HBV lifecycle. Our goal has been to develop a combination therapy approach, including existing approved treatments such as a nucleoside reverse transcriptase inhibitor, or NUC, with EDP-514 and one or more other mechanisms, which could lead to a functional cure for patients with chronic HBV infection. Final data from two Phase 1b studies of EDP-514 demonstrate the compound is safe with strong antiviral activity in two different chronic HBV patient populations – those who have a high viral load and those who are on a treatment with a nucleoside reverse transcriptase inhibitor. Advancement of this program is dependent upon our accessing another compound that could be developed with EDP-514 for such a treatment regimen.

Immunology Program:

- KIT: We have a discovery stage program to develop KIT inhibitors to treat CSU and potentially other indications by depleting mast cells, thereby addressing a primary driver of these diseases. We have discovered novel, potent and selective oral inhibitors of KIT, which are now being optimized in preclinical development. Our prototype inhibitors demonstrate potent nanomolar activity in both binding and cellular function assays and are highly selective for KIT versus other kinases. These inhibitors also demonstrate strong *in vitro* and *in vivo* ADME properties. We are continuing to evaluate multiple compounds in preclinical studies, including toxicology studies. Our goal is to select a lead development candidate in calendar Q4 2024.
- We plan to expand our presence in immunology with the introduction of a second program in the fourth quarter of calendar 2024.

We have utilized our internal chemistry and drug discovery capabilities to generate all of our development-stage programs. We continue to invest substantial resources in research programs to discover compounds targeting new disease areas.

The following table summarizes our product development pipeline in our virology and immunology programs:



*Fixed-dose antiviral combination contains glecaprevir and AbbVie's NS5A inhibitor, pibrentasvir. Marketed by AbbVie as MAVYRET® (U.S.) and MAVIRET® (ex-U.S.).
**Continued development dependent on a future collaboration.

Our Royalty Revenue Collaboration and Royalty Sale Agreement

Our royalty revenue is generated through our Collaborative Development and License Agreement with AbbVie, under which we have discovered and out-licensed to AbbVie two protease inhibitor compounds that have been clinically tested, manufactured, and commercialized by AbbVie as part of its combination regimens for HCV.

Glecaprevir is the HCV protease inhibitor we discovered that was developed by AbbVie in a fixed-dose combination with its NS5A inhibitor, pibrentasvir, for the treatment of chronic HCV. This patented combination, currently marketed under the brand names MAVYRET® (U.S.) and MAVIRET® (ex-U.S.), is referred to in this report as MAVYRET/MAVIRET. The first protease inhibitor developed through this collaboration, paritaprevir, is part of AbbVie's initial HCV regimens, which have been almost entirely replaced by MAVYRET/MAVIRET. Since August 2017, substantially all of our royalty revenue has been derived from AbbVie's net sales of MAVYRET/MAVIRET. Our ongoing royalty revenues from this regimen consist of annually tiered, double-digit, per-product royalties on 50% of the calendar year net sales of the 2-DAA glecaprevir/pibrentasvir combination in MAVYRET/MAVIRET. The annual royalty tiers return to the lowest tier for sales on and after each January 1.

In April 2023, we entered into a royalty sale agreement with an affiliate of OMERS, a Canadian public employee pension fund, pursuant to which we were paid a $200.0 million cash purchase price in exchange for 54.5% of our future quarterly royalty payments on net sales of MAVYRET/MAVIRET, after June 30, 2023, through June 30, 2032, subject to a cap on aggregate payments to OMERS equal to 1.42 times the purchase price.

For accounting purposes, we continue to record 100% of HCV royalties earned under the AbbVie agreement as royalty revenue in our condensed consolidated statements of operations. The $200.0 million received in April 2023 was recognized on our condensed consolidated balance sheets as a liability, which will be reduced by the payments made to OMERS over the term of the Agreement. We recognize imputed interest expense over the life of the royalty sale agreement based on our estimated future MAVYRET/MAVIRET royalties.

Financial Operations Overview

We are currently funding all research and development for our wholly-owned programs, which are targeted toward the discovery and development of novel compounds. As of the date of this report, we are conducting two Phase 2 studies for zelicapavir and a Phase 2 challenge study of EDP-323. We are also conducting preclinical discovery research efforts in other disease areas.

As a result of the timing of our clinical and preclinical development programs, we expect our research and development expenses will fluctuate from period to period. However, in the next 12 months, we expect our external research and development expenses generally to decrease since we will not conduct any further development of EDP-235 into Phase 3 studies and we have made important adjustments to reduce our spending significantly in 2024.

To date, we have funded our operations primarily through royalty payments received under our collaboration agreement with AbbVie, a $200.0 million payment received in April 2023 from our royalty sale agreement, and our existing cash, cash equivalents, and

short-term and long-term marketable securities. We believe that our existing cash, cash equivalents and short-term and long-term marketable securities, as well as the cash flows from our retained portion of future HCV royalties will enable us to fund our operating expenses and capital expenditure requirements through the third quarter of fiscal 2027.

Revenue

Our revenue is primarily derived from our collaboration agreement with AbbVie and AbbVie's sales of MAVYRET/MAVIRET, an 8-week treatment regimen for chronic HCV. During the first quarter of fiscal 2023, we also generated $1.0 million of license revenue from an upfront payment related to a license agreement for one of the antibacterial compounds we are no longer developing.

The following table is a summary of revenue recognized for the three and nine months ended June 30, 2024 and 2023:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2024	2023	2024	2023
	(in thousands)			
Revenue				
Royalty revenue	$ 17,971	$ 18,892	$ 53,028	$ 59,272
License revenue	—	—	—	1,000
Total revenue	$ 17,971	$ 18,892	$ 53,028	$ 60,272

AbbVie Agreement

To date, we have received annually tiered, double-digit royalties on our protease inhibitor product glecaprevir included in AbbVie's net sales of MAVYRET/MAVIRET. Under the terms of our AbbVie Agreement, 50% of AbbVie's net sales of MAVYRET/MAVIRET are allocated to glecaprevir. Beginning with each January 1, the cumulative net sales of MAVYRET/MAVIRET start at zero for purposes of calculating the tiered royalties. As disclosed above regarding the OMERS royalty sale agreement, we only retain 45.5% of the cash payments from royalties on net sales of MAVYRET/MAVIRET occurring after June 30, 2023 through June 30, 2032, subject to a cap on aggregate payments to OMERS equal to 1.42 times OMERS' purchase price.

Internal Programs

As our internal product candidates are currently in Phase 1 or Phase 2 clinical development, we have not generated any revenue from our own product sales. We do not expect to generate any revenue from product sales derived from these product candidates for at least the next several years.

Operating Expenses

Our operating expenses are comprised of research and development expenses and general and administrative expenses.

Research and Development Expenses

Research and development expenses consist of costs incurred to conduct basic research, such as the discovery and development of novel small molecules as therapeutics, as well as any external expenses of preclinical and clinical development activities. We expense all costs of research and development as incurred. These expenses consist primarily of:

- third-party contract costs relating to research, formulation, manufacturing, preclinical study, and clinical trial activities;
- personnel costs, including salaries, related benefits, and stock-based compensation for employees engaged in scientific research and development functions;
- allocated facility-related costs;
- laboratory consumables; and
- third-party license fees.

At any given time, we have later stage programs in clinical development as well as several active early-stage research and drug discovery projects. Our internal resources, employees and infrastructure are utilized across multiple projects, including our early-stage discovery projects. As such, we report information regarding costs incurred based on our programs (i.e., disease area) rather than on a project specific basis. All indirect costs are allocated to programs based on headcount and square footage of our facilities. We expect that our research and development expenses will fluctuate from period to period as we advance our research and development programs. To date, we have not identified any significant impact of inflation on spending in research and development, but it is uncertain whether there will be inflationary impacts in future periods.

Our research and drug discovery and development programs are in early stages; therefore, the successful development of our product candidates is highly uncertain and may not result in approved products. Completion dates and completion costs can vary significantly

for each product candidate and are difficult to predict. Given the uncertainty associated with clinical trial enrollments and the risks inherent in the development process, we are unable to determine the duration and completion costs of the current or future clinical trials of our product candidates or if, or to what extent, we will generate revenue from the commercialization and sale of any of our product candidates. We anticipate that we will make determinations as to which development programs to pursue and how much funding to direct to each program on an ongoing basis in response to the preclinical and clinical success and prospects of each product candidate, as well as ongoing assessments of the commercial potential of each product candidate.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel costs, which include salaries, related benefits and stock-based compensation, of our executive, finance, business and corporate development and other administrative functions. General and administrative expenses also include travel expenses, allocated facility-related costs not otherwise included in research and development expenses, directors' and officers' liability insurance premiums, professional fees for auditing, tax, and legal services, patent expenses and litigation expenses associated with prosecuting our patent infringement suit.

We expect that general and administrative expenses may increase in the long term. To date we have not experienced a significant impact of inflation on general and administrative expenses, but we anticipate inflation may impact future periods.

Other Income (Expense)

Other income (expense) consists of interest expense, interest and investment income, net and the change in fair value of our outstanding Series 1 nonconvertible preferred stock. Interest expense consists of the interest expense and amortization of debt issuance costs associated with the royalty sale agreement with an affiliate of OMERS. Interest income consists of interest earned on our cash equivalents and marketable securities balances. Investment income consists of the amortization or accretion of any purchased premium or discount, respectively, on our marketable securities. The change in fair value of our Series 1 nonconvertible preferred stock relates to the remeasurement of these financial instruments from period to period as these instruments may require a transfer of assets because of the liquidation preference features of the underlying instrument.

Income Tax Benefit (Expense)

Income tax benefit (expense) is based on our best estimate of taxable net income (loss), applicable income tax rates, net research and development tax credits and carryforwards, net operating loss carrybacks and interest earned on such refunds, changes in valuation allowance estimates and deferred income taxes.

Results of Operations

Comparison of the Three Months Ended June 30, 2024 and 2023

	Three Months Ended June 30,	
	2024	2023
	(in thousands)	
Revenue	$ 17,971	$ 18,892
Research and development	28,742	42,987
General and administrative	13,414	12,618
Interest expense	(2,355)	(1,997)
Interest and investment income, net	3,487	3,866
Income tax benefit (expense)	395	(4,221)
Net loss	$ (22,658)	$ (39,065)

Revenue

We recognized revenue of $18.0 million during the three months ended June 30, 2024 as compared to $18.9 million during the three months ended June 30, 2023. The $0.9 million decrease in revenue was primarily due to AbbVie's lower reported HCV sales as compared to the comparable period in 2023.

Our royalty revenues eligible to be earned in the future will depend on AbbVie's HCV market share, the pricing of the MAVYRET/MAVIRET regimen and the number of patients treated. In addition, at the beginning of each calendar year (the second quarter of our fiscal year), our royalty rate resets to the lowest tier for each of our royalty-bearing products licensed to AbbVie.

Beginning with the quarter ended September 30, 2023, 54.5% of our quarterly royalty payments on net sales of MAVYRET/MAVIRET that are included in our total revenue are paid to OMERS through June 30, 2032, subject to a cap on aggregate payments equal to 1.42 times the purchase price. The $200.0 million received in April 2023 was recognized on our condensed consolidated balance sheets as a liability which will be reduced by the payments made to OMERS over the term of the royalty sale agreement. We will continue to record 100% of HCV royalties earned under the AbbVie Agreement as royalty revenue in our condensed consolidated statements of operations since the AbbVie Agreement has not been amended and is independent of our agreement with OMERS.

Research and development expenses

	Three Months Ended June 30,	
	2024	2023
	(in thousands)	
R&D programs:		
Virology		
RSV	$ 17,935	$ 20,102
COVID-19	(112)	18,704
HBV	67	1,530
Total Virology	$ 17,890	$ 40,336
Immunology		
CSU	5,753	—
Total Immunology	$ 5,753	$ —
Other Programs		
NASH	92	809
Early discovery	5,007	1,842
Total Other Programs	$ 5,099	$ 2,651
Total research and development expenses	$ 28,742	$ 42,987

Research and development expenses for the three months ended June 30, 2024 decreased by $14.2 million compared to the same period in 2023.

Virology

The costs in our virology program decreased $22.4 million primarily due to a decrease in costs associated with our COVID-19 program as we stopped further internal development and will only progress the program in the context of one or more collaborations.

Immunology

The costs in our immunology programs increased by $5.8 million as this is a new therapeutic area of focus for the company.

Other Programs

Other program costs increased by $2.4 million as we focused on early-stage drug discovery programs, offset by a decrease in costs for our NASH program as we continued to wind down this program.

General and administrative expenses

General and administrative expenses increased by $0.8 million for the three months ended June 30, 2024 compared to the same period in 2023. The change was primarily due to an increase in legal expenses related to our patent infringement suit against Pfizer.

Other income (expense)

Changes in components of other income (expense) were as follows:

Interest expense

Interest expense increased $0.4 million for the three months ended June 30, 2024, as compared to the same period in 2023 due to interest expense and amortization of debt issuance costs associated with the royalty sale agreement entered into during April 2023 with an affiliate of OMERS.

Interest and investment income, net

Interest and investment income, net, decreased $0.4 million for the three months ended June 30, 2024, as compared to the same period in 2023. The decrease was due to lower cash and investment balances year over year.

Income tax benefit (expense)

During the three months ended June 30, 2024, we recorded an income tax benefit of $0.4 million representing interest recorded on a pending federal tax refund. The income tax expense during the three months ended June 30, 2023 was driven by the receipt of $200.0 million from the royalty sale agreement, which is taxable for federal and state purposes, partially offset by utilization of federal net operating losses and research and development tax credit carryforwards as well as a deduction for foreign derived intangible income.

Results of Operations

Comparison of the Nine Months Ended June 30, 2024 and 2023

	Nine Months Ended June 30,	
	2024	2023
	(in thousands)	
Revenue	$ 53,028	$ 59,272
License revenue	—	1,000
Research and development	100,698	127,357
General and administrative	44,167	39,092
Interest expense	(8,359)	(1,997)
Interest and investment income, net	11,594	6,696
Income tax benefit (expense)	1,380	(4,231)
Net loss	$ (87,222)	$ (105,709)

Revenue

We recognized revenue of $53.0 million during the nine months ended June 30, 2024 as compared to $59.3 million during the nine months ended June 30, 2023. The $6.2 million decrease in revenue was primarily due to AbbVie's lower reported HCV sales as compared to the comparable period in 2023.

Research and development expenses

	Nine Months Ended June 30,	
	2024	2023
	(in thousands)	
R&D programs:		
Virology		
RSV	$ 67,936	$ 56,608
COVID-19	3,871	58,218
HBV	239	5,652
Total Virology	$ 72,046	$ 120,478
Immunology		
CSU	13,873	—
Total Immunology	$ 13,873	$ —
Other Programs		
NASH	518	2,175
Early discovery	14,261	4,704
Total Other Programs	$ 14,779	$ 6,879
Total research and development expenses	$ 100,698	$ 127,357

Research and development expenses for the nine months ended June 30, 2024 decreased by $26.7 million compared to the same period in 2023.

Virology

The costs in our virology program decreased $48.4 million primarily due to a decrease in costs associated with our COVID-19 program as we stopped further internal development and will only progress the program in the context of one or more collaborations. This decrease was offset by an increase in costs for our RSV clinical programs as we had two ongoing Phase 2 studies of zelicapavir and a challenge study initiated for EDP-323 in the nine months ended June 30, 2024. Costs associated with HBV decreased as we continued to wind down this program.

Immunology

The costs in our immunology increased by $13.9 million as this is a new therapeutic area of focus for the company.

Other Programs

Other program costs increased by $7.9 million as we focused on early-stage drug discovery programs, offset by a decrease in costs for our NASH program as we continued to wind down this program.

General and administrative expenses

General and administrative expenses increased by $5.1 million for the nine months ended June 30, 2024 compared to the same period in 2023. The change was primarily due to an increase in legal expenses related to our patent infringement suit against Pfizer.

Other income (expense)

Changes in components of other income (expense) were as follows:

Interest expense

Interest expense increased $6.4 million for the nine months ended June 30, 2024 as compared to the same period in 2023 due to interest expense and amortization of debt issuance costs associated with the royalty sale agreement entered into during April 2023 with an affiliate of OMERS.

Interest and investment income, net

Interest and investment income, net, increased $4.9 million for the nine months ended June 30, 2024 as compared to the same period in 2023. The increase was due to an increase in average invested cash due to receipt of $200.0 million from OMERS in April 2023 as well as changes in interest rates year over year.

Income tax benefit (expense)

During the nine months ended June 30, 2024, we recorded an income tax benefit of $1.4 million driven by interest recorded on a pending federal tax refund. During the nine months ended June 30, 2023, we recorded income tax expense of $4.2 million driven by the receipt of $200.0 million from the royalty sale agreement, which is taxable for federal and state purposes, partially offset by utilization of federal net operating losses and research and development tax credit carryforwards as well as a deduction for foreign derived intangible income.

Liquidity and Capital Resources

We fund our operations with cash flows from our retained portion of our royalty revenue and our existing financial resources. At June 30, 2024, our principal sources of liquidity were cash and cash equivalents and short-term and long-term marketable securities of $272.6 million.

The following table shows a summary of our cash flows:

	Nine Months Ended June 30,	
	2024	2023
	(in thousands)	
Cash provided by (used in):		
Operating activities	$ (68,364)	$ (81,552)
Investing activities	39,162	(65,414)
Financing activities	(20,411)	198,149
Net increase (decrease) in cash, cash equivalents and restricted cash	$ (49,613)	$ 51,183

Net cash used in operating activities

Cash used in operating activities was $68.4 million for the nine months ended June 30, 2024 as compared to cash used in operating activities of $81.6 million for the same period in 2023. Our cash used in operating activities decreased $13.2 million primarily due to lower research and development payments, offset by lower cash receipts associated with our AbbVie agreement as we now only retain 45.5% of cash royalties following the royalty sale agreement with OMERS.

Net cash provided by (used in) investing activities

Cash provided by investing activities was $39.2 million for the nine months ended June 30, 2024 as compared to cash used in investing activities of $65.4 million for the same period in 2023. Our cash provided by investing activities increased $104.6 million, driven by the timing of purchases, sales and maturities of marketable securities in 2024 compared to 2023.

Net cash provided by (used in) financing activities

Cash used in financing activities was $20.4 million for the nine months ended June 30, 2024 as compared to cash provided by financing activities of $198.1 million for the same period in 2023. Our cash provided by financing activities decreased $218.6 million, driven primarily by the timing of receipt of $200.0 million from OMERS for our royalty sale agreement executed in April 2023.

Funding Requirements

As of June 30, 2024, we had $272.6 million in cash, cash equivalents and short-term and long-term marketable securities. We believe that our existing cash, cash equivalents and short-term and long-term marketable securities as of June 30, 2024, as well as the cash flows from our retained portion of future HCV royalties will enable us to fund our operating expenses and capital expenditure requirements through the third quarter of fiscal 2027. However, our projection of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially.

Our future capital requirements are difficult to forecast and will depend on many factors, including:

- the number and characteristics of our research and development programs;
- the scope, progress, results and costs of researching and developing our product candidates on our own, including conducting advanced clinical trials;
- our ability to establish new collaborations, licensing or other arrangements, if any, and the financial terms of such arrangements;
- the amount of our retained portion of royalties generated from MAVYRET/MAVIRET sales under our existing collaboration with AbbVie;
- delays and additional expenses in our clinical trials;
- the cost of manufacturing our product candidates for clinical development and any products we successfully commercialize independently;
- opportunities to in-license or otherwise acquire new technologies and therapeutic candidates;
- costs associated with prosecuting our patent infringement suit regarding use of a coronavirus 3CL protease inhibitor in Paxlovid, Pfizer's antiviral treatment for COVID-19;
- the timing of, and the costs involved in, obtaining regulatory approvals for any product candidates we develop independently;
- the cost of commercialization activities, if any, of any product candidates we develop independently that are approved for sale, including marketing, sales and distribution costs;
- the timing and amount of any sales of our product candidates, if any, or royalties thereon;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patents, including any litigation costs and the outcomes of any such litigation; and
- potential fluctuations in foreign currency exchange rates.

Off-Balance Sheet Arrangements

We do not engage in any off-balance sheet financing activities. We do not have any interest in entities referred to as variable interest entities, which include special purpose entities and other structured finance entities.

Contractual Obligations and Commitments

Facility Leases

We currently lease space in Watertown, Massachusetts, under two separate lease agreements with one landlord and entered into a third lease agreement with the same landlord in May 2022 to lease additional laboratory and office space located at a to-be-constructed facility at Arsenal on the Charles in Watertown, Massachusetts.

Our first lease for office and laboratory space at 500 Arsenal Street was to expire on September 1, 2027. In May 2022, we entered into a new ten-year lease for laboratory and office space in Watertown, Massachusetts, adjacent to our 400 Talcott Avenue premises at Arsenal on the Charles at 4 Kingsbury Avenue. The construction of the facility shell was completed and we gained access to the building to construct tenant improvements during the three months ended March 31, 2024. Upon gaining access to the 4 Kingsbury Avenue building, we capitalized a right-of-use asset and lease liability of approximately $32 million on our consolidated balance sheets which reflects our fixed base rent payments, net of approximately $15 million of a tenant improvement allowance provided by the landlord, over the 10-year term of the lease.

In conjunction with the commencement of our lease at 4 Kingsbury Avenue during the quarter, we adjusted our 500 Arsenal Street lease liability to shorten the expiration date from September 2027 to the date the Kingsbury Avenue facility is ready for our occupancy which is expected to be by the end of November 2024. This resulted in a decrease in the lease liability and right-of-use asset on our consolidated balance sheets by approximately $9 million.

Total estimated minimum lease payments for the next 5 years and thereafter under our existing facility and leased equipment agreements are $8.2 million in 2025, $8.5 million in 2026, $8.7 million in 2027, $9.0 million in 2028 and $59.2 million thereafter.

OMERS Agreement

In April 2023, we entered into a royalty sale agreement with an affiliate of OMERS, pursuant to which we were paid a $200.0 million cash purchase price in exchange for 54.5% of our future quarterly royalty payments on net sales of MAVYRET/MAVIRET after June 30, 2023, through June 30, 2032, subject to a cap on aggregate payments equal to 1.42 times the purchase price.

The $200.0 million received in April 2023 was recognized on our condensed consolidated balance sheets as a liability which will be reduced by the payments made to OMERS over the term of the Agreement.

Critical Accounting Policies

Our condensed consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of our condensed consolidated financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amount of assets, liabilities, revenue, costs and expenses, and related disclosures. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions and conditions. See our 2023 Form 10-K for information about our critical accounting policies as well as a description of our other significant accounting policies. There have been no significant changes to our critical accounting policies since the beginning of this fiscal year.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is set forth in Note 2 to the condensed consolidated financial statements included in this Form 10-Q.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

During the nine months ended June 30, 2024, there were no material changes to our market risk disclosures as set forth in Part II, Item 7A "Quantitative and Qualitative Disclosures About Market Risk" in our Annual Report on Form 10-K for the fiscal year ended September 30, 2023.

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures and Internal Control over Financial Reporting

Evaluation of Disclosure Controls and Procedures.

Our management, with the participation of the principal executive officer and principal financial officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act), as of the end of the period covered by this quarterly report. Based on this evaluation, the principal executive officer and principal financial officer concluded that these disclosure controls and procedures are effective and designed to ensure that the information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the requisite time periods.

Changes in Internal Control Over Financial Reporting.

There were no changes in our internal control over financial reporting that occurred during the quarter ended June 30, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

For the fiscal year ending September 30, 2024, we will be a non-accelerated filer under the Exchange Act and not required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002. Therefore, our annual report will not include an attestation report of our registered public accounting firm regarding the assessment of internal control over financial reporting. We will continue to maintain our internal control environment and management will continue to attest to its effectiveness.

PART II —OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Information with respect to legal proceedings is included in Note 12 of the Notes to the Unaudited Condensed Consolidated Financial Statements contained in Part I, Item 1 of this Quarterly Report on Form 10-Q, which is incorporated herein by reference.

ITEM 1A. RISK FACTORS

Our business faces significant risks and uncertainties. Certain factors may have a material adverse effect on our business prospects, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the detailed discussion of risk factors included in our 2023 Form 10-K and our Quarterly Report for the period ended December 31, 2023.

Except as set forth below, there have been no material changes to such risk factors during the quarter ended June 30, 2024. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our business, prospects, financial condition and results of operations.

ITEM 5. OTHER INFORMATION

Rule 10b5-1 Trading Arrangements. During the three months ended June 30, 2024, the following officers (as defined in Rule 16a-1(f) under the Exchange Act) of the Company adopted a "Rule 10b5-1 trading arrangement" as that term is defined in Item 408(a) of Regulation S-K, all of which were entered into during an open trading window in accordance with the Company's Securities Trading Policy and all of which were intended to satisfy Rule 10b5-1(c):

- On June 13, 2024, Jay R. Luly, Ph.D., our President, Chief Executive Officer and Director, adopted a Rule 10b5-1 trading plan providing for the sale of up to 140,250 shares of common stock vested under outstanding stock options, which are set to expire on November 20, 2024, so long as the market price of our common stock is higher than certain minimum threshold prices specified in the plan in various periods between September 16, 2024 and May 30, 2025, or such earlier date as all authorized sales under the plan are completed;
- On June 14, 2024, Paul J. Mellett, our Chief Financial and Administrative Officer, adopted a Rule 10b5-1 trading plan providing for the sale of up to 46,250 shares of our common stock, including shares vested under outstanding stock

options, which are set to expire on November 20, 2024, as well as shares vested under certain performance stock units and restricted stock units, so long as the market price of our common stock is higher than certain minimum threshold prices specified in the plan in various periods between September 16, 2024 and May 30, 2025, or such earlier date as all authorized sales under the plan are completed;

Except as set forth above, no director or officer (as defined in Rule 16a-1(f) under the Exchange Act) of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-rule 10b5-1 trading arrangement," as each term is defined in item 408(a) of Regulation S-K.

ITEM 6. EXHIBITS

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	Date	Exhibit Number	File Number	
3.1	Restated Certificate of Incorporation of Enanta Pharmaceuticals, Inc.	8-K	03/28/2013	3.1	001-35839	
3.2	Amended and Restated Bylaws of Enanta Pharmaceuticals, Inc. (as amended and restated in August 2015)	8-K	08/18/2015	3.2	001-35839	
10.1	2024 Inducement Stock Incentive Plan	S-8	05/08/2024	99.2	333-279217	
31.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.	—	—	—	—	X
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.	—	—	—	—	X
32.1	Certification of the Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	—	—	—	—	X
101.INS	XBRL Instance Document - The instance document does not appear in the interactive data file because its XBRL tags are embedded within the inline XBRL document					X
101.SCH	Inline XBRL Taxonomy Extension Schema with embedded Linkbases document					X
104	Cover Page Interactive Data File (formatted as Inline XBRL with applicable Taxonomy Extension information contained in Exhibit 101).					X

ENANTA PHARMACEUTICALS, INC.

SIGNATURE

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 7, 2024

/s/ Paul J. Mellett

Paul J. Mellett
Chief Financial and Administrative Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION

I, Jay R. Luly, Ph.D., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Enanta Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 7, 2024

/s/ Jay R. Luly, Ph.D.
Jay R. Luly, Ph.D.
Chief Executive Officer

Exhibit 31.2

CERTIFICATION

I, Paul J. Mellett, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Enanta Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 7, 2024

/s/ Paul J. Mellett

Paul J. Mellett

Chief Financial and Administrative Officer

Exhibit 32.1

ENANTA PHARMACEUTICALS, INC.

Certification of Periodic Financial Report
Pursuant to 18 U.S.C. Section 1350
as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Each of the undersigned officers of Enanta Pharmaceuticals, Inc. ("Enanta") certifies, to his knowledge and solely for the purposes of 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report on Form 10-Q of Enanta for the quarter ended June 30, 2024 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of Enanta.

Dated: August 7, 2024

By: /s/ Jay R. Luly, Ph.D.
Jay R. Luly, Ph.D.
Chief Executive Officer

Dated: August 7, 2024

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