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 December 31, 2022

OR

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

Commission File Number 001-35839

ENANTA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.01 per share	ENTA	NASDAQ

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

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

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

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

As of January 31, 2023, the registrant had 20,886,433 shares of common stock, $0.01 par value per share, outstanding.

Table of Contents

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 10p-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)

	December 31, 2022	September 30, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 42,223	$ 43,994
Short-term marketable securities	172,247	205,238
Accounts receivable	22,585	20,318
Prepaid expenses and other current assets	17,946	13,445
Income tax receivable	28,703	28,718
Total current assets	283,704	311,713
Long-term marketable securities	26,939	29,285
Property and equipment, net	8,682	6,173
Operating lease, right-of-use assets	23,540	23,575
Restricted cash	3,968	3,968
Other long-term assets	701	696
Total assets	$ 347,534	$ 375,410
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,352	$ 6,000
Accrued expenses and other current liabilities	15,163	20,936
Operating lease liabilities	3,486	2,891
Total current liabilities	23,001	29,827
Operating lease liabilities, net of current portion	21,859	22,372
Series 1 nonconvertible preferred stock	1,423	1,423
Other long-term liabilities	414	454
Total liabilities	46,697	54,076
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Common stock; $0.01 par value per share, 100,000 shares authorized; 20,884 and 20,791 shares issued and outstanding at December 31, 2022 and September 30, 2022, respectively	209	208
Additional paid-in capital	405,468	398,029
Accumulated other comprehensive loss	(2,675)	(3,724)
Accumulated deficit	(102,165)	(73,179)
Total stockholders' equity	300,837	321,334
Total liabilities and stockholders' equity	$ 347,534	$ 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 December 31,	
	2022	2021
Revenue		
Royalty revenue	$ 22,585	$ 27,648
License revenue	1,000	—
Total revenue	23,585	27,648
Operating expenses:		
Research and development	40,902	48,549
General and administrative	12,696	9,508
Total operating expenses	53,598	58,057
Loss from operations	(30,013)	(30,409)
Other income (expense):		
Interest and investment income, net	993	258
Total other income, net	993	258
Loss before income taxes	(29,020)	(30,151)
Income tax benefit	34	36
Net loss	$ (28,986)	$ (30,115)
Net loss per share, basic and diluted	$ (1.39)	$ (1.48)
Weighted average common shares outstanding, basic and diluted	20,816	20,388

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

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

	Three Months Ended December 31,	
	2022	2021
Net loss	$ (28,986)	$ (30,115)
Other comprehensive income (loss):		
Net unrealized gains (losses) on marketable securities	1,049	(624)
Total other comprehensive income (loss)	1,049	(624)
Comprehensive loss	$ (27,937)	$ (30,739)

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 at 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 at December 31, 2022	20,884	$ 209	$ 405,468	$ (2,675)	$ (102,165)	$ 300,837

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Retained Earnings	Total Stockholders' Equity
	Shares	Amount				
Balances at 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 at December 31, 2021	20,506	$ 205	$ 366,724	$ (1,006)	$ 18,461	$ 384,384

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

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

	Three Months Ended December 31,	
	2022	**2021**
Cash flows from operating activities		
Net loss	$ (28,986)	$ (30,115)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	7,139	6,062
Depreciation and amortization expense	511	780
Premium paid on marketable securities	—	(474)
Amortization (accretion) of premiums (discounts) on marketable securities	(339)	546
Change in operating assets and liabilities:		
Accounts receivable	(2,267)	(4,072)
Prepaid expenses and other current assets	(4,501)	2,682
Income tax receivable	15	8,504
Operating lease, right-of-use assets	834	1,436
Other long-term assets	(5)	—
Accounts payable	(686)	(1,663)
Accrued expenses	(6,599)	4,206
Operating lease liabilities	(717)	(1,461)
Other long-term liabilities	(40)	298
Net cash used in operating activities	(35,641)	(13,271)
Cash flows from investing activities		
Purchase of marketable securities	(67,375)	(62,902)
Proceeds from maturities and sales of marketable securities	104,100	108,766
Purchase of property and equipment	(3,156)	(363)
Net cash provided by investing activities	33,569	45,501
Cash flows from financing activities		
Proceeds from exercise of stock options	1,126	10,409
Payments for settlement of share-based awards	(825)	(777)
Net cash provided by financing activities	301	9,632
Net increase (decrease) in cash, cash equivalents and restricted cash	(1,771)	41,862
Cash, cash equivalents and restricted cash at beginning of period	47,962	57,814
Cash, cash equivalents and restricted cash at end of period	$ 46,191	$ 99,676
Supplemental disclosure of noncash information:		
Purchases of fixed assets included in accounts payable and accrued expenses	$ 1,079	$ 46
Operating lease liabilities arising from obtaining right-of-use assets	$ 799	$ 15,559

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

1. Nature of the Business and Basis of Presentation

Enanta Pharmaceuticals, Inc. (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, hepatitis B virus ("HBV") and human metapneumovirus ("hMPV").

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 extent and severity of any continuing impact on the Company's business and clinical trials will be determined largely by the extent to which there are disruptions in the supply chains for its research and product candidates, delays in the conduct of ongoing and future clinical trials, or reductions in the number of patients accessing AbbVie's HCV regimens, or any combination of those events. In addition, AbbVie experienced a decline in HCV sales compared to periods prior to March 2020 as a result of reduced numbers of patients accessing AbbVie's HCV regimens due to the COVID-19 pandemic.

The extent to which the COVID-19 pandemic will continue to impact, directly or indirectly, 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 announced ending of emergency public health measures.

Unaudited Interim Financial Information

The consolidated balance sheet at 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 December 31, 2022 and for the three months ended December 31, 2022 and 2021 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 December 31, 2022 and results of operations for the three months ended December 31, 2022 and 2021 and cash flows for the three months ended December 31, 2022 and 2021 have been made. The results of operations for the three months ended December 31, 2022 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 $28,986 for the three months ended December 31, 2022 and $121,755 for the year ended September 30, 2022. As of December 31, 2022, the Company had an accumulated deficit of $102,165. 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 December 31, 2022, the Company had $241.4 million in cash, cash equivalents and short-term and long-term marketable securities. The Company expects that its cash, cash equivalents and short-term and long-term marketable securities and cash flows from continuing HCV royalties 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, or other non-dilutive financings, collaborations, strategic alliances and 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. 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; 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. The future developments of the COVID-19 pandemic also may directly or indirectly impact the Company's business. The Company has made estimates of the impact of COVID-19 in the Company's consolidated financial statements as of December 31, 2022. Actual results could differ from the Company's estimates.

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 months ended December 31, 2022 and 2021. 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:

	Three Months Ended December 31,	
	2022	2021
	(in thousands)	
Options to purchase common stock	4,511	4,177
Unvested rTSRUs	151	144
Unvested PSUs	151	144
Unvested restricted stock units	439	224

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 December 31, 2022 and September 30, 2022, and indicate the fair value hierarchy of the valuation inputs utilized to determine such fair value:

	Fair Value Measurements at December 31, 2022 Using:			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets:				
Cash equivalents:				
Money market funds	$ 21,291	$ —	$ —	$ 21,291
Marketable securities:				
U.S. Treasury notes	58,569	—	—	58,569
Corporate bonds	—	61,668	—	61,668
Commercial paper	—	78,949	—	78,949
	$ 79,860	$ 140,617	$ —	$ 220,477
Liabilities:				
Series 1 nonconvertible preferred stock	$ —	$ —	$ 1,423	$ 1,423
	$ —	$ —	$ 1,423	$ 1,423

	Fair Value Measurements at 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
	$ 105,233	$ 143,195	$ —	$ 248,428
Liabilities:				
Series 1 nonconvertible preferred stock	$ —	$ —	$ 1,423	$ 1,423
	$ —	$ —	$ 1,423	$ 1,423

During the three months ended December 31, 2022 and 2021, there were no transfers between Level 1, Level 2 and Level 3.

The outstanding shares of Series 1 nonconvertible preferred stock as of December 31, 2022 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:

	Range	
Unobservable Input	December 31, 2022	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 months ended December 31, 2022 or 2021.

4. Marketable Securities

As of December 31, 2022 and September 30, 2022, the fair value of available-for-sale marketable securities, by type of security, was as follows:

	December 31, 2022				
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Credit Losses	Fair Value
	(in thousands)				
Corporate bonds	$ 63,407	$ —	$ (1,739)	$ —	$ 61,668
Commercial paper	78,949	—	—	—	78,949
U.S. Treasury notes	59,121	—	(552)	—	58,569
	$ 201,477	$ —	$ (2,291)	$ —	$ 199,186

	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
	$ 237,863	$ —	$ (3,340)	$ —	$ 234,523

As of December 31, 2022 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 three years and an aggregate fair value of $26,939 and $29,285, respectively.

5. Accrued Expenses

Accrued expenses and other current liabilities consisted of the following as of December 31, 2022 and September 30, 2022:

	December 31, 2022	September 30, 2022
	(in thousands)	
Accrued pharmaceutical drug manufacturing	$ 3,828	$ 6,932
Accrued research and development expenses	6,862	5,532
Accrued payroll and related expenses	2,593	6,439
Accrued other	1,880	2,033
	$ 15,163	$ 20,936

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 $1,228,000 through December 31, 2022.

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. Series 1 Nonconvertible Preferred Stock

As of December 31, 2022, 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.

8. 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 and March 2022. The Company also has outstanding stock option awards under its 2012 Equity Incentive Plan (the "2012 Plan") and its amended and restated 1995 Equity Incentive Plan (the "1995 Plan"), but is no longer granting awards under these plans.

The following table summarizes stock option activity, including performance-based options, for the year-to-date period ending December 31, 2022:

	Shares Issuable Under Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
	(in thousands)		(in years)	(in thousands)
Outstanding as of September 30, 2022	3,993	$ 53.57	6.2	$ 28,778
Granted	618	44.89		
Exercised	(56)	20.25		
Forfeited	(44)	74.31		
Outstanding as of December 31, 2022	4,511	$ 52.59	6.6	$ 17,648
Options vested and expected to vest as of December 31, 2022	4,511	$ 52.59	6.6	$ 17,648
Options exercisable as of December 31, 2022	2,685	$ 50.75	5.1	$ 15,547

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 December 31, 2022:

	PSUs		rTSRUs	
	Shares	Weighted Average Grant Date Fair Value	Shares	Weighted Average Grant Date Fair Value
	(in thousands, except per share data)			
Unvested at September 30, 2022	101	$ 54.50	101	$ 36.14
Granted	50	47.24	50	40.32
Vested	—	—	—	—
Cancelled	—	—	—	—
Unvested at December 31, 2022	151	$ 52.10	151	$ 37.52

Restricted Stock Units

The following table summarizes the restricted stock unit activity for the year-to-date period ending December 31, 2022:

	Restricted Stock Units	Weighted Average Grant Date Fair Value
	(in thousands, except per share data)	
Unvested at September 30, 2022	219	$ 64.03
Granted	277	45.00
Vested	(56)	61.10
Cancelled	(1)	71.75
Unvested at December 31, 2022	439	$ 52.40

Stock-Based Compensation Expense

During the three months ended December 31, 2022 and 2021 the Company recognized the following stock-based compensation expense:

	Three Months Ended December 31,	
	2022	2021
	(in thousands)	
Research and development	$ 2,532	$ 2,584
General and administrative	4,607	3,478
	$ 7,139	$ 6,062

	Three Months Ended December 31,	
	2022	2021
	(in thousands)	
Stock options	$ 5,046	$ 4,748
rTSRUs	461	433
Performance stock units	367	292
Restricted stock units	1,265	589
	$ 7,139	$ 6,062

During the three months ended December 31, 2022 and 2021, 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 December 31, 2022, the Company had an aggregate of $79,225 of unrecognized stock-based compensation cost, which is expected to be recognized over a weighted average period of 2.7 years.

9. 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 December 31, 2022.

Leases

The Company leases office space under various non-cancelable operating leases. There have been no material changes to the Company's leases during the three months ended December 31, 2022. 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 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, as well as other coronaviruses, with estimates suggesting that COVID-19 has caused over 240,000 deaths and over 1.7 million hospitalizations in the U.S. in 2022 through October 29, with comparable, or at least significant, impact in other major populations of the world and with new variants still emerging;
- 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; and
- 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.

Since fiscal 2020, we have reported a net loss. Our ability to generate revenue sufficient to achieve profitability will depend on the successful further development and commercialization of our products. We generated revenue of $23.6 million and $27.6 million for the three months ended December 31, 2022 and 2021, respectively, and incurred net losses of $29.0 million and $30.1 million for those same periods. As of December 31, 2022, we had an accumulated deficit of $102.2 million. We expect to continue to incur net losses for the foreseeable future. As a result, we may 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, or other non-dilutive financings, collaborations, strategic alliances and 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 December 31, 2022, we had $241.4 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 and revenue from continuing HCV royalties, will enable us to fund our operating expenses and capital expenditure requirements into approximately the fourth quarter of fiscal 2024. 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, HBV and hMPV:

- 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 N-protein inhibitor of activity of both major subgroups of RSV, referred to as RSV-A and RSV-B. It has been investigated in a Phase 2a challenge study and is currently in three ongoing Phase 2 studies, each in a different patient population. In addition, we recently announced the initiation of a Phase 1 clinical study of EDP-323, an inhibitor of the RSV L-protein.
    - *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 was reported out 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 continues to have 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 and planned clinical studies, including pediatric patients, adult hematopoietic stem cell recipients and 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, will evaluate multiple ascending doses in up to four 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. We plan to enroll approximately 200 adult subjects 18 to 75 years of age, within 72 hours of symptom onset, who will receive EDP-938 or placebo for 21 days and will be monitored for the incidence of lower respiratory tract complications within 28 days of enrollment.
        - *RSVHR:* On October 3, 2022, we announced the initiation of a Phase 2b study called RSVHR 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 800 mg of 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.
    - The three ongoing studies are expected to continue through 2023 and we are monitoring RSV epidemiology to determine the impact on trial enrollment and timing for the data readouts.
    - *EDP-323 - L-protein Inhibitor Candidate:* Our newest clinical candidate for RSV 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 shown nanomolar potency against RSV-A and RSV-B *in vitro* and is not expected to have cross-resistance to other classes of inhibitors. EDP-323 has the potential to be used alone or in combination with other RSV mechanisms, such as EDP-938, to broaden the treatment window or addressable patient populations. We initiated a Phase 1 clinical study of EDP-323 in October 2022 and expect to report data from this study in the second quarter of 2023.
- COVID-19: We have been leveraging our expertise in developing protease inhibitors to discover new compounds specifically designed to target the SARS-CoV-2 virus and potentially other coronaviruses.
    - *EDP-235 - Protease Inhibitor Candidate:* Our lead clinical candidate for COVID-19, EDP-235, is an oral inhibitor of 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 SARS-CoV-2, 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.
        - *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 400 mg for seven days with strong exposure multiples over the EC_{90}, which is a measure of potency, specifically the concentration of drug that results in 90% inhibition of viral replication *in vitro*. EDP-235 200 mg taken once daily with food resulted in mean trough plasma levels at steady state that were 7-fold over the plasma-protein-adjusted EC_{90} for the Omicron variant of SARS-CoV-2, while 400 mg resulted in levels that were 13-fold over the plasma-protein-adjusted EC_{90}. These target exposure multiples were achieved without the need for ritonavir boosting and its associated drug-drug interactions. EDP-235 is projected to have four times higher drug levels in lung tissue compared to plasma, which would be expected to drive the 400 mg multiples to 28-fold and 52-fold for the respective variants. Adverse events were infrequent and mild.

- *Phase 2 Study* – In November 2022, we initiated SPRINT (**S**ARS-CoV-2 **Pr**otease **In**hibitor **T**reatment), a Phase 2 clinical trial of EDP-235 in non-hospitalized, symptomatic adults with mild or moderate COVID-19. This randomized, double-blind, placebo-controlled study is designed to evaluate the safety, tolerability and antiviral activity of 200 mg and 400 mg once-daily doses of EDP-235 compared to placebo. The study will enroll approximately 200 non-hospitalized, symptomatic patients with mild to moderate COVID-19 who are not at increased risk for developing severe disease. Patients will be eligible to participate if they have had symptoms for five days or less and have not received a SARS-CoV-2 vaccine or been infected with SARS-CoV-2 within 90 days of enrollment. Patients will receive EDP-235 orally with food at a dose of 200 mg or 400 mg or placebo once daily for five days. The primary objective of the study includes evaluation of safety and tolerability, and secondary objectives include pharmacokinetics and multiple virology measures to guide dose selection for other trials. We expect to report data from this Phase 2 study in the second quarter of 2023 and, if supported by the SPRINT data, initiate a Phase 3 study of EDP-235 in the second half of 2023.

- *PLpro inhibitor program:* We are also researching additional compounds that might be eligible to be designated for clinical development for SARS-CoV-2. In January 2023, we announced a new research program focused on the discovery and development of inhibitors of the SARS-CoV-2 PLpro for the oral treatment of COVID-19. PLpro is an essential enzyme, which, along with the 3CL protease (3CLpro, or Mpro), plays an important role in viral replication and also acts to suppress the innate immune response. Inhibition of PLpro blocks viral replication and has the potential to restore the dysregulated immune response to SARS-CoV-2 infection. As this mechanism is distinct from 3CL protease inhibition, it has the potential to be used alone or in combination with 3CL protease inhibitors such as EDP-235 or other compounds to provide a range of treatment regimens for different patient populations suffering from COVID-19.

- 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.

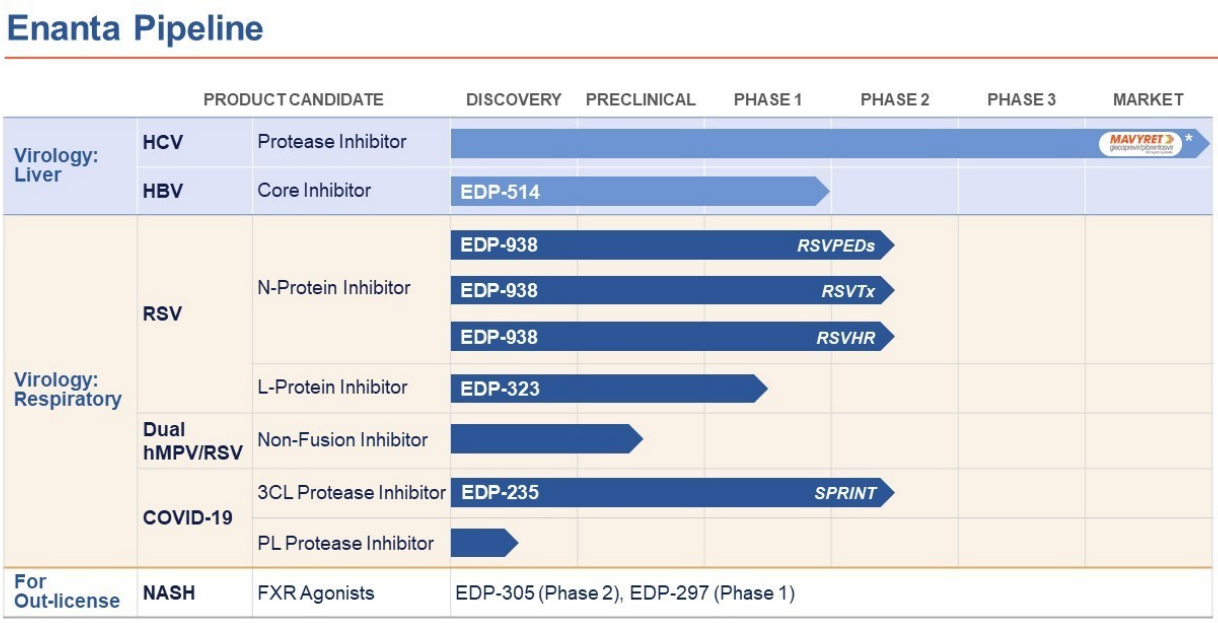
  - *EDP-514 - Core Inhibitor Candidate:* In June 2022, final data from two of our Phase 1b studies of EDP-514 were presented at The International Liver Congress™ 2022. EDP-514, which has Fast Track designation from the FDA, has been shown to be safe and potent in two different chronic HBV patient populations – those who have a high viral load and those who are on a treatment with a nucleoside reverse transcriptase inhibitor. Based on these data, we remain convinced that EDP-514 has the potential to be a best-in-class core inhibitor for HBV.

- 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.

  - *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. We expect to select a clinical dual hMPV/RSV candidate in the fourth quarter of 2023.

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 and liver disease programs:



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

Our Royalty Revenue Collaboration

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.

COVID-19 Update

The COVID-19 pandemic had an impact on our royalty revenues received from AbbVie. We continued to report lower royalty revenue during fiscal 2022 and in the first quarter of fiscal 2023 as compared to periods ending before March 2020. The pandemic resulted in a decline in patient volumes, HCV diagnoses, HCV prescriptions and sales of MAVYRET/MAVIRET.

Please see Item 1A "Risk Factors" in our 2022 Form 10-K for additional discussion of risks and potential risks of the COVID-19 pandemic on our business, results of operations and financial condition.

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 and one Phase 1 study in our RSV program and one Phase 2 study in our SARS-CoV-2 program. We are also progressing other compounds into preclinical development.

As a result of the timing of our clinical and preclinical development programs, we expect our research and development expenses to fluctuate from period to period. However, in the coming years, we expect our research and development expenses generally to increase as our wholly-owned programs advance.

We are funding our operations primarily through royalty payments received under our collaboration agreement with AbbVie and our existing cash, cash equivalents, and short-term and long-term marketable securities. Our revenue is currently dependent on royalty payments we receive from AbbVie on its sales of MAVYRET/MAVIRET. Absent a significant increase in the level of AbbVie's MAVYRET/MAVIRET sales that generate our royalty revenue, and given the planned levels of our future expenditures for the advancement of our internally developed compounds, we expect to continue to have net losses in fiscal 2023 and for the foreseeable future.

Revenue

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

The following table is a summary of revenue recognized for the three months ended December 31, 2022 and 2021:

	Three Months Ended December 31,	
	2022	2021
	(in thousands)	
Revenue		
Royalty revenue	$ 22,585	$ 27,648
License revenue	1,000	—
Total revenue	$ 23,585	$ 27,648

AbbVie Agreement

We currently receive 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, as amended in October 2014, 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.

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:

- personnel costs, including salaries, related benefits and stock-based compensation for employees engaged in scientific research and development functions;
- third-party contract costs relating to research, formulation, manufacturing, preclinical study and clinical trial activities;
- laboratory consumables;
- allocated facility-related costs; 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 increase in the future as we advance our research and development programs. To date we have not identified any significant impact of inflation on spending in research and development, but it is uncertain whether there will be inflationary impacts in future periods.

Our research and drug discovery and development programs are 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, particularly in the context of the COVID-19 pandemic, 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 and investment income, net and the change in fair value of our outstanding Series 1 nonconvertible preferred stock. 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 Benefit

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

Results of Operations

Comparison of the Three Months Ended December 31, 2022 and 2021

	Three Months Ended December 31,	
	2022	2021
	(in thousands)	
Royalty revenue	$ 22,585	$ 27,648
License revenue	1,000	—
Research and development	40,902	48,549
General and administrative	12,696	9,508
Interest and investment income, net	993	258
Income tax benefit	34	36
Net loss	$ (28,986)	$ (30,115)

Royalty Revenue

We recognized royalty revenue of $22.6 million during the three months ended December 31, 2022 as compared to $27.6 million during the three months ended December 31, 2021. The $5.0 million decrease in royalty revenue was due to AbbVie's lower reported HCV sales as compared to the comparable period in 2021. HCV patient volumes continue to remain below pre-COVID-19 levels.

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.

License Revenue

We also recognized $1.0 million of license revenue during the three months ended December 31, 2022 related to an up front payment received for a license agreement for one of the antibacterial compounds we are no longer developing.

Research and development expenses

	Three Months Ended December 31,	
	2022	2021
	(in thousands)	
R&D programs:		
Virology	$ 38,758	$ 42,522
Liver disease (non-viral)	851	5,554
Other	1,293	473
Total research and development expenses	$ 40,902	$ 48,549

The level of research and development expenses for the three months ended December 31,2022 decreased by $7.6 million compared to the same period in 2021. The decrease in costs of $3.8 million in our virology program was primarily due to a decrease in manufacturing and clinical trial costs due to the timing and scope of clinical trials. The costs in our non-viral liver disease program decreased by $4.7 million as we wound down our non-alcoholic steatohepatitis, or NASH, program, which is now substantially complete.

We expect our research and development expenses will increase in the future as we conduct more clinical development activities.

General and administrative expenses

General and administrative expenses increased by $3.2 million for the three months ended December 31,2022 compared to the same period in 2021. The increase was due to an increase in stock-based compensation expense and an increase in headcount in support of expansion of our research and development operations.

Interest and investment income, net

Interest and investment income, net, increased $0.7 million for the three months ended December 31, 2022, as compared to the same period in 2021. The increase was due to changes in interest rates year over year.

Liquidity and Capital Resources

We fund our operations with cash flows from our royalty revenue and our existing financial resources. At December 31, 2022, our principal sources of liquidity were cash, cash equivalents and short-term and long-term marketable securities totaling $241.4 million.

The following table shows a summary of our cash flows for the three months ended December 31, 2022 and 2021:

	Three Months Ended December 31,	
	2022	2021
	(in thousands)	
Cash provided by (used in):		
Operating activities	$ (35,641)	$ (13,271)
Investing activities	33,569	45,501
Financing activities	301	9,632
Net increase (decrease) in cash, cash equivalents and restricted cash	$ (1,771)	$ 41,862

Net cash used in operating activities

Cash used in operating activities was $35.6 million for the three months ended December 31, 2022 as compared to cash used in operating activities of $13.3 million for the same period in 2021. Our cash used in operating activities increased $22.4 million, driven by timing of our research and development payments year-over-year as well as a federal tax refund of $8.5 million received in 2021.

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 investing activities

Cash provided by investing activities was $33.6 million for the three months ended December 31, 2022 as compared to cash provided by investing activities of $45.5 million for the same period in 2021. Our cash provided by investing activities decreased $11.9 million, driven by timing of purchases, sales and maturities of marketable securities in 2022 compared to 2021 and increased capital expenditures in 2022 for the buildout of our 400 Talcott Avenue expansion.

Net cash provided by financing activities

Cash provided by financing activities was $0.3 million for the three months ended December 31, 2022 as compared to cash provided by financing activities of $9.6 million for the same period in 2021. Our cash provided by financing activities decreased $9.3 million, driven by an decrease in proceeds from stock option exercises.

Funding requirements

As of December 31, 2022, we had $241.4 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 December 31, 2022, and cash flows from our continuing HCV royalties, will be sufficient to meet our anticipated cash requirements into approximately the fourth quarter of fiscal 2024. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially.

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

- the amount of royalties generated from MAVYRET/MAVIRET sales under our existing collaboration with AbbVie, including any continuing impact of COVID-19 on the number of treated HCV patients;
- 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 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; 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

There have been no material changes to the contractual obligations reported in our 2022 Form 10-K.

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 critical accounting policies as well as a description of our other significant accounting policies.

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

Interest Rate Sensitivity

We had cash, cash equivalents and short-term and long-term marketable securities of $241.4 million and $347.7 million at December 31, 2022 and 2021, respectively, consisting of cash, money market funds, commercial paper, treasury notes and corporate bonds. Interest income is sensitive to changes in the general level of interest rates; however, due to the nature of these investments, a change in market interest rates of 1% would not be expected to have a material impact on our financial condition or results of operations. We had no debt outstanding as of December 31, 2022.

Foreign Exchange Risk

As we continue to progress our wholly-owned programs into clinical development, we will conduct clinical trials and clinical manufacturing outside of the U.S. and thus will face exposure to movements in foreign currency exchange rates, primarily the British Pound and Euro, against the U.S. Dollar, arising from our accounts payable and accrued expenses. During the three months ended December 31, 2022 and 2021, the impact of foreign currency exposure was immaterial and thus did not have a significant impact on our consolidated financial statements. Our operations may become subject to more significant fluctuations in foreign currency exchange rates in the future if we continue to contract with vendors outside of the U.S.

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 December 31, 2022 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 December 31, 2022. 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 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	
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 December 31, 2022 formatted in Inline XBRL: (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Comprehensive Income, (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: February 8, 2023

/s/ Paul J. Mellett

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

Exhibit 31.1

CERTIFICATION

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

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

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

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

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

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

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

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

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

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

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

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

Date: February 8, 2023

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

Exhibit 31.2

CERTIFICATION

I, Paul J. Mellett, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: February 8, 2023

/s/ Paul J. Mellett

Paul J. Mellett

Chief Financial Officer

Exhibit 32.1

ENANTA PHARMACEUTICALS, INC.

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

Each of the undersigned officers of Enanta Pharmaceuticals, Inc. ("Enanta") certifies, to his knowledge and solely for the purposes of 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report on Form 10-Q of Enanta for the quarter ended December 31, 2022 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: February 8, 2023

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

Dated: February 8, 2023

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