

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, 2023

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

(State or other jurisdiction of
incorporation or organization)

04-3205099

(I.R.S. Employer
Identification Number)

500 Arsenal Street

Watertown, Massachusetts

(Address of principal executive offices)

02472

(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	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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 1, 2023, the registrant had 21,055,392 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, 2022.

PART I—UNAUDITED FINANCIAL INFORMATION

ITEM 1. CONSOLIDATED FINANCIAL STATEMENTS

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

	June 30, 2023	September 30, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 95,177	\$ 43,994
Short-term marketable securities	291,408	205,238
Accounts receivable	18,892	20,318
Prepaid expenses and other current assets	17,071	13,445
Income tax receivable	25,917	28,718
Total current assets	448,465	311,713
Long-term marketable securities	5,924	29,285
Property and equipment, net	12,014	6,173
Operating lease, right-of-use assets	23,968	23,575
Restricted cash	3,968	3,968
Other long-term assets	830	696
Total assets	\$ 495,169	\$ 375,410
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 7,932	\$ 6,000
Accrued expenses and other current liabilities	18,196	20,936
Liability related to the sale of future royalties	36,693	—
Operating lease liabilities	5,368	2,891
Total current liabilities	68,189	29,827
Liability related to the sale of future royalties, net of current portion	164,979	—
Operating lease liabilities, net of current portion	22,333	22,372
Series 1 nonconvertible preferred stock	1,423	1,423
Other long-term liabilities	426	454
Total liabilities	257,350	54,076
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Common stock; \$0.01 par value per share, 100,000 shares authorized; 21,056 and 20,791 shares issued and outstanding at June 30, 2023 and September 30, 2022, respectively	210	208
Additional paid-in capital	418,001	398,029
Accumulated other comprehensive loss	(1,504)	(3,724)
Accumulated deficit	(178,888)	(73,179)
Total stockholders' equity	237,819	321,334
Total liabilities and stockholders' equity	\$ 495,169	\$ 375,410

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

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

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2023	2022	2023	2022
Revenue				
Royalty revenue	\$ 18,892	\$ 19,479	\$ 59,272	\$ 65,843
License revenue	—	—	1,000	—
Total revenue	<u>18,892</u>	<u>19,479</u>	<u>60,272</u>	<u>65,843</u>
Operating expenses:				
Research and development	42,987	39,090	127,357	129,726
General and administrative	12,618	12,929	39,092	32,913
Total operating expenses	<u>55,605</u>	<u>52,019</u>	<u>166,449</u>	<u>162,639</u>
Loss from operations	<u>(36,713)</u>	<u>(32,540)</u>	<u>(106,177)</u>	<u>(96,796)</u>
Other income (expense):				
Interest expense	(1,997)	—	(1,997)	—
Interest and investment income, net	3,866	393	6,696	942
Total other income, net	<u>1,869</u>	<u>393</u>	<u>4,699</u>	<u>942</u>
Loss before income taxes	(34,844)	(32,147)	(101,478)	(95,854)
Income tax (expense) benefit	(4,221)	447	(4,231)	447
Net loss	<u>\$ (39,065)</u>	<u>\$ (31,700)</u>	<u>\$ (105,709)</u>	<u>\$ (95,407)</u>
Net loss per share, basic and diluted	<u>\$ (1.86)</u>	<u>\$ (1.53)</u>	<u>\$ (5.05)</u>	<u>\$ (4.64)</u>
Weighted average common shares outstanding, basic and diluted	<u>21,054</u>	<u>20,710</u>	<u>20,939</u>	<u>20,552</u>

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

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

	<u>Three Months Ended June 30,</u>		<u>Nine Months Ended June 30,</u>	
	<u>2023</u>	<u>2022</u>	<u>2023</u>	<u>2022</u>
Net loss	\$ (39,065)	\$ (31,700)	\$ (105,709)	\$ (95,407)
Other comprehensive income (loss):				
Net unrealized gains (losses) on marketable securities	311	(583)	2,220	(3,238)
Total other comprehensive income (loss)	311	(583)	2,220	(3,238)
Comprehensive loss	<u>\$ (38,754)</u>	<u>\$ (32,283)</u>	<u>\$ (103,489)</u>	<u>\$ (98,645)</u>

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

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

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
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	<u>21,056</u>	<u>\$ 210</u>	<u>\$ 418,001</u>	<u>\$ (1,504)</u>	<u>\$ (178,888)</u>	<u>\$ 237,819</u>

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Retained Earnings (Accumulated Deficit)	Total Stockholders' Equity
	Shares	Amount				
Balances, September 30, 2021	20,238	\$ 202	\$ 351,033	\$ (382)	\$ 48,576	\$ 399,429
Exercise of stock options	248	2	10,407	—	—	10,409
Vesting of restricted stock units, net of withholding	20	1	(778)	—	—	(777)
Stock-based compensation expense	—	—	6,062	—	—	6,062
Other comprehensive loss	—	—	—	(624)	—	(624)
Net loss	—	—	—	—	(30,115)	(30,115)
Balances, December 31, 2021	20,506	205	366,724	(1,006)	18,461	384,384
Exercise of stock options	97	1	3,801	—	—	3,802
Vesting of restricted stock units, net of withholding	15	—	(451)	—	—	(451)
Stock-based compensation expense	—	—	6,471	—	—	6,471
Other comprehensive loss	—	—	—	(2,031)	—	(2,031)
Net loss	—	—	—	—	(33,592)	(33,592)
Balances, March 31, 2022	20,618	206	376,545	(3,037)	(15,131)	358,583
Exercise of stock options	102	1	4,119	—	—	4,120
Stock-based compensation expense	—	—	7,603	—	—	7,603
Other comprehensive loss	—	—	—	(583)	—	(583)
Net loss	—	—	—	—	(31,700)	(31,700)
Balances, June 30, 2022	<u>20,720</u>	<u>\$ 207</u>	<u>\$ 388,267</u>	<u>\$ (3,620)</u>	<u>\$ (46,831)</u>	<u>\$ 338,023</u>

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

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

	Nine Months Ended June 30,	
	2023	2022
Cash flows from operating activities		
Net loss	\$ (105,709)	\$ (95,407)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	21,500	20,136
Depreciation and amortization expense	1,702	2,318
Non-cash interest expense associated with the sale of future royalties	1,997	—
Premium paid on marketable securities	(73)	(846)
Amortization (accretion) of premiums (discounts) on marketable securities	(2,792)	1,118
Loss on disposal of property and equipment	7	—
Change in operating assets and liabilities:		
Accounts receivable	1,426	4,097
Prepaid expenses and other current assets	(3,626)	2,648
Income tax receivable	2,801	8,527
Operating lease, right-of-use assets	3,187	3,932
Other long-term assets	(134)	(611)
Accounts payable	2,682	(8,555)
Accrued expenses	(3,350)	(3,253)
Operating lease liabilities	(1,142)	(3,235)
Other long-term liabilities	(28)	(117)
Net cash used in operating activities	(81,552)	(69,248)
Cash flows from investing activities		
Purchase of marketable securities	(267,274)	(162,714)
Proceeds from maturities and sales of marketable securities	209,550	190,068
Purchase of property and equipment	(7,690)	(688)
Net cash provided by (used in) investing activities	(65,414)	26,666
Cash flows from financing activities		
Proceeds from the exercise of stock options	2,208	18,331
Proceeds from the sale of future royalties	200,000	—
Payments for debt issuance costs	(325)	—
Payments for settlement of share-based awards	(3,734)	(1,228)
Net cash provided by financing activities	198,149	17,103
Net increase (decrease) in cash, cash equivalents and restricted cash	51,183	(25,479)
Cash, cash equivalents and restricted cash as of the beginning of period	47,962	57,814
Cash, cash equivalents and restricted cash as of the end of period	\$ 99,145	\$ 32,335
Supplemental disclosure of non-cash information:		
Purchases of fixed assets included in accounts payable and accrued expenses	\$ 1,075	\$ 412
Operating lease liabilities arising from obtaining right-of-use assets	\$ 3,580	\$ 22,984

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

ENANTA PHARMACEUTICALS, INC.
NOTES TO 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 become a leader in the discovery and development of small molecule drugs, with an emphasis on treatments for viral infections. 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). Royalties from the Company’s AbbVie collaboration and its existing financial resources provide funding to support the Company’s wholly-owned research and development programs, which are primarily focused on the following disease targets: respiratory syncytial virus (“RSV”), SARS-CoV-2, human metapneumovirus (“hMPV”) and hepatitis B virus (“HBV”).

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.

COVID-19

In March 2020, the World Health Organization declared COVID-19 a global pandemic and countries worldwide implemented various measures to contain the spread of the SARS-CoV-2 virus. National, state and local governments in affected regions implemented varying safety precautions, including quarantines, border closures, increased border controls, travel restrictions, shelter-in-place orders and shutdowns, business closures, cancellations of public gatherings and other measures. The pandemic caused minor disruptions in the supply chains for the Company’s research and product candidates, significant delays in the conduct of ongoing clinical trials and reductions in the number of patients accessing AbbVie’s HCV regimens which impacted royalties earned.

The extent to which COVID-19 will have further impact on the Company’s business, results of operations and financial condition will depend on future developments that are highly uncertain and cannot be accurately predicted, including new variants and public health actions taken to contain their impact, as well as the cumulative economic impact of both of those factors and the public health impact of the ending of emergency public health measures.

Unaudited Interim Financial Information

The consolidated balance sheet as of September 30, 2022 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 consolidated financial statements as of June 30, 2023 and for the three and nine months ended June 30, 2023 and 2022 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 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, 2022.

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, 2023 and results of operations for the three and nine months ended June 30, 2023 and 2022 and cash flows for the nine months ended June 30, 2023 and 2022 have been made. The results of operations for the three and nine months ended June 30, 2023 are not necessarily indicative of the results of operations that may be expected for subsequent quarters or the year ending September 30, 2023.

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

The accompanying 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 \$105,709 for the nine months ended June 30, 2023 and \$121,755 for the year ended September 30, 2022. As of June 30, 2023, the Company had an accumulated deficit of \$178,888. 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, 2023, the Company had \$392,509 in cash, cash equivalents and short-term and long-term marketable securities. The Company expects that its cash, cash equivalents, 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 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, 2022 and the liability related to the sale of future royalties below. 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 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 consolidated financial statements, and the reported amounts of revenues and expenses during the reporting period. Significant estimates and assumptions reflected in these 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.

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 the Company's future quarterly royalty payments on net sales of MAVYRET/MAVIRET. The Company recognized the \$200,000 received from OMERS as a liability on its consolidated balance sheets because the \$200,000 will be paid back to OMERS up to a 1.42 capped amount and the Company has significant continuing involvement under the AbbVie Agreement. Interest expense for the liability related to the sale of future royalties is recognized using the effective interest rate method over the term of the royalty sale agreement.

The liability related to the sale of future royalties and related interest expense are based on current estimates of future royalties, which the Company determines by using third-party forecasts of MAVYRET/MAVIRET sales. The Company periodically assesses the forecasted sales and to the extent the amount or timing of future estimated royalty payments is materially different than previous estimates, the Company will account for any such change by adjusting the liability related to the sale of future royalties and prospectively recognizing the related non-cash interest expense.

Net Income (Loss) per Share

Basic net income (loss) per common share is computed by dividing the net income (loss) by the weighted average number of shares of common stock outstanding for the period. Diluted net income (loss) per common share is computed by dividing net income (loss) by the weighted average number of common shares outstanding for the period, including potential dilutive common shares assuming the dilutive effect of outstanding stock options and unvested restricted stock units. For periods presented, 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.

The Company reported net losses for each of the three and nine months ended June 30, 2023 and 2022. The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share for the periods indicated because including them would have had an anti-dilutive effect:

	As of June 30,	
	2023	2022
	(in thousands)	
Options to purchase common stock	4,455	4,020
Unvested rTSRUs	81	98
Unvested PSUs	81	98
Unvested restricted stock units	423	201

Recently Issued Accounting Pronouncements

Other accounting standards that have been issued or proposed by the FASB or other standards-setting bodies that do not require adoption until a future date are not expected to have a material impact on the Company's consolidated financial statements upon adoption.

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, 2023 and September 30, 2022, and indicate the fair value hierarchy of the valuation inputs utilized to determine such fair value:

	Fair Value Measurements as of June 30, 2023 Using:			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets:				
Cash equivalents:				
Money market funds	\$ 30,373	\$ —	\$ —	\$ 30,373
U.S. Treasury notes	59,591	—	—	59,591
Marketable securities:				
U.S. Treasury notes	194,261	—	—	194,261
Corporate bonds	—	36,256	—	36,256
Commercial paper	—	66,815	—	66,815
	<u>\$ 284,225</u>	<u>\$ 103,071</u>	<u>\$ —</u>	<u>\$ 387,296</u>
Liabilities:				
Series 1 nonconvertible preferred stock	\$ —	\$ —	\$ 1,423	\$ 1,423
	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 1,423</u>	<u>\$ 1,423</u>

	Fair Value Measurements as of September 30, 2022 Using:			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets:				
Cash equivalents:				
Money market funds	\$ 13,905	\$ —	\$ —	\$ 13,905
Marketable securities:				
U.S. Treasury notes	91,328	—	—	91,328
Corporate bonds	—	76,411	—	76,411
Commercial paper	—	66,784	—	66,784
	<u>\$ 105,233</u>	<u>\$ 143,195</u>	<u>\$ —</u>	<u>\$ 248,428</u>
Liabilities:				
Series 1 nonconvertible preferred stock	\$ —	\$ —	\$ 1,423	\$ 1,423
	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 1,423</u>	<u>\$ 1,423</u>

During the three and nine months ended June 30, 2023 and 2022, there were no transfers between Level 1, Level 2 and Level 3.

The outstanding shares of Series 1 nonconvertible preferred stock as of June 30, 2023 and September 30, 2022 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 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:

Unobservable Input	Range	
	June 30, 2023	September 30, 2022
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, 2023 or 2022.

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 which is recorded at fair value. The fair value of the liability is based on significant inputs not observable in the market, which represent a Level 3 measurement within the fair value hierarchy. The Company estimates the liability based on current estimates of future royalties expected to be paid to OMERS over the next 10 years. Changes in the fair value of the liability are recognized as interest expense in the consolidated statements of operations. The recurring Level 3 fair value measurement includes a weighted average interest rate of approximately 5.5% as of June 30, 2023. See Note 7 for a rollforward of the liability.

4. Marketable Securities

As of June 30, 2023 and September 30, 2022, the fair value of available-for-sale marketable securities, by type of security, was as follows:

	June 30, 2023				
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Credit Losses	Fair Value
	(in thousands)				
Corporate bonds	\$ 37,210	\$ —	\$ (954)	\$ —	\$ 36,256
Commercial paper	66,815	—	—	—	66,815
U.S. Treasury notes	194,427	22	(188)	—	194,261
	<u>\$ 298,452</u>	<u>\$ 22</u>	<u>\$ (1,142)</u>	<u>\$ —</u>	<u>\$ 297,332</u>

	September 30, 2022				
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Credit Losses	Fair Value
	(in thousands)				
Corporate bonds	\$ 78,663	\$ —	\$ (2,252)	\$ —	\$ 76,411
Commercial paper	66,784	—	—	—	66,784
U.S. Treasury notes	92,416	—	(1,088)	—	91,328
	<u>\$ 237,863</u>	<u>\$ —</u>	<u>\$ (3,340)</u>	<u>\$ —</u>	<u>\$ 234,523</u>

As of June 30, 2023 and September 30, 2022, marketable securities consisted of investments that mature within one year, with the exception of certain corporate bonds and U.S. Treasury notes, which have maturities between one and two years and an aggregate fair value of \$5,924 and \$29,285, respectively.

5. Accrued Expenses

Accrued expenses and other current liabilities consisted of the following as of June 30, 2023 and September 30, 2022:

	June 30, 2023	September 30, 2022
	(in thousands)	
Accrued pharmaceutical drug manufacturing	\$ 5,508	\$ 6,932
Accrued research and development expenses	5,702	5,532
Accrued payroll and related expenses	5,031	6,439
Accrued other	1,955	2,033
	<u>\$ 18,196</u>	<u>\$ 20,936</u>

6. 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 \$1,268,000 through June 30, 2023.

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.

7. 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 consolidated balance sheets which will be amortized as interest expense in the 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 consolidated statements of operations.

The Company’s liability related to the sale of future royalties is estimated based on forecasted worldwide MAVYRET/MAVIRET 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 consolidated balance sheets.

At June 30, 2023, the estimated future cash flows resulted in an effective annual imputed interest rate of approximately 5.5%.

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, 2022	\$	—
Proceeds from sale of future royalties		200,000
Debt issuance cost		(325)
Royalty payments		—
Non-cash interest expense		1,997
Balance - June 30, 2023	\$	201,672

8. Series 1 Nonconvertible Preferred Stock

As of June 30, 2023, 1,930 shares of Series 1 nonconvertible preferred stock were issued and outstanding. Since these shares qualify as a derivative, the outstanding shares are carried at fair value as a liability on the Company's consolidated balance sheets.

9. 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 and March 2023. 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, 2023:

	Shares Issuable Under Options (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of September 30, 2022	3,993	\$ 53.57	6.2	\$ 28,778
Granted	755	44.87		
Exercised	(124)	17.83		
Forfeited	(169)	62.89		
Outstanding as of June 30, 2023	<u>4,455</u>	\$ 52.74	6.3	\$ 2
Options vested and expected to vest as of June 30, 2023	<u>4,455</u>	\$ 52.74	6.3	\$ 2
Options exercisable as of June 30, 2023	<u>2,922</u>	\$ 51.92	5.0	\$ 2

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, 2023:

	PSUs		rTSRUs	
	Shares (in thousands)	Weighted Average Grant Date Fair Value	Shares (in thousands)	Weighted Average Grant Date Fair Value
Unvested as of September 30, 2022	101	\$ 54.50	101	\$ 36.14
Granted	50	47.24	50	36.91
Vested	(70)	44.58	(70)	23.89
Unvested as of June 30, 2023	<u>81</u>	\$ 58.58	<u>81</u>	\$ 45.82

During the nine months ended June 30, 2023, a total of 100% of the target PSUs and 127% of the target rTSRUs granted in December 2020 vested, resulting in the issuance of an aggregate of 104 common shares, net of share withholding.

Restricted Stock Units

The following table summarizes the restricted stock unit activity for the year-to-date period ending June 30, 2023:

	Restricted Stock Units (in thousands)	Weighted Average Grant Date Fair Value
Unvested as of September 30, 2022	219	\$ 64.03
Granted	277	45.00
Vested	(56)	61.10
Cancelled	(17)	54.92
Unvested as of June 30, 2023	423	\$ 52.32

Stock-Based Compensation Expense

During the three and nine months ended June 30, 2023 and 2022 the Company recognized the following stock-based compensation expense:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2023	2022	2023	2022
	(in thousands)			
Research and development	\$ 2,385	\$ 2,202	\$ 7,437	\$ 7,496
General and administrative	4,613	5,401	14,063	12,640
	\$ 6,998	\$ 7,603	\$ 21,500	\$ 20,136

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2023	2022	2023	2022
	(in thousands)			
Stock options	\$ 4,963	\$ 5,079	\$ 15,020	\$ 14,790
rTSRUs	440	207	1,447	1,171
Performance stock units	—	1,559	542	1,930
Restricted stock units	1,595	758	4,491	2,245
	\$ 6,998	\$ 7,603	\$ 21,500	\$ 20,136

During the three and nine months ended June 30, 2023 and 2022, 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, 2023, the Company had an aggregate of \$69,426 of unrecognized stock-based compensation cost, which is expected to be recognized over a weighted average period of 2.4 years.

10. Income Taxes

For the three and nine months ended June 30, 2023, the Company recorded income tax expense of \$4,221 and \$4,231, respectively, due to \$200,000 received from the royalty sale agreement with OMERS in April 2023 which is taxable for federal and state purposes. This was 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. For the three and nine months ended June 30, 2022, the Company recorded an income tax benefit of \$447 due to the release of a state tax reserve during the period.

11. 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. For example, 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.

On June 21, 2022, the Company filed suit in the United States District Court for the District of Massachusetts, 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. The Company records all legal expenses associated with the patent infringement suit as incurred in the consolidated statements of operations.

The Company currently is not a party to any other litigation.

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 consolidated financial statements as of June 30, 2023.

Leases

The Company leases laboratory and office space under various non-cancelable operating leases. There have been no material changes to the Company's leases during the three and nine months ended June 30, 2023. For additional information, please read Note 11, Leases, to the consolidated financial statements in the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2022.

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 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, 2022 included in our Annual Report on Form 10-K for that fiscal year, which is referred to as our 2022 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 become a leader in the discovery and development of small molecule drugs, with an emphasis on treatments for viral infections. 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). Our royalties from our AbbVie collaboration, combined with the proceeds from our recently completed royalty sale transaction, provide us funding to support our wholly-owned research and development programs, which are primarily focused on the following disease targets:

- 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 has caused nearly 7 million deaths worldwide, and with new variants still emerging;
- Human metapneumovirus, or hMPV, an important, relatively recently identified cause of respiratory tract infections, particularly in children, the elderly and immunocompromised individuals, with symptoms similar to RSV; 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.

Since fiscal 2020, we have reported net losses. Our ability to generate revenue sufficient to achieve profitability will depend on the successful further development and commercialization of our product candidates. We generated revenue of \$60.3 million and \$65.8 million for the nine months ended June 30, 2023 and 2022, respectively, and incurred net losses of \$105.7 million and \$95.4 million for those same periods. As of June 30, 2023, we had an accumulated deficit of \$178.9 million. We expect to continue to incur net losses for the foreseeable future. As a result, we expect to need additional funding for expenses related to our operating activities, including general and administrative expenses and research and development expenses.

Because of the numerous risks and uncertainties associated with clinical development and commercialization, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve or maintain profitability. Until such time, if ever, as we can generate substantial revenue sufficient to achieve profitability, we expect to finance our operations through a combination of equity offerings, non-dilutive financings, collaborations, strategic alliances or licensing agreements. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we are unable to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back or discontinue the further development and commercialization efforts of one or more of our products, or may be forced to reduce or terminate our operations.

As of June 30, 2023, we had \$392.5 million in cash, cash equivalents and short-term and long-term marketable securities. We believe that our existing cash, cash equivalents, short-term and long-term marketable securities and our continuing portion of HCV royalties, will enable us to fund our operating expenses and capital expenditure requirements into the second half of fiscal 2027. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See "Liquidity and Capital Resources."

Our Wholly-Owned Programs

Our primary wholly-owned research and development programs are in virology, namely RSV, SARS-CoV-2, hMPV and HBV:






- **RSV:** We have a clinical stage program for RSV, with two compounds in clinical trials – EDP-938 and EDP-323. EDP-938, which has Fast Track designation from the U.S. Food and Drug Administration, or FDA, is a potent inhibitor of N-protein activity for both major subgroups of RSV, referred to as RSV-A and RSV-B. It is currently in three ongoing Phase 2 studies, each in a different patient population. We completed a Phase 1 clinical study of EDP-323, an inhibitor of the RSV L-protein with Fast Track designation from the FDA, and reported positive topline results in June 2023.
 - o **EDP-938 - N-protein Inhibitor Candidate:** We have studied EDP-938 in two Phase 2 studies that were designed to be proof-of-concept and exploratory studies to understand better viral response in the context of RSV infection. These studies were conducted in otherwise healthy adults. The first study was the challenge study, which had a data readout in mid-2019. The second study, known as RSVP, was in an adult outpatient population with community-acquired RSV infection that had a data read out in May 2022. EDP-938 has demonstrated a favorable safety profile, consistent with that observed in approximately 500 subjects exposed to EDP-938 to date. We believe that EDP-938 has the greatest potential to show optimal efficacy in high-risk populations, as 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 EDP-938. Based on the efficacy and growing safety profile of EDP-938, we are continuing to evaluate EDP-938 in high-risk populations in the following ongoing clinical studies, including pediatric patients, adult hematopoietic stem cell recipients and other high-risk adults, all of which have significant unmet need:
 - **RSVPEDs:** RSVPEDs is a Phase 2 study in pediatric patients. 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 the selected dose for antiviral activity.
 - **RSVTx:** RSVTx is a Phase 2b study in adult hematopoietic cell transplant recipients with acute RSV infection and symptoms of upper respiratory tract infection. The study is designed for approximately 200 adult subjects who must be 18 to 75 years of age. Subjects receive EDP-938 or placebo for 21 days and are monitored for the incidence of lower respiratory tract complications within 28 days of enrollment.
 - **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 EDP-938 or placebo for five days and evaluated for 28 days thereafter. The primary endpoint of the study is time to resolution of RSV lower respiratory tract disease symptoms.
 - o The three ongoing studies are expected to continue through at least 2023. We expect to complete enrollment in one or more of our ongoing Phase 2 studies of EDP-938 in the upcoming Northern Hemisphere RSV season and to report data in fiscal 2024, pending a return to a normal, pre-pandemic type of RSV season in the Northern Hemisphere.
 - o **EDP-323 - L-protein Inhibitor Candidate:** In June 2023, we completed a Phase 1 clinical study and reported positive topline results for EDP-323, 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. Based on these positive data, we are targeting a fourth quarter initiation of a Phase 2 challenge study.
- **COVID-19:** We have leveraged our expertise in developing protease inhibitors to discover new compounds specifically designed to target the SARS-CoV-2 virus and potentially other coronaviruses.
 - o **EDP-235 - Protease Inhibitor Candidate:** EDP-235 is an oral inhibitor of the coronavirus 3CL protease, also referred to as 3CLpro or the main coronavirus protease, or Mpro, which has been granted Fast Track designation by the FDA. 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 is projected to have four times higher drug levels in lung tissue compared to plasma.

- Phase 1 Study – In July 2022, we completed a Phase 1 study and reported positive topline results. This first-in-human, randomized, double-blind, placebo-controlled study enrolled healthy volunteers to evaluate the safety, tolerability, and pharmacokinetics, or PK, of oral EDP-235 in single ascending doses, and multiple ascending doses, for seven days, and the effect of food. Data from the Phase 1 study demonstrated EDP-235 was generally safe and well-tolerated in doses up to 400mg for seven days and adverse events were infrequent and mild.
 - Phase 2 Study – In May 2023, we reported topline results from SPRINT (SARS-CoV-2 Protease Inhibitor Treatment), a Phase 2 clinical trial of EDP-235. This randomized, double-blind, placebo-controlled study evaluated the safety, tolerability, antiviral activity and clinical symptoms of EDP-235 compared to placebo in approximately 230 non-hospitalized, symptomatic patients with mild to moderate COVID-19 who were not at increased risk for developing severe disease. Patients were eligible to participate if they had symptoms for five days or less and had not received a SARS-CoV-2 vaccine or been infected with SARS-CoV-2 within 90 days of enrollment. Patients received either 200mg or 400mg EDP-235 or placebo orally with food once daily for five days. EDP-235 met the primary endpoint of the trial and was generally safe and well-tolerated. A dose-dependent improvement in symptoms was observed with EDP-235 treatment compared to placebo, which achieved statistical significance ($p < 0.05$) in the 400mg treatment group at multiple time points, starting as early as one day after the first dose. In a prespecified population consisting of patients enrolled within three days of symptom onset, a statistically significant improvement was observed with EDP-235 at 400mg at all time points. While no difference was observed in time to improvement of 14 targeted COVID-19 symptoms, an analysis of a subset of these symptoms showed a two-day shorter time to improvement in patients receiving EDP-235 400mg 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 negative (indicating no recent natural infection with SARS-CoV-2), a viral load decline was observed at day five in the 400mg group of 0.8 log overall and 1 log in the patients with symptom onset within three days before treatment with EDP-235. An additional analysis of patients with a baseline viral load greater than 5 logs showed a decline of 0.4 log at day three in both EDP-235 treatment arms compared to placebo.
 - Next Steps – Going forward, we will continue to focus on potential partnerships or collaborations to progress our COVID-19 program. In particular, we continue to focus on progressing EDP-235 into Phase 3 trials with a partner, as well as engaging in regulatory discussions regarding the registrational development pathway for EDP-235 moving forward.
- hMPV: Human metapneumovirus, or hMPV, is a virus that is a significant cause of respiratory tract infections, or RTIs, particularly in children, the elderly and immunocompromised individuals. It is the second most common cause of lower respiratory tract infections in children, with symptoms similar to RSV. The viral structure and lifecycle of hMPV are also similar to RSV.
 - o hMPV/RSV Dual-Inhibitor: In January 2023, we announced a new research program with broader spectrum antiviral activity, targeting hMPV and RSV with a single agent, which we refer to as a dual-inhibitor. In preclinical studies, these dual-inhibitors maintained activity against multiple genotypes and strains of hMPV and RSV in a range of cell types, and blocked replication in a dose-dependent manner in respective mouse models of each virus. We expect to select a dual hMPV/RSV clinical candidate in the fourth quarter of 2023.
 - 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 is 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. We are in the process of seeking other compounds that could be developed with EDP-514 for such a treatment regimen.
 - o EDP-514 - Core Inhibitor Candidate: Final data from two Phase 1b studies of EDP-514 demonstrate the compound is safe and potent in two different chronic HBV patient populations – those who are viremic and those who are on a treatment with a nucleoside reverse transcriptase inhibitor. Based on these data, we remain convinced that EDP-514, which has Fast Track designation, has the potential to be a best-in-class core inhibitor for HBV.

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 back-up compounds as well as new compounds targeting different mechanisms of action, both in our disease areas of focus as well as potentially in other disease areas.

The following table summarizes our product development pipeline in our virology program:

Enanta Pipeline

PRODUCT CANDIDATE			DISCOVERY	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	MARKET
Virology: Liver	HCV	Protease Inhibitor	Glecaprevir* 					
	HBV	Core Inhibitor	EDP-514					
Virology: Respiratory	RSV	N-Protein Inhibitor	EDP-938 					
			EDP-938 					
			EDP-938 					
		L-Protein Inhibitor	EDP-323					
	Dual hMPV/RSV	Non-Fusion Inhibitor						
	COVID-19	3CL Protease Inhibitor	EDP-235 					
Non-Virology	Various	Undisclosed						

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

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, 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 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 consolidated statements of operations since the AbbVie Agreement has not been amended and is independent of our agreement with OMERS.

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 with an emphasis on treatments for viral infections. As of the date of this report, we are conducting three Phase 2 studies for EDP-938 and are set to start a Phase 2 challenge study in the fall for EDP-323. We are also progressing our dual hMPV/RSV program and 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 a Phase 3 trial of EDP-235 on our own.

To date, we have funded our operations primarily through royalty payments received under our collaboration agreement with AbbVie, a \$200.0 million payment 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 our continuing portion of HCV royalties, will enable us to fund our operating expenses and capital expenditure requirements into the second half 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 nine months ended June 30, 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, 2023 and 2022:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2023	2022	2023	2022
	(in thousands)			
Revenue				
Royalty revenue	\$ 18,892	\$ 19,479	\$ 59,272	\$ 65,843
License revenue	—	—	1,000	—
Total revenue	\$ 18,892	\$ 19,479	\$ 60,272	\$ 65,843

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 will only retain 45.5% of 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 and 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.

Project-specific expenses reflect costs directly attributable to our clinical development candidates and preclinical candidates nominated and selected for further development. Our remaining research and development expenses are reflected in research and drug discovery, which represents early-stage drug discovery programs. At any given time, we typically have several active early-stage research and drug discovery projects. Our internal resources, employees, and infrastructure are not directly tied to any individual

research or drug discovery project and are typically deployed across multiple projects. As such, we do not report information regarding costs incurred for our early-stage research and drug discovery programs on a project-specific basis. We expect that our research and development expenses will fluctuate from period to period in the future as we advance our research and development programs. However, in the next 12 months, we expect our external research and development expenses generally to decrease since we will not conduct a Phase 3 trial of EDP-235 on our own. 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 at 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 and patent expenses.

We expect that general and administrative expenses will continue to increase in the future primarily due to the ongoing expansion of our operating activities in support of our own research and development programs, as well as our patent litigation seeking damages for infringement of one of our COVID-19 patents. To date we have not experienced a significant impact of inflation on spending in general and administrative, 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 non-cash 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 short-term and long-term marketable securities balances and interest earned for any refunds received from tax authorities. Investment income consists of the amortization or accretion of any purchased premium or discount, respectively, on our short-term and long-term 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 (Expense) Benefit

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

Results of Operations

Comparison of the Three Months Ended June 30, 2023 and 2022

	Three Months Ended June 30,	
	2023	2022
	(in thousands)	
Royalty revenue	\$ 18,892	\$ 19,479
Research and development	42,987	39,090
General and administrative	12,618	12,929
Interest expense	1,997	—
Interest and investment income, net	3,866	393
Income tax (expense) benefit	(4,221)	447
Net loss	<u>\$ (39,065)</u>	<u>\$ (31,700)</u>

Royalty revenue

We recognized royalty revenue of \$18.9 million during the three months ended June 30, 2023 as compared to \$19.5 million during the three months ended June 30, 2022. The \$0.6 million decrease in royalty revenue was due to AbbVie's lower reported HCV sales as compared to the comparable period in 2022.

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.

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 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 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,	
	2023	2022
	(in thousands)	
R&D programs:		
Virology	\$ 40,336	\$ 34,042
Liver disease (non-viral)	809	4,540
Other	1,842	508
Total research and development expenses	<u>\$ 42,987</u>	<u>\$ 39,090</u>

The level of research and development expenses for the three months ended June 30, 2023 increased by \$3.9 million compared to the same period in 2022. The increase in costs of \$6.3 million in our virology program was primarily due to an increase in clinical trial costs and an increase in headcount, partially offset by a decrease in preclinical and manufacturing costs due to timing of our studies in our virology programs. The costs in our non-viral liver disease program decreased by \$3.7 million as we wound down our non-alcoholic steatohepatitis, or NASH, program, which is now substantially complete. The costs in our other discovery programs increased by \$1.3 million due to an increase in headcount and increase in lab material and supply purchases.

In the next 12 months, we expect our external research and development expenses generally to decrease since we will not conduct a Phase 3 trial of EDP-235 on our own.

General and administrative expenses

General and administrative expenses decreased by \$0.3 million for the three months ended June 30, 2023 compared to the same period in 2022. The change was due to a decrease in stock compensation expense, partially offset by an increase in legal fees related to our patent infringement suit against Pfizer.

Interest expense

Interest expense increased \$2.0 million for the three months ended June 30, 2023, as compared to the same period in 2022 due to the non-cash 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 \$3.5 million for the three months ended June 30, 2023, as compared to the same period in 2022. The increase was due to an increase in our cash balance due to receipt of the \$200.0 million from OMERS as well as changes in interest rates year over year.

Income tax (expense) benefit

During the three months ended June 30, 2023 and 2022, we recorded income tax expense of \$4.2 million and an income tax benefit of \$0.4 million, respectively. The income tax expense in 2023 was driven by the receipt of the \$200.0 million from the royalty sale agreement, which is taxable for federal and state purposes, and is 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. The income tax benefit for 2022 was driven by a release of a state tax reserve during the period.

Comparison of the Nine Months Ended June 30, 2023 and 2022

	Nine Months Ended June 30,	
	2023	2022
	(in thousands)	
Royalty revenue	\$ 59,272	\$ 65,843
License revenue	1,000	—
Research and development	127,357	129,726
General and administrative	39,092	32,913
Interest expense	1,997	—
Interest and investment income, net	6,696	942
Income tax (expense) benefit	(4,231)	447
Net loss	<u>\$ (105,709)</u>	<u>\$ (95,407)</u>

Royalty revenue

We recognized royalty revenue of \$59.3 million during the nine months ended June 30, 2023 as compared to \$65.8 million during the nine months ended June 30, 2022. The \$6.6 million decrease in royalty revenue was due to AbbVie's lower reported HCV sales as compared to the comparable period in 2022.

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.

License revenue

We also recognized \$1.0 million of license revenue during the nine months ended June 30, 2023 related to an upfront payment received for a license agreement for one of the antibacterial compounds we are no longer developing.

Research and development expenses

	Nine Months Ended June 30,	
	2023	2022
	(in thousands)	
R&D programs:		
Virology	\$ 120,478	\$ 112,476
Liver disease (non-viral)	2,175	15,641
Other	4,704	1,609
Total research and development expenses	<u>\$ 127,357</u>	<u>\$ 129,726</u>

The level of research and development expenses for the nine months ended June 30, 2023 decreased by \$2.4 million compared to the same period in 2022. The increase in costs of \$8.0 million in our virology program was primarily due to an increase in clinical trial costs and an increase headcount partially offset by a decrease in preclinical and manufacturing costs due to the timing and scope of clinical trials. The costs in our non-viral liver disease program decreased by \$13.5 million as we wound down our non-alcoholic steatohepatitis, or NASH, program, which is now substantially complete. The costs in our other discovery programs increased by \$3.1 million due to an increase in headcount and increase in lab material and supply purchases.

General and administrative expenses

General and administrative expenses increased by \$6.2 million for the nine months ended June 30, 2023 compared to the same period in 2022. The increase was due to an increase in stock-based compensation expense and an increase in legal fees related to our patent infringement suit against Pfizer.

Interest expense

Interest expense increased \$2.0 million for the nine months ended June 30, 2023, as compared to the same period in 2022 due to non-cash interest expense and amortization of debt issuance costs recorded as a result of the royalty sale agreement with an affiliate of OMERS, which was entered into in the third quarter of 2023.

Interest and investment income, net

Interest and investment income, net, increased \$5.8 million for the nine months ended June 30, 2023, as compared to the same period in 2022. The increase was due to an increase in our cash balance due to receipt of the \$200.0 million from OMERS as well as changes in interest rates year over year.

Income tax (expense) benefit

During the nine months ended June 30, 2023 and 2022, we recorded income tax expense of \$4.2 million and an income tax benefit of \$0.4 million, respectively. The income tax expense in 2023 was driven by the receipt of the \$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. The income tax benefit for 2022 was driven by a release of a state tax reserve during the period.

Liquidity and Capital Resources

We fund our operations with cash flows from our royalty revenue and our existing financial resources. At June 30, 2023, our principal sources of liquidity were cash, cash equivalents and short-term and long-term marketable securities totaling \$392.5 million.

The following table shows a summary of our cash flows for the nine months ended June 30, 2023 and 2022:

	Nine Months Ended June 30,	
	2023	2022
	(in thousands)	
Cash provided by (used in):		
Operating activities	\$ (81,552)	\$ (69,248)
Investing activities	(65,414)	26,666
Financing activities	198,149	17,103
Net increase (decrease) in cash, cash equivalents and restricted cash	<u>\$ 51,183</u>	<u>\$ (25,479)</u>

Net cash used in operating activities

Cash used in operating activities was \$81.6 million for the nine months ended June 30, 2023 as compared to cash used in operating activities of \$69.2 million for the same period in 2022. Our cash used in operating activities increased \$12.3 million, driven by timing of our research and development payments year-over-year and was offset by a federal tax refund of \$8.5 million received in 2022.

For the foreseeable future, we expect to continue to incur substantial costs associated with research and development for our internally developed programs.

Net cash provided by (used in) investing activities

Cash used in investing activities was \$65.4 million for the nine months ended June 30, 2023 as compared to cash provided by investing activities of \$26.7 million for the same period in 2022. Our cash used in investing activities increased \$92.1 million, driven by timing of purchases, sales and maturities of marketable securities in 2023 compared to 2022, offset by increased capital expenditures in fiscal 2023 for the buildout of our leased premises at 400 Talcott Avenue.

Net cash provided by financing activities

Cash provided by financing activities was \$198.1 million for the nine months ended June 30, 2023 as compared to cash provided by financing activities of \$17.1 million for the same period in 2022. Our cash provided by financing activities increased \$181.0 million, driven by the proceeds from the sale of future royalties partially offset by the decrease in proceeds from stock option exercises.

Funding requirements

As of June 30, 2023, we had \$392.5 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, 2023, as well as the cash flows from our continuing portion of HCV royalties will be sufficient to meet our anticipated cash requirements into the second half 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.

During the quarter ended June 30, 2023, we completed the transfer of all of our cash, cash equivalents and short-term and long-term marketable securities previously held at Silicon Valley Bank to a larger financial institution.

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

- the scope, progress, results and costs of researching and developing our product candidates on our own, including conducting advanced clinical trials;
- the number and characteristics of our research and development programs;

- the amount of our retained portion of royalties generated from MAVYRET/MAVIRET sales under our existing collaboration with AbbVie;
- the cost of manufacturing our product candidates for clinical development and any products we successfully commercialize independently;
- our ability to establish new collaborations, licensing or other arrangements, if any, and the financial terms of such arrangements;
- 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;
- any potential effects of future inflation on our operations; 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

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 consolidated balance sheets as a liability which will be reduced by the payments made to OMERS over the term of the Agreement. We will recognize imputed interest expense over the life of the royalty sale agreement based on our estimated future MAVYRET/MAVIRET royalties. We will continue to record 100% of HCV royalties earned under the AbbVie agreement as royalty revenue in our consolidated statements of operations since the AbbVie Agreement has not been amended and is independent of our agreement with OMERS.

Critical Accounting Policies

Our consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of our 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 2022 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 other than with respect to the liability related to the sale of future royalties described below.

Liability Related to the Sale of Future Royalties

We account for the \$200.0 million payment from OMERS as a liability on our consolidated balance sheets because (1) under the royalty sale agreement OMERS will receive a portion of our royalty payments up to a capped amount of 1.42 times the original payment to us, and (2) we have significant continuing involvement in the generation of cash flows under the AbbVie Agreement. Interest expense for the liability related to the sale of future royalties will be recognized using the effective interest rate method over the term of the royalty sale agreement.

The liability related to the sale of future royalties and the related interest expense are based on our current estimates of future royalties, which we determine by using third-party forecasts of MAVYRET/MAVIRET sales. Third-party forecasts are updated periodically based on the latest pricing, market share and patient data. Changes in the amount or timing of estimated royalties will affect the interest rate utilized in the calculation of the liability related to the sale of future royalties.

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 consolidated financial statements included in this Form 10-Q.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

During the three and nine months ended June 30, 2023, 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, 2022.

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, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

ITEM 1A. RISK FACTORS

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 2022 Form 10-K. There have been no material changes to such risk factors during the quarter ended June 30, 2023. 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

During the three months ended June 30, 2023, no director or officer of the Company adopted or terminated a “Rule 10b5-1 trading arrangement” or a “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	Royalty Purchase Agreement between Enanta Pharmaceuticals, Inc. and OCM Life Sciences Portfolio LP dated as of April 25, 2023	8-K	04/27/2023	10.1	001-35839	
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	The following financial statements from the Quarterly Report of Enanta Pharmaceuticals, Inc. on Form 10-Q for the quarter ended June 30, 2023 formatted in Inline XBRL: (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Comprehensive Loss, (iv) Consolidated Statements of Stockholders' Equity, (v) Consolidated Statements of Cash Flows, (vi) and Notes to Consolidated Financial Statements, tagged as blocks of text and including detailed tags					X
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).					X

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 8, 2023

/s/ Paul J. Mellett

Paul J. Mellett

Chief Financial Officer

(Principal Financial and Accounting Officer)

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 8, 2023

/s/ Jay R. Luly, Ph.D.

Jay R. Luly, Ph.D.

Chief Executive Officer

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 8, 2023

/s/ Paul J. Mellett

Paul J. Mellett

Chief Financial Officer

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, 2023 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 8, 2023

By: /s/ Jay R. Luly, Ph.D.

Jay R. Luly, Ph.D.

Chief Executive Officer

Dated: August 8, 2023

By: /s/ Paul J. Mellett

Paul J. Mellett

Chief Financial Officer

