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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 March 31, 2013

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	2834	04-3205099
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

500 Arsenal Street
Watertown, Massachusetts 02472
(617) 607-0800
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files): Yes ☒ No ☐

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒ (Do not check if a smaller reporting company)	Smaller reporting company	☐

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

The number of shares of the registrant's Common Stock, $0.01 par value, outstanding as of May 10, 2013, was 17,818,796 shares.

ENANTA PHARMACEUTICALS, INC.
FORM 10-Q — Quarterly Report
For the Quarterly Period Ended March 31, 2013

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PART I—FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

ENANTA PHARMACEUTICALS, INC.
BALANCE SHEETS
(unaudited)
(In thousands, except share and per share amounts)

	March 31, 2013	September 30, 2012
Assets		
Current assets:		
Cash and cash equivalents	$ 74,464	$ 10,511
Short-term marketable securities	34,647	33,251
Accounts receivable	669	1,049
Unbilled receivables	768	1,893
Prepaid expenses and other current assets	1,116	604
Total current assets	111,664	47,308
Property and equipment, net	876	611
Long-term marketable securities	12,629	1,656
Restricted cash	436	436
Other assets	22	2,151
Total assets	$ 125,627	$ 52,162
Liabilities, Redeemable and Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 2,371	$ 1,851
Accrued expenses	2,465	3,866
Deferred revenue	115	17
Total current liabilities	4,951	5,734
Warrant liability	1,767	2,001
Other long-term liabilities	534	498
Total liabilities	7,252	8,233
Commitments and contingencies (Note 10)		
Redeemable convertible preferred stock (Series C, D, E, F, G-1 and G-2); $0.01 par value; no shares authorized, issued or outstanding at March 31, 2013; 45,421,288 shares authorized, 43,115,343 shares issued and outstanding at September 30, 2012	—	158,955
Convertible preferred stock (Series A and B); $0.01 par value; no shares authorized, issued or outstanding at March 31, 2013; 566,450 shares authorized, issued and outstanding at September 30, 2012	—	327
Stockholders' equity (deficit):		
Common stock; $0.01 par value; 100,000,000 and 70,000,000 shares authorized at March 31, 2013 and September 2012, respectively; 18,027,612 and 1,343,147 shares issued and 17,818,796 and 1,134,331 shares outstanding at March 31, 2013 and September 30, 2012, respectively	180	13
Additional paid-in capital	217,073	—
Treasury stock, at par value; 208,816 shares at March 31, 2013 and September 30, 2012, respectively	(2)	(2)
Accumulated other comprehensive income (loss)	(7)	10
Accumulated deficit	(98,869)	(115,374)
Total stockholders' equity (deficit)	118,375	(115,353)
Total liabilities, redeemable and convertible preferred stock and stockholders' equity (deficit)	$ 125,627	$ 52,162

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

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

	Three Months Ended March 31,		Six Months Ended March 31,	
	2013	2012	2013	2012
Revenue	$ 1,196	$ 36,565	$ 29,055	$ 37,306
Operating expenses:				
Research and development	3,704	3,263	8,502	5,935
General and administrative	1,493	1,207	2,645	2,458
Total operating expenses	5,197	4,470	11,147	8,393
Income (loss) from operations	(4,001)	32,095	17,908	28,913
Other income (expense):				
Interest income	47	15	82	29
Interest expense	(9)	—	(16)	—
Change in fair value of warrant liability	214	1	234	10
Total other income, net	252	16	300	39
Net income (loss)	(3,749)	32,111	18,208	28,952
Accretion of redeemable convertible preferred stock to redemption value	(1,244)	(1,331)	(2,526)	(2,705)
Net income attributable to participating securities	—	(28,152)	(13,670)	(24,071)
Net income (loss) attributable to common stockholders	$ (4,993)	$ 2,628	$ 2,012	$ 2,176
Net income (loss) per share attributable to common stockholders:				
Basic	$ (2.28)	$ 2.41	$ 1.21	$ 2.06
Diluted	$ (2.28)	$ 2.17	$ 1.09	$ 1.87
Weighted average common shares outstanding:				
Basic	2,192,470	1,088,251	1,669,578	1,053,912
Diluted	2,192,470	2,536,900	3,084,084	2,377,211

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

ENANTA PHARMACEUTICALS, INC.
STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(unaudited)
(In thousands)

	Three Months Ended March 31,		Six Months Ended March 31,	
	2013	2012	2013	2012
Net income (loss)	$(3,749)	$32,111	$18,208	$28,952
Other comprehensive loss:				
Net unrealized losses on marketable securities, net of tax of $0	(3)	(17)	(17)	(14)
Total other comprehensive loss	(3)	(17)	(17)	(14)
Comprehensive income (loss)	$(3,752)	$32,094	$18,191	$28,938

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

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

	Six Months Ended March 31,	
	2013	2012
Cash flows from operating activities		
Net income	$ 18,208	$ 28,952
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization expense	87	98
Non-cash interest expense	16	—
Change in fair value of warrant liability	(234)	(10)
Stock-based compensation expense	538	86
Gain on disposal of property and equipment	—	(55)
Amortization of premium on marketable securities	401	126
Change in operating assets and liabilities:		
Accounts receivable	380	176
Unbilled receivables	1,125	(1,242)
Prepaid expenses and other current assets	271	(6)
Other assets	—	(32)
Accounts payable	(469)	(117)
Accrued expenses	(1,369)	139
Deferred revenue	98	—
Other long-term liabilities	26	38
Net cash provided by operating activities	19,078	28,153
Cash flows from investing activities		
Purchases of property and equipment	(352)	(94)
Proceeds from sales of property and equipment	—	58
Purchases of marketable securities	(45,706)	(29,549)
Sales of marketable securities	2,454	—
Maturities of marketable securities	30,245	14,050
Change in restricted cash	—	1,140
Net cash used in investing activities	(13,359)	(14,395)
Cash flows from financing activities		
Proceeds from exercise of stock options	415	107
Proceeds from initial public offering, net of commissions	59,892	—
Payments of initial public offering costs	(2,073)	—
Net cash provided by financing activities	58,234	107
Net increase in cash and cash equivalents	63,953	13,865
Cash and cash equivalents at beginning of period	10,511	6,837
Cash and cash equivalents at end of period	$ 74,464	$ 20,702
Supplemental disclosure of noncash financing activities:		
Accretion of redeemable convertible preferred stock to redemption value	$ 2,526	$ 2,705
Initial public offering costs included in accounts payable or accrued expenses	$ 1,466	$ —
Conversion of preferred stock into common stock	$161,808	$ —

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

ENANTA PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS
(unaudited)
(Amounts in thousands, except share and per share data)

1. Nature of the Business and Basis of Presentation

Enanta Pharmaceuticals, Inc. (the "Company"), incorporated in Delaware in 1995, is a research and development-focused biotechnology company that uses its chemistry-driven approach and drug discovery capabilities to create small molecule drugs in the infectious disease field. The Company is developing novel protease, NS5A, cyclophilin and nucleotide polymerase inhibitors targeted against the hepatitis C virus ("HCV"). Additionally, the Company has created a new class of bridged bicyclic antibiotics known as Bicyclolides that overcomes bacterial resistance. Antibacterial focus areas include "superbugs," respiratory tract infections, and intravenous and oral treatments for hospital and community Methicillin-resistant *Staphylococcus aureus* ("MRSA").

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

On March 26, 2013 the Company completed an initial public offering ("IPO") of its common stock, which resulted in the sale of 4,600,000 shares at a price of $14.00 per share. The Company received net proceeds from the IPO of approximately $59,892 based upon the price of $14.00 per share and after deducting underwriting discounts and commissions paid by the Company.

Unaudited Interim Financial Information

The balance sheet at September 30, 2012 was derived from audited financial statements, but does not include all disclosures required by GAAP. The accompanying unaudited financial statements as of March 31, 2013 and for the three and six months ended March 31, 2013 and 2012 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 financial statements should be read in conjunction with the Company's audited financial statements and the notes thereto for the year ended September 30, 2012 included in the Company's final prospectus filed pursuant to rule 424(b) under the Securities Act of 1933, as amended, filed with the Securities and Exchange Commission on March 21, 2013.

In the opinion of management, all adjustments, consisting only of normal recurring adjustments necessary for a fair statement of the Company's financial position as of March 31, 2013 and results of operations for the three and six months ended March 31, 2013 and 2012 and cash flows for the six months ended March 31, 2013 and 2012 have been made. The results of operations for the three and six months ended March 31, 2013 are not necessarily indicative of the results of operations that may be expected for the year ending September 30, 2013.

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). All dollar amounts in the financial statements and in the notes to the consolidated financial statements, except share and per share amounts, are in thousands unless otherwise indicated.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of 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

ENANTA PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS—(Continued)
(unaudited)
(Amounts in thousands, except share and per share data)

liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Significant estimates and assumptions reflected in these financial statements include, but are not limited to, management's judgments of separate units of accounting and best estimate of selling price of those units of accounting within its revenue arrangements; the valuation of common stock, warrants and stock-based awards; the useful lives of property and equipment; and the accounting for income taxes, including uncertain tax positions and the valuation of net deferred tax assets. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Actual results could differ from the Company's estimates.

Revenue Recognition

The Company's revenue is generated primarily through collaborative research and license agreements. The terms of these agreements contain multiple deliverables, which may include (i) licenses, (ii) research and development activities, and (iii) participation in joint research and development steering committees. The terms of these agreements may include nonrefundable upfront license fees, payments for research and development activities, payments based upon the achievement of certain milestones, and royalty payments based on product sales derived from the collaboration. In all instances, revenue is recognized only when the price is fixed or determinable, persuasive evidence of an arrangement exists, delivery has occurred or the services have been rendered, collectibility of the resulting receivable is reasonably assured, and the Company has fulfilled its performance obligations under the contract.

For multiple element agreements entered into or materially modified after October 1, 2011, the Company applies the principles included in Accounting Standards Update ("ASU") No. 2009-13, *Multiple-Deliverable Revenue Arrangements* ("ASU 2009-13") to account for revenue. Under this guidance the selling prices of deliverables under the arrangement may be derived using third-party evidence ("TPE") or a best estimate of selling price ("BESP"), if vendor specific objective evidence ("VSOE") is not available. The objective of BESP is to determine the price at which the Company would transact a sale if the element within the license agreement was sold on a standalone basis. Establishing BESP involves management's judgment and considers multiple factors, including market conditions and company-specific factors including those factors contemplated in negotiating the agreements as well as internally developed models that include assumptions related to market opportunity, discounted cash flows, estimated development costs, probability of success, and the time needed to commercialize a product candidate pursuant to the license. In validating the Company's BESP, the Company considers whether changes in key assumptions used to determine the BESP will have a significant effect on the allocation of the arrangement consideration between the multiple deliverables. Deliverables under the arrangement are separate units of accounting if (i) the delivered item has value to the customer on a standalone basis, and (ii) if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item is considered probable and substantially within the control of the Company. The arrangement consideration that is fixed or determinable at the inception of the arrangement is allocated to the separate units of accounting based on their relative selling prices. The appropriate revenue recognition model is applied to each element, and revenue is accordingly recognized as each element is delivered. The Company may exercise significant judgment in determining whether a deliverable is a separate unit of accounting.

In determining the separate units of accounting, the Company evaluates whether the license has standalone value to the collaborator based on consideration of the relevant facts and circumstances for each arrangement. Factors considered in this determination include the research and development capabilities of the collaborator and the availability of relevant research expertise in the marketplace. In addition, the Company considers whether or not (i) the collaborator can use the license for its intended purpose without the receipt of the remaining deliverables, (ii) the value of the license is dependent on the undelivered items, and (iii) the collaborator or other vendors can provide the undelivered items.

ENANTA PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS—(Continued)
(unaudited)
(Amounts in thousands, except share and per share data)

Under a collaborative research and license agreement, a steering committee is typically responsible for overseeing the general working relationships, determining the protocols to be followed in the research and development performed, and evaluating the results from the continued development of the product in order to determine the clinical studies to be performed. The Company evaluates whether its participation in joint research and development steering committees is a substantive obligation or whether the services are considered inconsequential or perfunctory. The Company's participation on a steering committee is considered "participatory" and therefore accounted for as a separate element when the collaborator requires the participation of the Company to ensure all elements of an arrangement are maximized. Steering committee services that are considered participatory are combined with other research services or performance obligations required under an arrangement, if any, in determining the level of effort required in an arrangement and the period over which the Company expects to complete its aggregate performance obligations. Alternatively, the Company's participation on a steering committee is considered "protective" and therefore not accounted for as a separate element in a case where the Company can exercise or control when to be involved at its own discretion. Factors the Company considers in determining if its participation in a joint steering committee is participating or protective include: (i) which party negotiated or requested the steering committee, (ii) how frequently the steering committee meets, (iii) whether or not there are any penalties or other recourse if the Company does not attend the steering committee meetings, (iv) which party has decision making authority on the steering committee, and (v) whether or not the collaborator has the requisite experience and expertise associated with the research and development of the licensed intellectual property.

For agreements entered into prior to October 1, 2011, the Company accounted for the multiple elements within the agreements as a single unit of accounting and all payments received were recognized as revenue over the estimated period of performance of the entire arrangement as the Company was not able to separately recognize revenue for the elements under the provisions of previously applicable revenue recognition guidance.

For all periods presented, whenever the Company determines that an element is delivered over a period of time, revenue is recognized using either a proportional performance model or a straight-line model over the period of performance, which is typically the research and development term. Full-time equivalents ("FTEs") are typically used as the measure of performance. At each reporting period, the Company reassesses its cumulative measure of performance and makes appropriate adjustments, if necessary. The Company recognizes revenue using the proportional performance model whenever the Company can make reasonably reliable estimates of the level of effort required to complete its performance obligations under an arrangement. Revenue recognized under the proportional performance model at each reporting period is determined by multiplying the total expected payments under the contract (excluding royalties and payments contingent upon achievement of milestones) by the ratio of the level of effort incurred to date to the estimated total level of effort required to complete the performance obligations under the arrangement. Revenue is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined using the proportional performance model as of each reporting period. Alternatively, if the Company cannot make reasonably reliable estimates the level of effort required to complete its performance obligations under an arrangement, then revenue under the arrangement is recognized on a straight-line basis over the period expected to complete the Company's performance obligations. If and when a contingent milestone payment is earned, the additional consideration to be received is allocated to the separate units of accounting in the arrangement based on their relative selling prices at the inception of the arrangement. Revenue is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined on a straight-line basis as of the period end date. If the Company cannot reasonably estimate when its performance obligation period ends, then revenue is deferred until the Company can reasonably estimate when the performance obligation period ends.

ENANTA PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS—(Continued)
(unaudited)
(Amounts in thousands, except share and per share data)

Royalty revenue, if any, is recognized based on contractual terms when reported sales are reliably measurable and collectibility is reasonably assured, provided that there are no performance obligations then remaining. To date, none of the Company's products have been approved, and therefore the Company has not earned any royalty revenue from product sales.

During the three and six months ended March 31, 2013 and 2012 the Company also generated revenue from a government contract that reimburses the Company for certain allowable costs for the funded project. Revenue from the government contract is recognized when the related service is performed. The related costs incurred by the Company under the government contract are included in research and development expense in the statements of operations.

Amounts received prior to satisfying all revenue recognition criteria are recorded as deferred revenue in the accompanying balance sheets. Amounts not expected to be recognized as revenue within the next twelve months of the balance sheet date are classified as long-term deferred revenue.

In the event that a collaborative research and license agreement is terminated and the Company then has no further performance obligations, the Company recognizes as revenue any amounts that had not previously been recorded as revenue but were classified as deferred revenue at the date of such termination.

Recently Issued and Adopted Accounting Pronouncements

In February 2013, the FASB issued ASU No. 2013-02, *Comprehensive Income (Topic 220): Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income* ("ASU 2013-02"). This newly issued accounting standard requires an entity to provide information about the amounts reclassified out of accumulated other comprehensive income by component. In addition, an entity is required to present, either on the face of the statement where net income is presented or in the notes, significant amounts reclassified out of accumulated other comprehensive income by the respective line items of net income but only if the amount reclassified is required under U.S. GAAP to be reclassified to net income in its entirety in the same reporting period. For other amounts that are not required under U.S. GAAP to be reclassified in their entirety to net income, an entity is required to cross-reference to other disclosures required under U.S. GAAP that provide additional detail about those amounts. ASU 2013-02 is effective for fiscal years and interim periods within those years beginning after December 15, 2012 and will become effective for the Company on October 1, 2013. The Company does not believe the adoption of this standard will have an impact on the Company's financial position or results of its operations.

Other accounting standards that have been issued 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 financial statements upon adoption.

ENANTA PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS—(Continued)
(unaudited)
(Amounts in thousands, except share and per share data)

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 March 31, 2013 and September 30, 2012 and indicate the fair value hierarchy of the valuation inputs utilized to determine such fair value:

	Fair Value Measurements as of March 31, 2013 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	$ 72,016	$ —	$ —	$ 72,016
Marketable securities	1,010	46,266	—	47,276
	$ 73,026	$ 46,266	$ —	$119,292
Liabilities:				
Warrant liability	$ —	$ —	$ 1,767	$ 1,767
	$ —	$ —	$ 1,767	$ 1,767

	Fair Value Measurements as of September 30, 2012 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	$ 6,471	$ —	$ —	$ 6,471
Marketable securities	1,015	33,892	—	34,907
	$ 7,486	$ 33,892	$ —	$ 41,378
Liabilities:				
Warrant liability	$ —	$ —	$ 2,001	$ 2,001
	$ —	$ —	$ 2,001	$ 2,001

Cash equivalents at March 31, 2013 and September 30, 2012 consist of money market funds.

During the three or six months ended March 31, 2013 and 2012, there were no transfers between Level 1, Level 2 and Level 3.

As of September 30, 2012, the warrant liability is comprised of the values of warrants for the purchase of Series E redeemable convertible preferred stock and warrants for the purchase of Series 1 nonconvertible preferred stock, measured at fair value, and are based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The Company's valuation of the warrant liability utilized the Black-Scholes option-pricing model, which incorporates assumptions and estimates to value the Series E warrants and Series 1 warrants. Related to the valuation of warrants for the purchase of Series 1 nonconvertible preferred stock, the most significant quantitative elements associated with the Company's Level 3 inputs impacting fair value measurement was the fair value per share of the underlying Series 1 nonconvertible preferred stock. The Company determined that the fair value of the Series 1 nonconvertible preferred stock equals its stated liquidation preference of $1.00 per share and was $1,981 as of September 30, 2012. Since the Series 1 nonconvertible preferred stock ranks senior to all other classes of stock and its liquidation preference is small relative to the Company's equity value, the probability of a 100% payout on the Series 1 nonconvertible preferred stock was considered to be high. The fair value of warrants for the purchase of Series E redeemable

ENANTA PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS—(Continued)
(unaudited)
(Amounts in thousands, except share and per share data)

convertible preferred stock was $20, as of September 30, 2012. The Company assesses these assumptions and estimates on a quarterly basis as additional information impacting the assumptions is obtained. Changes in the fair value of the warrant liability are recognized in the statements of operations.

As of March 31, 2013, the warrant liability consists solely of the warrants for the purchase of Series 1 nonconvertible preferred stock. The Series E warrants expired during the six months ended March 31, 2013. As of March 31, 2013, the Company utilized a probability-weighted valuation model which takes into consideration various outcomes that may require the Company to transfer assets upon exercise and determined that the fair value of the Series 1 warrants was $1,767.

The following table provides a rollforward of the aggregate fair values of the Company's warrants for the purchase of Series E preferred stock and Series 1 nonconvertible preferred stock for which fair value is determined by Level 3 inputs:

Balance, September 30, 2012	$2,001
Warrants expired	(20)
Decrease in fair value	(214)
Balance, March 31, 2013	$1,767

4. Marketable Securities

As of March 31, 2013 and September 30, 2012, the fair value of available-for-sale marketable securities by type of security was as follows:

	March 31, 2013			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial paper	$ 10,186	$ —	$ —	$ 10,186
Corporate bonds	28,084	5	(14)	28,075
U.S. Agency bonds	4,555	—	—	4,555
Certificate of deposit	3,450	—	—	3,450
U.S. Treasury notes	1,008	2	—	1,010
	$ 47,283	$ 7	$ (14)	$ 47,276

	September 30, 2012			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial paper	$ 8,143	$ —	$ —	$ 8,143
Corporate bonds	25,741	9	(1)	25,749
U.S. Treasury notes	1,013	2	—	1,015
	$ 34,897	$ 11	$ (1)	$ 34,907

At March 31, 2013, marketable securities consisted of investments that mature within one year, with the exception of certain U.S. Agency and corporate bonds, which have maturities within two years and an aggregate fair value of $12,629.

ENANTA PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS—(Continued)
(unaudited)
(Amounts in thousands, except share and per share data)

5. Accrued Expenses and Other Long-Term Liabilities

Accrued expenses (current) and other long-term liabilities consisted of the following as of March 31, 2013 and September 30, 2012:

	March 31, 2013	September 30, 2012
Accrued expenses:		
Accrued payroll and related expenses	$ 493	$ 1,305
Accrued vendor manufacturing	23	1,330
Accrued professional fees	629	718
Accrued third-party license fees	728	222
Accrued other	592	291
	$ 2,465	$ 3,866
Other long-term liabilities:		
Accrued rent expense	$ 101	$ 75
Present value of accrued third-party license fees	433	423
	$ 534	$ 498

6. Collaboration Agreements

AbbVie Collaboration

On November 27, 2006, the Company entered into a Collaborative Development and License Agreement (the “Abbott Agreement” or “AbbVie Agreement”) with Abbott Laboratories (“Abbott”) to identify, develop and commercialize HCV NS3 and NS3/4A protease inhibitor compounds, including ABT-450. The agreement, which was amended in January and December 2009, was assigned to AbbVie Inc. (“AbbVie”) on January 1, 2013 in connection with Abbott’s transfer of its research-based pharmaceuticals business to AbbVie. Under the terms of the AbbVie Agreement, as amended, AbbVie paid to the Company upfront license payments and FTE reimbursements to fund research activities. The Company is also eligible to receive milestone payments for the successful development by AbbVie of one or more HCV compounds as well as tiered royalties per product ranging from the low double digits up to twenty percent, or on a blended basis from the low double digits up to the high teens, on net sales by AbbVie allocable to the collaboration’s protease inhibitors. Deliverables under the AbbVie Agreement included a license, research services and participation on a steering committee. The Company concluded that all deliverables under the AbbVie Agreement should be treated as a single unit of accounting. Accordingly, revenue was recognized using the proportional performance model over the period during which the Company performed research services. The Company completed all remaining obligations under the agreement as of June 2011. All milestone payments received after June 2011 are recognized as revenue when each milestone is achieved by AbbVie.

Through June 2011, under the AbbVie Agreement the Company had received upfront license payments, research funding, and milestone payments totaling $92,450, all of which has been recognized as revenue as of June 30, 2011. In December 2012, the Company received an additional $15,000 milestone payment under the AbbVie Agreement as a result of AbbVie’s initiation of dosing in a Phase 3 clinical trial involving ABT-450. This amount was recognized as revenue during the three months ended December 31, 2012.

During the three months ended March 31, 2013 and 2012, the Company recognized no revenue related to this agreement. During the six months ended March 31, 2013 and 2012, the Company recognized revenue of $15,000 and $0, respectively.

ENANTA PHARMACEUTICALS, INC.
NOTES TO FINANCIAL STATEMENTS—(Continued)
(unaudited)
(Amounts in thousands, except share and per share data)

As of March 31, 2013, the Company is eligible to receive additional future milestone payments totaling up to $40,000 upon AbbVie's achievement of regulatory filing milestones for the first protease inhibitor product resulting from its collaboration and additional milestone payments totaling up to $155,000 upon AbbVie's achievement of commercial regulatory approval milestones in selected world markets. The Company is also eligible to receive additional milestone payments totaling up to $80,000 upon AbbVie's achievement of similar commercial regulatory approval milestones for each additional product containing a new protease inhibitor.

Novartis Collaboration

On February 16, 2012, the Company entered into a license and collaboration agreement with Novartis (the "Novartis Agreement") for the development, manufacture and commercialization of its lead development candidate, EDP-239, from its NS5A HCV inhibitor program. Under the terms of the Novartis Agreement, Novartis agreed to pay a nonrefundable upfront fee to the Company and reimbursement of manufacturing and quality assurance expenses related to EDP-239 totaling $34,442. Under the agreement, the Company is eligible to receive aggregate milestone payments of up to $406,000 upon Novartis' initiation of clinical trials, achievement of regulatory approvals, and/or net sales of products containing the Company's NS5A inhibitors. The Company is also eligible to receive tiered royalties ranging on a blended basis from the low double digits up to the high teens on net product sales by Novartis allocable to the collaboration's NS5A inhibitors. Under the agreement, a clinical milestone payment of $11,000 was due to the Company upon Novartis' initiation of dosing in the first Phase 1 clinical trial involving EDP-239 or another NS5A inhibitor, and was received by the Company in January 2013. An additional milestone payment of $15,000 will be due upon Novartis' initiation of the first Phase 2 clinical trial using a combination containing an NS5A inhibitor. In addition, Novartis agreed to fund research activities for one year commencing February 2012, up to a total of $1,800. In March 2013, the agreement was amended to extend research funding for an additional six months through August 2013 at the same reimbursement rate.

The Company determined that the deliverables under the Novartis Agreement were the license and the research services. As each of these deliverables had standalone value it was determined that they each represented a separate unit of accounting. Arrangement consideration was allocated between the license and research services based on their relative selling prices using best estimate of selling price.

During the three months ended March 31, 2013 and 2012 the Company recognized total revenue of $465 and $34,667, respectively, related to the delivery of the license and the performance of the research services. During the six months ended March 31, 2013 and 2012, the Company recognized total revenue of $11,877 and $34,667, respectively, under the Novartis Agreement.

NIAID Contract

On September 30, 2011, the Company entered into a contract with the National Institute of Allergy and Infectious Diseases ("NIAID"), a division of the National Institutes of Health ("NIH"), which could provide up to $42,700 in development funding to the Company over a five-year period. The contract will fund the preclinical and clinical development of a new class of bridged bicyclic antibiotics known as Bicyclolides to be used as medical countermeasures against multiple biodefense Category A and B bacteria.

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The contract has an initial term of 30 months ending on March 30, 2014. NIAID has the option to extend the contract up to six times. If each extension option is exercised, the contract would be extended until September 30, 2016. The initial award under the initial term was $14,300, with the possibility of up to a total of $42,700 if each option period is exercised by NIAID.

The Company recognizes revenue under this agreement as development services are performed in accordance with the funding agreement. During the three months ended March 31, 2013 and 2012, $731 and $1,898 of revenue, respectively, was recognized under this agreement. During the six months ended March 31, 2013 and 2012, the Company recognized revenue of $2,178 and $2,639, respectively, under this agreement.

7. Stockholders' Equity

On March 1, 2013, the Company effected an increase in the number of authorized shares of its common stock from 70,000,000 to 100,000,000 shares. On March 1, 2013, the Company effected a 1-for-4.31 reverse stock split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratio for each series of Redeemable Convertible Preferred Stock and Convertible Preferred Stock. Accordingly, all share and per share amounts for all periods presented in these financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect the reverse stock split and adjustment of the preferred share conversion ratios.

On March 26, 2013 the Company completed an initial public offering ("IPO") of its common stock, which resulted in the sale of 4,600,000 shares at a price of $14.00 per share. The Company received net proceeds from the IPO of approximately $59,892 based upon the price of $14.00 per share and after deducting underwriting discounts and commissions paid by the Company.

Upon closing of the initial public offering, all outstanding shares of the Company's redeemable convertible preferred stock and convertible preferred stock were converted into 11,656,875 shares of common stock.

Warrants to Purchase Series E Preferred Stock

Warrants for the purchase of Series E redeemable convertible preferred stock ("Series E preferred stock") were issued by the Company in fiscal 2002 and fiscal 2004 during various financings. As these warrants are financial instruments that could have required a transfer of assets because of the redemption feature at the option of the holders of the Series E preferred stock, these warrants were classified as liabilities on the Company's balance sheet.

As of September 30, 2012, warrants for the purchase of 12,500 shares of Series E preferred stock remained outstanding. These warrants expired during the six months ended March 31, 2013.

Warrants to Purchase Series 1 Preferred Stock

In October and November 2010, a total of 1,999,989 warrants to purchase Series 1 nonconvertible preferred stock were issued. These warrants expire on October 4, 2017. As these warrants are free-standing financial instruments that may require the Company to transfer assets upon exercise, these warrants are classified as liabilities. These warrants had a fair value of $1,280 upon issuance. The Company is required to remeasure the fair value of these preferred stock warrants at each reporting date, with any adjustments recorded within the change in fair value of warrant liability included in other income (expense) in the statement of operations. The warrants were

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remeasured at each reporting period, resulting in net income of $214 and $0 for the three and six months ended March 31, 2013 and 2012, respectively. As of March 31, 2013 and September 30, 2012, the total fair value of the Series 1 nonconvertible preferred stock warrants was $1,767 and $1,981, respectively.

8. Stock-Based Awards

1995 Equity Incentive Plan

The 1995 Equity Incentive Plan (the "1995 Plan") provides for the Company to sell or issue common stock or restricted common stock, or to grant incentive stock options or nonqualified stock options for the purchase of common stock, to employees, members of the board of directors and consultants of the Company. Sales, issuances or grants of shares entitle the holder to purchase common stock from the Company, for a specified exercise price, during a period specified by the applicable equity award agreement. The 1995 Plan is administered by the board of directors and exercise prices, vesting and other restrictions are all determined at their discretion. Options granted under the 1995 Plan to non-executive employees generally vest 25% per year and expire after ten years; options granted to executive employees generally vest over one to four years; and options granted to the board of directors vest over a two-year period. On January 17, 2013, the Company's stockholders approved an amendment to the 1995 Equity Incentive Plan to increase the number of shares of common stock reserved for issuance under the plan by 232,018 shares to 2,772,777 shares. Upon closing of the Company's initial public offering, 26,742 shares reserved and not then subject to outstanding options were transferred to the 2012 Plan, and no further awards will be made under the 1995 Plan.

2012 Equity Incentive Plan

On January 17, 2013, the Company's stockholders approved the 2012 Equity Incentive Plan (the "2012 Plan"), which became effective immediately prior to the closing of the Company's initial public offering. The 2012 Plan permits the Company to sell or issue common stock or restricted common stock, to grant incentive stock options or nonqualified stock options for the purchase of common stock, or to grant restricted stock units, stock appreciation rights or other cash incentive awards, to employees, members of the board of directors and consultants of the Company. The total number of shares of common stock that may be issued under the plan is 348,355 shares, including 26,742 shares incorporated from the 1995 Plan that were reserved and not subject to outstanding options as of the closing of the Company's initial public offering. The number of shares of common stock that may be issued under the plan is also subject to increase by the number of shares forfeited under any options terminated and not exercised under the 1995, plus an increase in shares on the first day of each fiscal year by the lowest of (i) 3% of the Company's outstanding shares of common stock as of that date, (ii) 2,088,167 shares of common stock, or (iii) an amount determined by the board of directors.

During the three months ended March 31, 2013, the Company granted to certain executives 167,052 options that vest upon the achievement of certain performance-based targets. The fair value of these options at the grant date was $1,487. Through March 31, 2013, the Company recorded approximately $5 of stock compensation expense related to these awards for the portion of the service period incurred related to performance-based targets that were considered probable.

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Employee Stock Purchase Plan

On January 3, 2013, the Company's stockholders approved the Employee Stock Purchase Plan (the "ESPP"). A total of 185,614 shares of common stock were reserved for issuance under this plan, which became effective immediately prior the closing of the Company's initial public offering. As of March 31, 2013, the first offering period under the ESPP had not commenced and no shares have been issued.

Stock Option Valuation

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The Company historically has been a private company and lacks sufficient company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of its publicly traded peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future. The relevant data used to determine the value of the stock option grants is as follows, presented on a weighted average basis:

	Three Months Ended March 31,		Six Months Ended March 31,	
	2013	2012	2013	2012
Risk-free interest rate	1.08%	n/a	1.03%	n/a
Expected term (in years)	6.16	n/a	6.10	n/a
Expected volatility	71%	n/a	73%	n/a
Expected dividend yield	0%	n/a	0%	n/a

The Company recognizes compensation expense for only the portion of awards that are expected to vest. In developing a forfeiture rate estimate, the Company has considered its historical experience to estimate pre-vesting forfeitures for service-based awards. The impact of a forfeiture rate adjustment will be recognized in full in the period of adjustment, and if the actual forfeiture rate is materially different from the Company's estimate, the Company may be required to record adjustments to stock-based compensation expense in future periods.

As required by the 1995 Plan and 2012 Plan, the exercise price for awards granted is not to be less than the fair value of common shares as estimated by the Company as of the date of grant. For periods prior to the initial public offering of common stock, the Company valued its common stock by taking into consideration its most recently available valuation of common shares performed by management and the board of directors as well as additional factors which may have changed since the date of the most recent contemporaneous valuation through the date of grant.

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The following table summarizes stock option activity during the six months ended March 31, 2013:

	Shares Issuable Under Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (In years)	Aggregate Intrinsic Value
Outstanding as of September 30, 2012	1,771,471	$ 2.08	4.1	$ 19,911
Granted	350,682	14.03		
Exercised	(427,590)	0.97		
Expired	(2,864)	2.59		
Outstanding as of March 31, 2013	1,691,699	$ 4.84	5.3	$ 22,609
Options vested and expected to vest as of March 31, 2013	1,679,722	$ 4.77	5.3	$ 22,559
Options exercisable as of March 31, 2013	1,232,478	$ 2.08	3.7	$ 19,870

The Company recorded stock-based compensation expense for the three and six months ended March 31, 2013 and 2012 in the following expense categories:

	Three Months Ended March 31,		Six Months Ended March 31,	
	2013	2012	2013	2012
Research and development	$ 85	$ 13	$ 179	$ 29
General and administrative	172	18	359	57
	$ 257	$ 31	$ 538	$ 86

As of March 31, 2013, the Company had an aggregate of $1,721 of unrecognized stock-based compensation cost, which is expected to be recognized over a weighted average period of 2.8 years.

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9. Net Income (Loss) Per Share

Basic and diluted net income (loss) per share attributable to common stockholders was calculated as follows for the three and six months ended March 31, 2013 and 2012:

	Three Months Ended March 31,		Six Months Ended March 31,	
	2013	2012	2013	2012
Basic net income (loss) per share attributable to common stockholders:				
Numerator:				
Net income (loss)	$ (3,749)	$ 32,111	$ 18,208	$ 28,952
Accretion of redeemable convertible preferred stock to redemption value	(1,244)	(1,331)	(2,526)	(2,705)
Net income attributable to participating securities	—	(28,152)	(13,670)	(24,071)
Net income (loss) attributable to common stockholders	$ (4,993)	$ 2,628	$ 2,012	$ 2,176
Denominator:				
Weighted average common shares outstanding—basic	2,192,470	1,088,251	1,669,578	1,053,912
Net income (loss) per share attributable to common stockholders—basic	$ (2.28)	$ 2.41	$ 1.21	$ 2.06
Diluted net income (loss) per share attributable to common stockholders:				
Numerator:				
Net income (loss)	$ (3,749)	$ 32,111	$ 18,208	$ 28,952
Accretion of redeemable convertible preferred stock to redemption value	(1,244)	(1,331)	(2,526)	(2,705)
Net income attributable to participating securities	—	(25,279)	(12,329)	(21,802)
Net income (loss) attributable to common stockholders—diluted	$ (4,993)	$ 5,501	$ 3,353	$ 4,445
Denominator:				
Weighted average common shares outstanding—basic	2,192,470	1,088,251	1,669,578	1,053,912
Dilutive effect of common stock equivalents	—	1,448,649	1,414,506	1,323,299
Weighted average common shares outstanding—diluted	2,192,470	2,536,900	3,084,084	2,377,211
Net income (loss) per share attributable to common stockholders—diluted	$ (2.28)	$ 2.17	$ 1.09	$ 1.87

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Stock options for the purchase of 245,225 weighted average shares were excluded from the computation of diluted net income per share attributable to common stockholders for the three months ended March 31, 2013 and stock options for the purchase of 126,489 weighted average shares were excluded from the computation of diluted net income per share attributable to common stockholders for the six months ended March 31, 2013 because those options had an anti-dilutive impact due to the assumed proceeds per share using the treasury stock method being greater than the average fair value of the Company's common shares for those periods. Stock options for the purchase of 1,540,845 weighted average shares were excluded from the computation of diluted net loss per share attributable to common stockholders for the three months ended March 31, 2013 because those options had an anti-dilutive impact due to the net loss attributable to common stockholders incurred for the period.

There were no outstanding common stock equivalents that had an anti-dilutive impact on net income per share attributable to common stockholders for the three or six months ended March 31, 2012.

10. Commitments and Contingencies

Leases

The Company has an office and laboratory lease that expires in September 2018. Payment escalation as specified in the lease agreement is accrued such that rent expense is recognized on a straight-line basis over the terms of occupancy. The Company recorded rent expense of $237 for the three months ended March 31, 2013 and 2012, and $474 for the six months ended March 31, 2013 and 2012.

In connection with the lease, the Company has outstanding a $436 letter of credit, collateralized by a money market account. As of March 31, 2013 and September 30, 2012, the Company classified $436 related to the letter of credit as restricted cash.

Intellectual Property License

The Company has a non-exclusive intellectual property license agreement under which it is required to pay the licensor future license fees of $250, $250 and $200 in fiscal years 2013, 2014 and 2015, respectively. In addition, the Company is required to pay (1) annual maintenance fees of $105 for each year that the agreement remains in effect in order to maintain the right to use the license, and (2) a one-time fee of $50 in each circumstance in which the Company provides the licensed intellectual property to one of its collaborators with the prior consent of the licensor. As of March 31, 2013, the Company had accrued expense relating to this obligation of $661 of which $228 was included in accrued expenses and $433 was included in other long-term liabilities.

Litigation and Contingencies Related to Use of Intellectual Property

As of March 31, 2013 the Company was aware of a potential license it may need to acquire with respect to patents it used, or may have used, in prior years or periods. During the three months ended March 31, 2013, the Company first determined that the probable license costs could be reasonably estimated. As a result, during that period, the Company recorded an expense and a corresponding accrued liability of $500, based on its best estimate at that date of this contingent liability.

From time to time, the Company may become subject to legal proceedings, claims and litigation arising in the ordinary course of business. The Company currently is not a party to any threatened or pending litigation. However, third parties might allege that the Company or its collaborators are infringing their patent rights or that

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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, could 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 incurred and such expenditures can be reasonably estimated.

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, from services to be provided by 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 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. Despite the fact that the Company has obtained insurance coverage for certain of these indemnifications, 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. 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 it has not accrued any liabilities related to such obligations in its financial statements as of March 31, 2013.

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 financial statements and notes thereto included elsewhere in this Quarterly Report on Form 10-Q and the audited financial statements and notes thereto for the year ended September 30, 2012 included in our final prospectus filed with the Securities and Exchange Commission on March 21, 2013. This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements are often identified by the use of words such as "may," "will," "expect," "believe," "anticipate," "intend," "could," "should," "estimate," or "continue," and similar expressions or variations. Such forward-looking statements are subject to risks, uncertainties and other factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section titled "Risk Factors," set forth in Part II, Item 1A of this Quarterly Report on Form 10-Q. The forward-looking statements in this Quarterly Report on Form 10-Q represent our views as of the date of this Quarterly Report on Form 10-Q. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Quarterly Report on Form 10-Q.

Overview

We are a research and development-focused biotechnology company that uses its robust chemistry-driven approach and drug discovery capabilities to create small molecule drugs in the infectious disease field. We are discovering and developing inhibitors designed for use against the hepatitis C virus, referred to as HCV. We believe that a successful approach to a complete cure for HCV in most patients will likely require treatment with a combination of drugs that attack different mechanisms necessary for replication and survival of HCV. Further, as there are many variants of HCV, we are developing inhibitors that may be used in multiple combination therapies, each designed and tested for effectiveness against one or more of those variants. Our development of inhibitors for validated HCV target mechanisms, as well as our collaborations with AbbVie (which name refers to Abbott Laboratories for all periods before January 1, 2013) and Novartis, should allow us to participate in multiple unique drug combinations as we seek the best combination therapies for HCV in its various forms.

Our HCV portfolio includes inhibitors of four fundamental, validated HCV targets. Our lead product candidate, ABT-450, is a protease inhibitor being developed in several combination regimens in multiple Phase 2 and Phase 3 trials through our collaboration with AbbVie. AbbVie has funded all research and development of our protease inhibitors since we entered into the collaboration in November 2006, and is responsible for obtaining regulatory approvals and commercializing ABT-450 and any follow-on products worldwide. Our lead NS5A product candidate, EDP-239, is being developed through our collaboration with Novartis. Under our collaboration with Novartis, Novartis is responsible for all further development of our NS5A inhibitors. Novartis is also responsible for funding further research that we conduct to discover additional NS5A compounds at least through August 2013. Our independent research activities are focused on our lead cyclophilin inhibitor candidates, which are in preclinical development. We also have a small-molecule drug discovery effort underway for nucleotide polymerase inhibitors. We are currently funding all research and development for our cyclophilin inhibitor and nucleotide polymerase inhibitor programs. We expect to incur substantially greater expenses as we seek to advance these programs into clinical development.

In addition to our HCV programs, we have used our internal research capabilities to discover a new class of antibiotics called Bicyclolides, which we are developing for the treatment of multi-drug resistant bacteria, including methicillin-resistant *Staphylococcus aureus* bacteria, also referred to as MRSA. Up to $14.3 million of the preclinical development of our lead antibiotic candidate, EDP-788, is funded under a September 2011 contract with the National Institute of Allergy and Infectious Diseases, a division of the National Institutes of Health, an agency of the United States Department of Health and Human Services, or NIAID, and there is potential for further NIAID funding of early clinical development.

Since commencing our operations in 1995, we have devoted substantially all of our resources to the discovery and development of novel inhibitors for the treatment of infectious diseases. We have historically funded our operations primarily through the sale of convertible preferred stock and payments received under our collaborations and a government contract. On March 26, 2013, we completed our initial public offering of 4,600,000 shares of common stock at an offering price of $14.00 per share, which included the exercise in full by the underwriters of their option to purchase up to 600,000 additional shares of common stock. We received net proceeds of approximately $59.9 million, after deducting underwriting discounts and commissions. As of March 31, 2013, we had $121.7 million in cash and investments.

Our revenue from our collaboration agreements has resulted in our reporting net income in each of our past three fiscal years and in the first quarter of our fiscal 2013. However, we reported a net loss in the second quarter of our fiscal 2013, had an accumulated deficit of $98.9 million as of March 31, 2013 and have generated no royalties or other revenue from product sales. We expect that our revenue in the near term will continue to be substantially dependent on our collaborations with AbbVie and Novartis and their continued advancement of the related development programs. Given the schedule of potential milestone payments and the uncertain nature and timing of clinical development, we cannot predict when or whether we will receive further milestone payments under these collaborations or whether we will report either revenue or net income in future years.

Financial Operations Overview

Revenue

Since our inception, our revenue has been derived from two primary sources: collaboration agreements with pharmaceutical companies and one government research and development contract. We have not generated any revenue from product sales. In November 2006, we entered into a collaboration agreement with AbbVie and in February 2012 we entered into a collaboration agreement with Novartis. In September 2011, we entered into a contract with NIAID, which will fund the preclinical development of our lead product candidate in our new class of Bicyclolide antibiotics.

The following table is a summary of revenue recognized from our collaboration agreements and government contract for the three and six months ended March 31, 2013 and 2012:

	Three Months Ended March 31,		Six Months Ended March 31,	
	2013	2012	2013	2012
	(in thousands)			
AbbVie agreement:				
Milestone payments	$ —	$ —	$15,000	$ —
Novartis agreement:				
Upfront license payment and research funding	465	34,667	877	34,667
Milestone payments	—	—	11,000	—
NIAID contract	731	1,898	2,178	2,639
Total revenue	$1,196	$36,565	$29,055	$37,306

AbbVie Agreement

Under the terms of the AbbVie agreement, as amended, we received total payments comprised of an upfront license payment, payments to fund research and reimburse certain expenses and milestone payments totaling $92.5 million through June, 2011. We recognized revenue from these payments, as well as from a $1.6 million premium above fair value paid for Series G-1 redeemable convertible preferred stock that AbbVie purchased concurrently with the execution of the original agreement, over the period from the date of the original agreement through June, 2011 using the proportional performance model. Since all of our research obligations under the

agreement were concluded by June 30, 2011, any future milestone payments received will be recognized as revenue when each milestone is achieved by AbbVie. During the six months ended March 31, 2013, we earned and recognized as revenue a $15.0 million milestone payment based on AbbVie's initiation of dosing in a Phase 3 clinical trial that includes ABT-450. Under the terms of the AbbVie agreement, we are eligible to receive aggregate future milestone payments of $195 million related to the successful development of the first HCV treatment regimen by AbbVie incorporating our collaboration's protease inhibitor. We are also eligible to receive royalties on AbbVie's net sales, if any, allocable to any one of our collaboration's protease inhibitors.

Novartis Agreement

Under the terms of the Novartis agreement, we received an upfront payment of $34.4 million in February 2012 and a commitment to fund research at an agreed amount for one year. We recognized the upfront license payment upon receipt as we determined that the license to which the payment related and the research services were separable elements under the agreement that could be accounted for as each was delivered or provided. Our agreement with Novartis provides that we will receive up to $1.8 million in research funding during the first year of the agreement, which began in February 2012. In March 2013 the agreement was amended to extend the funding period for an additional six months through August 2013 at the same reimbursement rate. Additionally, our collaboration with Novartis provides for aggregate milestone payments of up to $406 million if certain goals related to drug development and net product sales are achieved by Novartis. In January 2013, we received an $11.0 million milestone payment based on Novartis' November 2012 initiation of dosing in a Phase 1 clinical trial that includes EDP-239. During the three months ended March 31, 2013 and 2012, revenue recognized under this agreement was $0.5 million and $34.7 million, respectively. The amounts recognized during the three months ended March 31, 2013 consisted of research funding and amounts recognized during the three months ended March 31, 2012 consisted of the upfront license payment and research funding earned during that period.

During the six months ended March 31, 2013, we recognized $11.9 million of revenue under the Novartis agreement, of which $11.0 million was attributed to license fees and $0.9 million was attributed to the performance of research services. An additional milestone payment of $15.0 million will be due upon Novartis' initiation of a subsequent Phase 2 trial using a combination containing an NS5A inhibitor. We are also eligible to receive royalties on Novartis' net sales, if any, allocable to our collaboration's NS5A inhibitors.

NIAID Contract

Under the terms of the NIAID contract, NIAID will pay us research and development funding payments of up to $14.3 million over an initial period of 30 months. The contract also contains six option periods, which in aggregate could extend the contract, at the option of NIAID, up to an additional 30 months and provide us additional funding of up to $28.4 million. We recognize revenue under this contract as research and development services are performed. We recognized revenue of $0.7 million and $1.9 million under this agreement during the three months ended March 31, 2013 and 2012, respectively, and $2.2 million and $2.6 million during the six months ended March 31, 2013 and 2012, respectively.

Operating Expenses

The following table summarizes our operating expenses for the three and six months ended March 31, 2013 and 2012:

	Three Months Ended March 31,		Six Months Ended March 31,	
	2013	2012	2013	2012
Research and development	$ 3,704	$ 3,263	$ 8,502	$ 5,935
General and administrative	1,493	1,207	2,645	2,458
Total operating expenses	$ 5,197	$ 4,470	$ 11,147	$ 8,393

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. 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;
- third-party license fees;
- laboratory consumables; and
- allocated facility-related costs.

Project-specific expenses reflect costs directly attributable to our clinical development candidates and preclinical candidates nominated and selected for further development. 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 maintain 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 two independent HCV programs and our antibiotic program for MRSA into clinical development. In our fiscal year ending September 30, 2013, we expect to incur approximately $21.0 million of expenses associated with research and development, which amount is exclusive of expenses incurred by our collaborators in developing our licensed product candidates ABT-450 and EDP-239.

Our research and drug discovery programs are at an early stage; 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 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, consisting of 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, and professional fees for auditing, tax and legal services, including legal expenses to pursue patent protection of our intellectual property.

We expect that general and administrative expenses will increase in the future as we expand our operating activities and incur additional costs associated with operating as a public company. These public company related increases will likely include costs of additional personnel, additional legal fees, accounting and audit fees and directors’ and officers’ liability insurance premiums, and costs related to investor relations.

Other Income (Expense)

Interest income. Interest income consists of interest earned on our cash and investment balances. Our interest income has not been significant due to the low rate of interest earned on invested balances. We anticipate that our interest income will increase in the future due to our higher cash and investment balances now existing as a result of the $34.4 million upfront payment we received from Novartis in March 2012, a $15.0 million milestone payment we received from AbbVie in December 2012 and an $11.0 million milestone payment we received from Novartis in January 2013, as well as our receipt of $59.9 million of cash proceeds, net of underwriters discounts and commissions, from our initial public offering in March 2013.

Interest expense. Interest expense consists of non-cash interest expense which is being accreted to the value of accrued third-party license fees over the term of the obligation.

Change in fair value of warrant liability. We have issued warrants for the purchase of our redeemable convertible preferred stock and nonconvertible preferred stock that we believe are financial instruments that may require a transfer of assets because of the redemption features of the underlying stock. Therefore, we have classified these warrants as liabilities that we remeasure to fair value at each reporting period and we record the changes in the fair value of the warrants as a component of other income (expense).

Critical Accounting Policies

Our financial statements are prepared in accordance with generally accepted accounting principles in the United States of America. The preparation of our 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 believe that the estimates and assumptions involved in the accounting policies described below may have the greatest potential impact on our financial statements and, therefore, consider these to be our critical accounting policies. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions and conditions. See also Note 2 to our financial statements included elsewhere in this Quarterly Report on Form 10-Q and our registration statement on Form S-1 for information about these accounting policies as well as a description of our other significant accounting policies. We believe that of our significant accounting policies, the following accounting policies involve the most judgment and complexity:

- Revenue recognition;
- Income taxes;
- Fair value of financial instruments; and
- Stock-based compensation

Accordingly, we believe the policies set forth above are critical to fully understanding and evaluating our financial condition and results of operations. If actual results or events differ materially from the estimates, judgments and assumptions used by us in applying these policies, our reported financial condition and results of operations could be materially affected.

There have been no material changes in our critical accounting policies since September 30, 2012. For further information, please see the discussion of critical accounting policies included in our registration statement on Form S-1.

Results of Operations

Comparison of Three Months Ended March 31, 2013 and 2012

	Three Months Ended March 31,	
	2013	2012
	(in thousands)	
Revenue	$1,196	$36,565
Research and development expenses	3,704	3,263
General and administrative expenses	1,493	1,207
Other income (expense):		
Interest income	47	15
Interest expense	(9)	—
Change in fair value of warrant liability	214	1

Revenue. We recognized revenue of $1.2 million during the three months ended March 31, 2013, as compared to $36.6 million during the three months ended March 31, 2012. During the three months ended March 31, 2013, $0.7 million of revenue was from the EDP-788 program related to the contract with NIAID and $0.5 million was related to our performance of research services under our Novartis agreement. During the three months ended March 31, 2012, revenue related to NIAID contract was $1.9 million. In addition, during the three months ended March 31, 2012, we received an upfront payment of $34.4 million and $0.3 million related to research services from Novartis, which we recognized as revenue during the period.

Research and development expenses.

	Three Months Ended March 31,	
	2013	2012
	(in thousands)	
Development programs:		
NS5A inhibitor	$ 461	$ 714
Antibiotic	611	1,272
Research and drug discovery	2,632	1,277
Total research and development expenses	$ 3,704	$ 3,263

Research and development expenses were $3.7 million in the three months ended March 31, 2013, as compared to $3.3 million for the same period in 2012. The $0.4 million increase period over period was due primarily to an increase of $1.3 million in expenses related to our early stage drug discovery programs offset by a $0.2 million decrease in expenses for our NS5A inhibitor program and a decrease of $0.7 million in preclinical expenses related to our antibiotic program, specifically EDP-788. Preclinical expenses related to our antibiotic program were higher in 2012 as compared to 2013 primarily due to the significant expense for materials necessary for the ramp-up of the development program under the contract with NIAID, which we entered into in September 2011. We incurred increased research expenses in 2013 as compared to 2012 in our early stage drug discovery programs due to an increase in the number of preclinical studies and the related costs. Our research costs related to our NS5A inhibitor program decreased as a result of our signing a collaboration agreement with Novartis in February 2012, at which time Novartis became responsible for further development costs. Prior to entering into the collaboration agreement with Novartis, we had been incurring costs for preclinical and clinical development of that program. We continue to incur research expense for NS5A to identify additional compounds, which research is being funded by Novartis through August 2013.

General and administrative expenses. General and administrative expenses increased by $0.3 million from $1.2 million in the three months ended March 31, 2012 to $1.5 million for the same period in 2013. The increase was

related primarily to an increase in stock-based compensation expense as a result of additional stock option grants to employees and a higher value of our common stock partially offset by a decrease in legal and patent fees in the 2013 period as a result of the timing of services provided and a decrease in the number of patent application filings.

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

Interest income. Interest income increased slightly due to higher investment balances during the three months ended March 31, 2013 as compared to the three months ended March 31, 2012.

Change in fair value of warrant liability. We account for our outstanding warrants for our Series 1 nonconvertible preferred stock as liabilities held at fair value, with changes in fair value recorded as a component of other income (expense). During the three months ended March 31, 2013, we recorded income of $0.2 million due to a decrease in the fair value of our warrant liability as a result of the remeasurement of our Series 1 nonconvertible preferred stock warrants.

Comparison of Six Months Ended March 31, 2013 and 2012

	Six Months Ended March 31,	
	2013	2012
	(in thousands)	
Revenue	$29,055	$37,306
Research and development expenses	8,502	5,935
General and administrative expenses	2,645	2,458
Other income (expense):		
Interest income	82	29
Interest expense	(16)	—
Change in fair value of warrant liability	234	10

Revenue. We recognized revenue of $29.1 million during the six months ended March 31, 2013, as compared to $37.3 million during the six months ended March 31, 2012. During the six months ended March 31, 2013, we received a $15.0 million milestone payment under our collaboration with AbbVie based on AbbVie's initiation of dosing in a Phase 3 clinical trial that includes ABT-450, which amount was recognized as revenue in the six months ended March 31, 2013. We did not have any revenue related to the AbbVie collaboration during the same period in 2012. During the six months ended March 31, 2013, we also recognized revenue of $11.9 million under our collaboration with Novartis, due primarily to an $11.0 million milestone payment we received in January 2013 based on Novartis' initiation of dosing in a Phase 1 clinical trial that includes EDP-239. During the comparable period in 2012, we received an upfront payment of $34.4 million and $0.3 million related to research services from Novartis, which we recognized as revenue during the period. Government contract revenue was $2.2 million and $2.6 million during the six months ended March 31, 2013 and 2012, respectively, related to the EDP-788 program related to our contract with NIAID.

Research and development expenses.

	Six Months Ended March 31,	
	2013	2012
	(in thousands)	
Development programs:		
NS5A inhibitor	$ 898	$2,031
Antibiotic	1,679	1,778
Research and drug discovery	5,925	2,126
Total research and development expenses	$8,502	$5,935

Research and development expenses were $8.5 million in the six months ended March 31, 2013, as compared to $5.9 million for the same period in 2012. The increase of $2.6 million from 2012 to 2013 was due primarily to a $3.8 million increase in preclinical expenses for our early stage drug discovery programs. This increase was partially offset by a decrease of $1.1 million in expenses for our NS5A inhibitor program and a decrease of $0.1 million in our expenses for our antibiotic program. We incurred preclinical expense for the development of EDP-788 as a result of the contract we entered into in September 2011 with NIAID, which is funding our research program for EDP-788. We incurred increased research expenses in our early stage drug discovery programs due to an increase in both the number of preclinical studies and the related costs. Our research costs related to our NS5A inhibitor program decreased as a result of our signing a collaboration agreement with Novartis in February 2012, at which time Novartis became responsible for further development costs. Prior to entering into the collaboration agreement with Novartis, we had been incurring costs for preclinical and clinical development of EDP-239. We continue to incur research expense for NS5A research to identify additional compounds, for which we are receiving funding from Novartis through at least August 2013.

General and administrative expenses. General and administrative expenses were $2.6 million during the six month ended March 31, 2013 and $2.5 million during the six months ended March 31, 2012. Total expenses increased by $0.1 million during the six months ended March 31, 2013, as a result of higher stock-based compensation expenses due to additional stock option grants to employees and the higher value of our common stock, partially offset by lower legal and patent fees in the 2013 period as a result of the timing of services provided and a reduced number of patent application filings.

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

Interest income. The increase in interest income for the six months ended March 31, 2013, as compared to the six months ended March 31, 2012, was due to higher average cash and investment balances primarily due to the receipt of the $15.0 million milestone payment received from AbbVie and $11.0 million milestone payment received from Novartis during the six months ended March 31, 2013.

Interest expense. Interest expense consists of non-cash interest expense which is being accreted to the value of accrued third-party license fees over the term of the obligation.

Change in fair value of warrant liability. We account for our outstanding warrants for our Series E redeemable convertible preferred stock and our Series 1 nonconvertible preferred stock as liabilities held at fair value, with changes in fair value recorded as a component of other income (expense). During the six months ended March 31, 2013, we recorded a small amount of income due to the expiration of our Series E warrants during the reporting period as well as a decrease in the fair value of our warrant liability during the six months ended March 31, 2013 due to the remeasurement of the fair value of warrants for Series 1 nonconvertible preferred stock.

Liquidity and Capital Resources

At March 31, 2013, our principal sources of liquidity were cash, cash equivalents and marketable securities of $121.7 million.

From our inception through March 31, 2013, we have financed our operations, primarily through contract payments under our collaborations, private placements of our equity, government research and development contracts and grants and our initial public offering that was completed in March 2013 for which we received $59.9 million, net of underwriting discounts and commissions. The following table shows a summary of our cash flows for each of the six months ended March 31, 2013 and 2012.

	Six Months Ended March 31,	
	2013	2012
Cash provided by (used in):		
Operating activities	$ 19,078	$ 28,153
Investing activities	$(13,359)	$(14,395)
Financing activities	$ 58,234	$ 107

Net cash provided by (used in) operating activities

During the six months ended March 31, 2013, operating activities provided $19.1 million of cash. Cash provided by operating activities primarily resulted from our net income of $18.2 million and net non-cash charges of $0.8 million. Our net income in the period was primarily due to milestone payments of $15.0 million from AbbVie and $11.0 million from Novartis. Our net non-cash charges in the period primarily consisted of $0.5 million of stock-based compensation expense, $0.4 million related to amortization of the premium on our marketable securities, offset by $0.2 million change in fair value of warrant liability. The $0.4 million decrease in accounts receivable as well as $1.1 million decrease in unbilled receivables was due to the timing of our billings under the NIAID contract and Novartis agreement. The $1.9 million use of cash from changes in accounts payable and accrued expenses was primarily due to the timing of payments made by us to vendors and to employees for annual bonuses.

During the six months ended March 31, 2012, operating activities provided $28.2 million of cash. The cash flow provided by operating activities primarily resulted from our net income of $29.0 million partially offset by net uses of cash of $1.0 million from changes in our operating assets and liabilities. Our net income in the period was primarily due to an upfront payment of $34.4 million from Novartis. Net uses of cash from changes in our operating assets and liabilities during the six months ended March 31, 2012 consisted primarily of a $1.2 million increase in unbilled receivables partially offset by a $0.2 million decrease in accounts receivable. The $1.2 million increase in unbilled receivables as well as the $0.2 million decrease in accounts receivable was due to the timing of our billings under the NIAID contract and Novartis agreement.

Net cash provided by (used in) investing activities

During the six months ended March 31, 2013, net cash used in investing activities was $13.4 million. Net cash used in investing activities during the period consisted primarily of $45.7 million used to purchase marketable securities, offset by cash received from sales and maturities of marketable securities of $32.7 million.

During the six months ended March 31, 2012, net cash used in investing activities was $14.4 million. Net cash used in investing activities during the period consisted primarily of $29.5 cash used to purchase marketable securities, offset by cash received from maturities of marketable securities of $14.1 million and an increase in cash of $1.1 million due to a release of a letter of credit in December 2011 related to our previous facility lease.

Net cash provided by (used in) financing activities

Net cash provided by financing activities during the six months ended March 31, 2013 was $58.2 million and consisted of proceeds, net of underwriting discounts and commissions, of $59.9 million from our initial public offering and proceeds of $0.4 million from the exercise of stock options, offset by $2.1 million of offering costs related to our initial public offering that were paid during the period.

Net cash provided by financing activities during the six months ended March 31, 2012 consisted of proceeds received from the exercise of stock options.

Funding requirements

As of March 31, 2013, we had $121.7 million in cash, cash equivalents and investments. We believe that our existing cash, cash equivalents and investments as of March 31, 2013, will be sufficient to meet our anticipated cash requirements for at least the next 24 months. 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:

- whether our existing collaborations continue to generate substantial milestone payments, and ultimately royalties, to us;
- the number and characteristics of the future product candidates we pursue;
- the scope, progress, results and costs of researching and developing any of our future product candidates on our own, and conducting preclinical research and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for any future product candidates we develop independently;
- the cost of commercialization activities, if any, of any future product candidates we develop independently that are approved for sale, including marketing, sales and distribution costs;
- the cost of manufacturing our future product candidates and any products we successfully commercialize independently;
- our ability to maintain existing collaborations and to establish new collaborations, licensing or other arrangements and the financial terms of such agreements;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patents, including litigation costs and the outcome of such litigation; and
- the timing, receipt and amount of sales of, or royalties on, ABT-450, EDP-239 and our future product candidates, if any.

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.

Recently Issued Accounting Pronouncements

In February 2013, the FASB issued ASU No. 2013-02, *Comprehensive Income (Topic 220): Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income, or* ASU 2013-02. This newly issued accounting standard requires an entity to provide information about the amounts reclassified out of accumulated other comprehensive income by component. In addition, an entity is required to present, either on the face of the statement where net income is presented or in the notes, significant amounts reclassified out of accumulated other comprehensive income by the respective line items of net income but only if the amount reclassified is required under U.S. GAAP to be reclassified to net income in its entirety in the same reporting period. For other amounts that are not required under U.S. GAAP to be reclassified in their entirety to net income, an entity is required to cross-reference to other disclosures required under U.S. GAAP that provide additional detail about those amounts. ASU 2013-02 is effective for fiscal years and interim periods within those years beginning after December 15, 2012 and will become effective for us on October 1, 2013. We do not believe the adoption of this standard will have a material impact on our financial position or results of operations.

Other accounting standards that have been issued 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 our financial statements upon adoption.

Contractual Obligations and Commitments

We lease office and laboratory space in Watertown, Massachusetts under a seven-year lease that commenced on October 1, 2011. In fiscal 2012, we entered into an intellectual property license agreement that will require us to make certain non-cancelable payments over the next three years.

There were no significant changes in our contractual obligations and commitments since September 30, 2012.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Interest Rate Sensitivity

We had cash, cash equivalents and marketable securities of $121.7 million at March 31, 2013, which consisted of cash, government securities, corporate bonds and certificate of deposit. Interest income is sensitive to changes in the general level of interest rates; however, due to the nature of these investments, we do not believe that we have any material exposure to changes in the fair value of our investment portfolio as a result of changes in interest rates. We had no debt outstanding as of March 31, 2013.

ITEM 4. CONTROLS AND PROCEDURES

a) *Conclusion Regarding the Effectiveness 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 (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.

b) *Changes in Internal Control Over Financial Reporting.*

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) identified in connection with the evaluation of our internal control performed during the last fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

ITEM 1A. RISK FACTORS

Our business faces significant risks and uncertainties. Certain factors may have a material adverse effect on our business prospects, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in its entirety, in addition to other information contained in or incorporated by reference into this Quarterly Report on Form 10-Q and our other public filings with the SEC. 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.

Risks Related to Our Business

Our financial prospects for the next several years are substantially dependent upon the development and marketing efforts of AbbVie for combination therapies incorporating ABT-450 for the treatment of HCV. AbbVie may act in its best interest rather than in our best interest, which could adversely affect our business.

We rely on AbbVie to fund and conduct the clinical development and commercialization of ABT-450 and other protease inhibitors, over which AbbVie has complete control. Our ability to generate significant revenue in the near term will depend primarily on the successful development, regulatory approval, marketing and commercialization by AbbVie of combination therapies incorporating ABT-450. Such success is subject to significant uncertainty, and we have limited control over the resources, time and effort that AbbVie may devote to ABT-450. Any of several events or factors could have a material adverse effect on our ability to generate revenue from AbbVie's potential commercialization of ABT-450 in combination therapies. For example, AbbVie:

- may be unable to successfully complete the clinical development of an ABT-450-containing regimen;
- may have to comply with additional requests and recommendations from the FDA, including additional clinical trials;
- may not make all regulatory filings and obtain all necessary approvals from the FDA and similar foreign regulatory agencies;
- may not commit sufficient resources to the development, regulatory approval, marketing and distribution of an ABT-450-containing regimen, whether for strategic reasons or otherwise due to a change in business priorities;
- may cease to perform its obligations under the terms of our collaboration agreement;
- may unilaterally terminate our collaboration agreement on specified prior notice without any reason and without any further commitment to continue development of any of our product candidates;
- may not be able to manufacture our product candidate in compliance with requirements of the FDA and similar foreign regulatory agencies and in commercial quantities sufficient to meet market demand;
- may not achieve market acceptance of combination therapies incorporating our product candidate by physicians, patients and third-party payors;
- may not compete successfully with any such combination therapies against alternative products and therapies for HCV; and
- may independently develop products that compete with our product candidate in the treatment of HCV.

We will not have access to all information regarding the products being developed and potentially commercialized by AbbVie, including information about clinical trial design and execution, safety reports from

clinical trials, spontaneous safety reports if the product is later approved and marketed, regulatory affairs, process development, manufacturing, marketing and other areas known by AbbVie. Thus, our ability to keep our stockholders informed about the status of product candidates under our collaboration will be limited by the degree to which AbbVie keeps us informed. If AbbVie does not perform in the manner we expect or fulfill its responsibilities in a timely manner, or at all, the clinical development, regulatory approval and commercialization efforts related to ABT-450 could be delayed or terminated or be commercially unsuccessful. In addition, AbbVie has the right to make decisions regarding the development and commercialization of product candidates without consulting us, and may make decisions with which we do not agree. Conflicts between us and AbbVie may arise if there is a dispute about the progress of the clinical development of a product candidate, the achievement and payment of a milestone amount, or the ownership of intellectual property developed during the course of our collaboration agreement. It may be necessary for us to assume responsibility at our own expense for the development of ABT-450 or other protease inhibitors. In that event, we would likely be required to limit the size and scope of one or more of our independent programs or increase our expenditures and seek additional funding which may not be available on acceptable terms or at all, and our business would be materially and adversely affected.

Our prospects for successful development of EDP-239 or any other NS5A inhibitor are dependent upon the development and marketing efforts of Novartis. Novartis may act in its best interest rather than in our best interest, which could adversely affect our business.

We rely on Novartis to fund and conduct the clinical development of EDP-239 and any other NS5A inhibitor product candidates under our collaboration, and for the successful regulatory approval, marketing and commercialization of one or more of them. Such success will be subject to significant uncertainty, and we have limited control over the resources, time and effort that Novartis may devote to our NS5A inhibitors. Moreover, Novartis may terminate the collaboration without any reason on 120 days notice to us. As with our AbbVie collaboration, any of several events or factors could have a material adverse effect on our ability to generate revenue from Novartis' development and commercialization of EDP-239, including ones similar to those described in the preceding risk factor regarding our AbbVie collaboration.

If Novartis does not perform in the manner we expect or fulfill its responsibilities in a timely manner, or at all, the clinical development, regulatory approval and commercialization efforts related to EDP-239 could be delayed, terminated or be commercially unsuccessful. Conflicts between us and Novartis may arise if there is a dispute with Novartis similar to potential disputes with AbbVie about any of the matters mentioned in the preceding risk factor. It may become necessary for us to assume the responsibility at our own expense for the development of EDP-239 or other NS5A inhibitors. In that event, we would likely be required to limit the size and scope of one or more of our independent programs or increase our expenditures and seek additional funding which may not be available on acceptable terms or at all, and our business would be materially and adversely affected.

We and our collaborators face substantial competition in the market for HCV drugs and for anti-infectives generally, which may result in others discovering, developing or commercializing products before us or doing so more successfully than we and our collaborators.

The pharmaceutical and biotechnology industries are intensely competitive and rapidly changing. Many large pharmaceutical and biotechnology companies, academic institutions, governmental agencies and other public and private research organizations are commercializing or pursuing the development of products that target HCV, MRSA and other infectious diseases that we may target in the future.

We expect our current and future product candidates to face intense and increasing competition as new products enter the HCV and antibacterial markets and advanced technologies become available, particularly in the case of HCV in combinations with existing products and other new products. Two drug products, Incivek™ (telaprevir) of Vertex and Victrelis™ (boceprevir) of Merck, were approved in 2011 by the FDA for the treatment of HCV

in combination with interferon and ribavirin, which in combination were the previous standard of care. These and other potential new treatment regimens may render our HCV product candidates noncompetitive. In particular, our HCV product candidates may not be able to compete successfully with other products in development in multiple classes of inhibitors of HCV, including protease inhibitors, polymerase inhibitors (nucleoside and non-nucleoside), NS5A inhibitors and cyclophilin inhibitors, under development by companies such as Achillion, Astra-Zeneca, Boehringer Ingelheim, Bristol-Myers Squibb, Gilead, GlaxoSmithKline, Idenix, Johnson & Johnson, Medivir, Merck, Pfizer, Presidio, Roche and Vertex, as well as by our collaborators.

Our MRSA program faces competition from other therapeutic products that address serious Gram-positive bacterial infections, such as Cubicin®, marketed by Cubist; vancomycin, marketed generically by AbbVie, Shionogi and others; and Zyvox®, marketed by Pfizer, as well as future competition from drug candidates currently in clinical development.

Many of our competitors have substantially greater commercial infrastructure and better financial, technical and personnel resources than we have, as well as drug candidates in late-stage clinical development.

Our competitors may succeed in developing competing products and obtaining regulatory approval before we or our collaborators do with our product candidates, or they may gain acceptance for the same markets that we are targeting. If we are not “first to market” with one of our product candidates, our competitive position could be compromised because it may be more difficult for us to obtain marketing approval for that product candidate and successfully market that product candidate as a second competitor. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful.

Competitive products in the form of other treatment methods or a vaccine for HCV or MRSA may render our product candidates licensed to others, as well as any future product candidates we may develop ourselves, obsolete or noncompetitive. Even if successfully developed and subsequently approved by the FDA, our product candidates will face competition based on their safety and effectiveness, the timing and scope of the regulatory approvals, the availability and cost of supply, marketing and sales capabilities, reimbursement coverage, price, patent position and other factors. If the product candidates developed under our collaboration agreements with AbbVie and Novartis face competition from generic products, the collaboration agreements provide that the royalty rate applicable to such product candidates is reduced significantly by a specified percentage on a product-by-product, country-by-country basis. If we and our collaborators are not able to compete effectively against our current and future competitors, our business will not grow and our financial condition, operations and stock price will suffer.

We have no approved products and no clinical development experience, which makes it difficult to assess our ability to develop and commercialize our future product candidates.

To date, AbbVie has been and will continue to be responsible for all of the clinical development of our ABT-450 and other protease inhibitor product candidates, and Novartis is responsible for all future clinical development of our EDP-239 and other NS5A product candidates. We have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties associated with late stage clinical development, regulatory approval and commercialization of therapeutic products such as the ones we plan to develop independently. For example, to execute our business plan for development of our independent programs for cyclophilin inhibitors and nucleotide polymerase inhibitors for HCV and antibiotics for MRSA, we will need to successfully:

- execute clinical development of our future product candidates;
- obtain required regulatory approvals for the development and commercialization of our future product candidates;
- develop and maintain any future collaborations we may enter into for any of these programs;

- build and maintain robust sales, distribution and marketing capabilities, either independently or in collaboration with future collaborators;
- gain market acceptance for our future product candidates; and
- manage our spending as costs and expenses increase due to clinical trials, regulatory approvals and commercialization.

If we are unsuccessful in accomplishing these objectives, we may not be able to successfully develop and commercialize our future product candidates and expand our business or continue our operations.

We may require substantial additional financing to achieve our goals if the development and commercialization of ABT-450 or EDP-239 is delayed or terminated. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development efforts.

Since our inception, most of our resources have been dedicated to the discovery and preclinical development of our product candidates. In particular, we have expended, and believe that we will continue to expend for the foreseeable future, substantial resources discovering and developing our proprietary preclinical product candidates. These expenditures will include costs associated with research and development, preclinical manufacturing of product candidates, conducting preclinical experiments and clinical trials and obtaining regulatory approvals, as well as commercializing any products later approved for sale. In our fiscal year ending September 30, 2013, we expect to incur approximately $21.0 million of costs associated with research and development, which amount is exclusive of costs incurred by our collaborators in developing our licensed product candidates ABT-450 and EDP-239.

Because the outcome of planned and anticipated clinical trials of our product candidates by our collaborators is highly uncertain, we cannot reasonably estimate the timing or amounts, if any, of future milestone payments we will receive from these collaborators. If we do not continue to receive substantial milestone payments from the continued development of our product candidates, we may require substantial additional financing.

Our future capital requirements depend on many factors, including:

- whether our existing collaborations continue to generate substantial milestone payments, and ultimately royalties, to us;
- the number and characteristics of the future product candidates we pursue;
- the scope, progress, results and costs of researching and developing any of our future product candidates on our own, and conducting preclinical research and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for any future product candidates we develop independently;
- the cost of commercialization activities, if any, of any future product candidates we develop independently that are approved for sale, including marketing, sales and distribution costs;
- the cost of manufacturing our future product candidates and any products we successfully commercialize independently;
- our ability to maintain existing collaborations and to establish new collaborations, licensing or other arrangements and the financial terms of such agreements;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patents, including litigation costs and the outcome of such litigation; and
- the timing, receipt and amount of sales of, or royalties on, ABT-450, EDP-239 and our future product candidates, if any.

Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. Our ability to raise funds will depend on financial, economic and market conditions and other factors, many of which are beyond our control. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other research and development activities for one or more of our product candidates.

If we are not successful in discovering further product candidates in addition to ABT-450 and EDP-239, our ability to expand our business and achieve our strategic objectives may be impaired.

Research programs designed to identify product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying additional potential product candidates, yet fail to yield product candidates for clinical development or commercialization for many reasons, including the following:

- the research methodology used may not be successful in identifying additional potential product candidates; competitors may develop alternatives that render our future product candidates obsolete;
- a future product candidate may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria; and
- a future product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all.

If we are unable to identify additional compounds suitable for preclinical and clinical development, we may not be able to obtain sufficient product revenue in future periods, which likely would result in significant harm to our financial position and adversely impact our stock price.

If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully develop our product candidates, conduct our clinical trials and commercialize our product candidates.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We are highly dependent upon our senior management, particularly Jay R. Luly, Ph.D., our Chief Executive Officer and President, and Yat Sun Or, Ph.D., our Senior Vice President, Research and Development and Chief Scientific Officer, as well as other employees and consultants. Although none of these individuals has informed us to date that he intends to retire or resign in the near future, the loss of services of any of these individuals or one or more of our other members of senior management could delay or prevent the successful development of our future product candidates.

Although we have not historically experienced unique difficulties attracting and retaining qualified employees, we could experience such problems in the future. For example, competition for qualified personnel in the biotechnology and pharmaceutical field is intense. In addition, we will need to hire additional personnel as we expand our clinical development and commercial activities. We may not be able to attract and retain quality personnel on acceptable terms.

We have incurred a substantial cumulative net loss since our inception and anticipate that we may incur substantial operating losses in one or more years in the future. To date, our principal sources of revenue have been our collaboration agreements, including our current agreements with AbbVie and Novartis, and future payments under these agreements are uncertain. We have had no products approved for commercial sale. As a result, our ability to achieve sustained profitability is unproven.

We have incurred cumulative net losses since our inception, and as of March 31, 2013, we had an accumulated deficit of $98.9 million. Our net income in the fiscal year ended September 30, 2010 resulted primarily from the

conclusion of a previous collaboration which accelerated $16.2 million of deferred revenue into fiscal 2010 that was related to cash received and spent in prior years, and our net income in the fiscal year ended September 30, 2011 resulted primarily from a substantial milestone payment from AbbVie. In the fiscal year ended September 30, 2012, our net income resulted primarily from a substantial upfront license payment from Novartis. During the six months ended March 31, 2013, our net income resulted primarily from milestone payments we earned from AbbVie and Novartis of $15.0 million and $11.0 million, respectively. There is no assurance, however, that we will recognize any additional collaboration revenue during fiscal 2013 or report net income in fiscal 2013 or subsequent years. To date, we have not commercialized any products or generated any revenue from product sales, directly or through any collaborator.

Our principal source of revenue has been our collaboration agreements, including our current agreements with AbbVie and Novartis. Future milestone payments are uncertain because our collaborators may choose not to continue research or development activities for one or more potential product candidates. For example, under a prior collaboration for the development of an antibiotic product candidate in Japan, our collaborator decided in 2010 not to pursue further development of the licensed product candidate due to its limited potency against *Haemophilus influenzae* in clinical trials of community-acquired pneumonia, which then resulted in our collaboration being terminated. In addition, we may not achieve the specified milestones, our product candidates may not be approved by the FDA or other regulatory authorities or, if they are approved, may not be accepted in the market. If we are unable to develop and commercialize one or more of our product candidates, either alone or with our collaborators, or if any such product candidate does not achieve market acceptance, we may never generate sufficient product royalties or product sales. Even if we do generate product royalties or product sales, we may never achieve or sustain profitability on a quarterly or annual basis. Our failure to sustain profitability would depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations. A decline in the market price of our common stock also could cause you to lose all or a part of your investment.

We may encounter difficulties in managing our growth and expanding our operations successfully.

As we seek to advance our product candidates through clinical trials, we will need to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Future growth will impose significant added responsibilities on members of management. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

Our government funded contract for our antibiotic program is subject to termination and uncertain future funding and there is no certainty that we will be able to enter into new agreements to provide these funds.

Under our agreement with the National Institute of Allergy and Infectious Diseases, or NIAID, a division of the National Institutes of Health, an agency of the United States Department of Health and Human Services, to support our antibiotic program, NIAID has the option to make future payments to fund our early clinical development of EDP-788. If NIAID exercises each option under the agreement, the aggregate funding commitment will be $42.7 million, of which only $14.3 million has been committed for the first 30 months of our work under the agreement. After the first 30 months, NIAID has several options to decide whether it wants to continue the program in its sole discretion. In addition, the ability of government agencies such as NIAID to perform under these types of agreements is dependent upon adequate continued funding of the agencies and their programs. We have no control over the resources and funding NIAID may devote to our agreement, which may be subject to periodic renewal and which generally may be terminated by NIAID at any time. For example, in

accordance with the spending cuts, known as sequestration, to implement the Budget Control Act of 2011, NIAID notified us on March 4, 2013 of the possibility that NIAID may not exercise the options on our contract or may negotiate lower prices or other terms via a bilateral modification. Any significant reductions in the funding of U.S. government agencies or in the funding areas targeted by our business could materially and adversely affect our antibiotic program and our results of operations and financial condition. If we fail to satisfy our contractual obligations under the agreement, the applicable Federal Acquisition Regulations allow the government to terminate the agreement in whole or in part, and we may be required to perform corrective actions, including but not limited to delivering to the government any incomplete work. If NIAID does not exercise future funding options under the agreement, terminates the agreement or fails to perform its responsibilities under the agreement, it could materially impact our antibiotic program and our financial results.

In addition, our contract related costs and fees, including allocated indirect costs, are subject to audits and adjustments by negotiation between us and the U.S. government. As part of the audit process, the government audit agency verifies that all charges made by a contractor against a contract are legitimate and appropriate. Audits may result in recalculation of contract revenues and non-reimbursement of some contract costs and fees. Any audits of our contract related costs and fees could result in material adjustments to our revenue. In addition, U.S. government contracts are conditioned upon the continuing availability of Congressional appropriations. Congress usually appropriates funds on a fiscal year basis even though contract performance may take several years. Consequently, at the outset of a major program, the contract is usually incrementally funded and additional funds are normally committed to the contract by the procuring agency as appropriations are made by Congress for future fiscal years. Any failure of NIAID to continue to fund our contract could have a material adverse effect on our business, results of operations and financial condition.

Risks Related to Development, Clinical Testing and Regulatory Approval of Our Product Candidates

Clinical drug development involves a lengthy and expensive process with uncertain timelines and uncertain outcomes. If clinical trials are prolonged or delayed, we or our collaborators may be unable to commercialize our product candidates on a timely basis.

Clinical testing is expensive and, depending on the stage of development, can take a substantial time period to complete. Its outcome is inherently uncertain, and failure can occur at any time during clinical development. The first patient in Phase 3 trials of ABT-450 in combination therapy was dosed in November 2012, and none of the other product candidates in our pipeline has yet advanced beyond Phase 2 clinical trials. The recently started ABT 450 Phase 3 trials or any future Phase 3 trials may fail to demonstrate sufficient safety and efficacy. Moreover, regulatory and administrative delays may adversely affect our or our collaborators' clinical development plans and jeopardize our or our collaborators' ability to attain product approval, commence product sales and generate revenues.

Clinical trials can be delayed for a variety of reasons, including delays related to:

- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- failure of third-party contractors, such as CROs, or investigators to comply with regulatory requirements;
- delay or failure in obtaining the necessary approvals from regulators or institutional review boards, or IRBs, in order to commence a clinical trial at a prospective trial site, or their suspension or termination of a clinical trial once commenced;
- difficulty in recruiting suitable patients to participate in a trial;
- difficulty in having patients complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol or dropping out of a trial;

- problems with drug product or drug substance storage and distribution;
- adding new clinical trial sites;
- our inability to manufacture, or obtain from third parties, adequate supply of drug product sufficient to complete our preclinical studies and clinical trials;
- governmental or regulatory delays and changes in regulatory requirements, policy and guidelines; or
- varying interpretations of data by the FDA and similar foreign regulatory agencies.

The results of any Phase 3 clinical trial may not be adequate to support marketing approval. These clinical trials are lengthy and usually involve from many hundreds to thousands of patients. In addition, if the FDA disagrees with our or our collaborator's choice of the key testing criteria, or primary endpoint, or the results for the primary endpoint are not robust or significant relative to the control group of patients not receiving the experimental therapy or are subject to confounding factors, or are not adequately supported by other study endpoints, the FDA may refuse to approve our or our collaborator's product candidate. The FDA also may require additional clinical trials as a condition for approving any of these product candidates. We estimate that it will likely be more than two years before an NDA for one of our or our collaborator's product candidates could be approved by the FDA.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trial is being conducted, by any Data Safety Monitoring Board, or DSMB, for such trial, or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, delays can occur due to safety concerns arising from trials or other clinical data regarding another company's product candidate in the same compound class as one of ours. For example, Novartis' drug candidate that is a cyclophilin inhibitor was recently placed on clinical hold by the FDA based on a small number of cases of pancreatitis in clinical trial patients, one of which resulted in a patient's death. This clinical hold could result in delays for development of other cyclophilin inhibitors, including delays due to additional preclinical or clinical testing protocols for all cyclophilin inhibitors. If we or our collaborators experience delays in the completion of, or termination of, any clinical trial of one of our product candidates, the commercial prospects of the product candidate will be harmed, and our or our collaborators' ability to commence product sales and generate product revenues from the product candidate will be delayed. In addition, any delays in completing our clinical trials will increase our costs and slow down our product candidate development and approval process. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

If we or our collaborators are required to suspend or discontinue clinical trials due to side effects or other safety risks associated with our product candidates, or if we or our collaborators are required to conduct studies on the long-term effects associated with the use of our product candidates, efforts to commercialize our product candidates could be delayed or halted.

Clinical trials involving our product candidates may be suspended or terminated at any time for a number of safety-related reasons. For example, we or our collaborators may voluntarily suspend or terminate clinical trials if at any time one of our product candidates, or a combination therapy including any of them, presents an unacceptable safety risk to the clinical trial patients. In addition, IRBs or regulatory agencies may order the temporary discontinuation or termination of clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements, including if they present an unacceptable safety risk to patients. Administering any product candidate to humans may produce undesirable side effects. The existence of undesirable side effects resulting from any of our product candidates, or a combination therapy

including any of them, could cause us, our collaborators or regulatory authorities, such as the FDA, to interrupt, delay or halt clinical trials of our product candidates and could result in the FDA or other regulatory agencies denying further development or approval of our product candidates for any or all targeted indications. This, in turn, could prevent us or our collaborators from commercializing our product candidates.

Our Bicyclolide product candidates are in a novel class of antibiotics. Regulatory authorities may require more extensive studies of the long-term effects for regulatory approval, which could delay development of EDP-788 or our other future antibiotic product candidates. These studies could also be required at any time after regulatory approval of any of our product candidates. Some or all of our product candidates may prove to be unsafe for human use.

Results of earlier clinical trials may not be predictive of the results of later-stage clinical trials.

The results of preclinical studies and early clinical trials of our product candidates, whether ABT-450, EDP-239, EDP-788 or any of our future product candidates, may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy results despite having progressed through preclinical studies and initial clinical trials. Many companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to adverse safety profiles or lack of efficacy, notwithstanding promising results in earlier studies. Similarly, future clinical trial results may not be successful for these or other reasons.

This product candidate development risk is heightened by any changes in the planned clinical trials compared to the completed clinical trials. As product candidates are developed through preclinical to early to late stage clinical trials towards approval and commercialization, it is customary that various aspects of the development program, such as manufacturing and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could make the results of planned clinical trials or other future clinical trials we or our collaborators may initiate less predictable and could cause our product candidates to perform differently, which could delay completion of clinical trials, delay approval of our product candidates and/or jeopardize our or our collaborators' ability to commence product sales and generate revenues.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and if we or our collaborators are ultimately unable to obtain timely regulatory approval for our product candidates, our business will be substantially harmed.

The regulatory approval process is expensive and, while the time required to gain FDA and foreign regulatory approval is uncertain, it may take years. Regulatory approval is unpredictable and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of preclinical and clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We or our collaborators may be required to undertake and complete certain additional preclinical studies to generate toxicity and other data required to support the submission of a New Drug Application, or NDA, to the FDA or other regulatory authority. Neither we nor our collaborators have obtained regulatory approval for any of our product candidates and it is possible that none of our existing product candidates or any of our future product candidates will ever obtain regulatory approval. Furthermore, approval in the United States by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our or our collaborators' clinical trials;

- we or our collaborators may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we or our collaborators may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our or our collaborators' interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we or our collaborators contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our or our collaborators' clinical data insufficient for approval.

We and our collaborators cannot be assured that after spending substantial time and resources, we or our collaborators will obtain regulatory approval. Even if we or our collaborators were to obtain approval, regulatory authorities may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Significant clinical trial delays could allow our competitors to obtain marketing approval before we or our collaborators do or could shorten the patent protection period during which we may have the exclusive right to commercialize our product candidates. In addition, we or our collaborators may not be able to ultimately achieve the prices intended for our products. In many foreign countries, a product candidate must be approved for reimbursement before it can be approved for sale in that country. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Even if we receive regulatory approval for any of our product candidates we develop independently, we will be subject to ongoing FDA obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we or our collaborators fail to comply with regulatory requirements or experience unanticipated problems with our products.

Any regulatory approvals that we receive for our product candidates we develop independently may be subject to limitations on the approved indicated uses for which the product may be marketed or subject to certain conditions of approval, or may contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate.

In addition, if the FDA approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, as well as continued compliance with current good manufacturing practices, or cGMP, and good clinical practices, or GCP, for any clinical trials that we or our collaborators conduct post-approval. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls;

- fines, warning letters or holds on any post-approval clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or our collaborators, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we or our collaborators are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or our collaborators are not able to maintain regulatory compliance, our product candidate may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

We or our collaborators may delay or terminate the development of a product candidate at any time if we or our collaborators believe the perceived market or commercial opportunity does not justify further investment, which could materially harm our business.

Even though the results of preclinical studies and clinical trials that we or our collaborators have conducted or may conduct in the future may support further development of one or more of our product candidates, we, or our collaborator in the case of our partnered product candidates, may delay, suspend or terminate the future development of a product candidate at any time for strategic, business, financial or other reasons, including the determination or belief that the emerging profile of the product candidate is such that it may not receive FDA approval, gain meaningful market acceptance, otherwise provide any competitive advantages in its intended indication or market or generate a significant return to stockholders. Such a delay, suspension or termination could materially harm our business, results of operations or financial condition. In addition, our collaborators may have the right to make decisions regarding the development and commercialization of product candidates without consulting us, and may make decisions with which we do not agree.

Our internal computer systems, or those of our collaborators, CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of development programs for our product candidates.

Despite the implementation of security measures, our internal computer systems and those of our collaborators, CROs, and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our independent drug development programs or those of our collaborators. For example, the loss of clinical trial data from ongoing or future clinical trials for any of our product candidates could result in delays in regulatory approval efforts and significantly increase costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to data or applications, or inappropriate disclosure of confidential or proprietary information, we or our collaborators could incur liability and the further development of our product candidates could be delayed.

Risks Related to Commercialization of Our Product Candidates

If, in the future, we are unable to establish our own sales, marketing and distribution capabilities or enter into licensing or collaboration agreements for these purposes, we may not be successful in commercializing any future product candidates.

We do not have a sales or marketing infrastructure and have no sales, marketing or distribution experience. We will seek to either build our own commercial infrastructure to commercialize any future products if and when

they are approved, or enter into licensing or collaboration agreements where our collaborator is responsible for commercialization, like in the case of our collaborations with Novartis and AbbVie, or where we have the right to assist in the future development and commercialization of such products. For example, we have a co-detail option with respect to any product that may be developed under our Novartis collaboration, which would allow us to establish a limited sales force in the United States for a portion of the product's sales.

To develop internal sales, distribution and marketing capabilities, we will have to invest significant amounts of financial and management resources, some of which will be committed prior to any confirmation that any of our proprietary product candidates will be approved. For product candidates for which we decide to perform sales, marketing and distribution functions ourselves, we could face a number of additional risks, including:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

Where and when appropriate, we may elect to utilize contract sales forces or distribution partners to assist in the commercialization of our product candidates. If we enter into arrangements with third parties to perform sales, marketing and distribution services for our products, the resulting revenues or the profitability from these revenues to us are likely to be lower than if we had sold, marketed and distributed our products ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of these third parties may fail to devote the necessary resources and attention to sell, market and distribute our products effectively.

If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

Our commercial success depends upon significant market acceptance among physicians, patients and healthcare payors of our product candidates licensed to AbbVie and Novartis, if approved, as well as of any future product candidates we plan to develop independently or in collaboration with others.

Even if ABT-450 or EDP-239 or any other product candidate that we may develop in the future obtains regulatory approval, whether as part of a combination therapy or as a monotherapy, the product may not gain market acceptance among physicians, healthcare payors, patients and the medical community. For example, the standard of care in HCV is likely to evolve rapidly as many new product candidates are being developed and tested. The degree of market acceptance of any products for which we receive approval for commercial sale depends on a number of factors, including:

- the efficacy and safety of our partnered product candidates, as demonstrated in clinical trials, and the degree to which these product candidates represent a clinically meaningful improvement in care as compared with other available therapies;
- the clinical indications for which any product candidates become approved;
- acceptance among physicians, major operators of clinics and patients of any of our product candidates as safe and effective treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;

- the potential and perceived advantages of our product candidates over alternative treatments;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate reimbursement and pricing by third parties and government authorities;
- the continued projected growth of the HCV drug market;
- the relative convenience and ease of administration of any combination therapies including our product candidates;
- the prevalence and severity of adverse side effects, whether involving the use of our products candidates or similar, competitive products; and
- the effectiveness of our or our collaborators' sales and marketing efforts.

If our product candidates are approved and then fail to achieve market acceptance, we would not be able to generate significant revenue. Further, if new, more favorably received therapies are introduced after our product candidates achieve market acceptance, then we may not be able to maintain that market acceptance over time.

Even if we or our collaborators are able to commercialize any product candidates, the resulting products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives in the United States, which would harm our business.

The regulations that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. In the United States, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010, collectively referred to as the ACA, may significantly change the way healthcare is financed by both governmental and private insurers. While we cannot predict what impact on federal reimbursement policies this law will have in general or specifically on any product that we or any of our collaborators commercializes, the ACA may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of new products. In addition, although the United States Supreme Court has upheld the constitutionality of most of the ACA, some states have indicated that they intend not to implement certain sections of the ACA, and some members of the U.S. Congress are still working to repeal the ACA. We cannot predict whether these challenges will continue or other proposals will be made or adopted, or what impact these efforts may have on us or any of our collaborators. Our or any collaborators' ability to commercialize any products successfully also will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product that we or any collaborator commercialize and, if reimbursement is available, the level of reimbursement. In addition, reimbursement may impact the demand for, or the price of, any product candidate for which we or a collaborator obtains marketing approval. If reimbursement is not available or is available only to limited levels, we or our collaborators may not be able to successfully commercialize any product candidate for which marketing approval is obtained.

There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also be insufficient to cover our and any collaborator's costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may

be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our or any collaborator's inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products that we or our collaborators develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Foreign governments tend to impose strict price controls, which may adversely affect our future profitability.

In most foreign countries, particularly in the European Union, prescription drug pricing and/or reimbursement is subject to governmental control. In those countries that impose price controls, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we or our collaborators may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies.

Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we or our collaborators might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues that are generated from the sale of the product in that country. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, or if there is competition from lower priced cross-border sales, our profitability will be negatively affected.

Risks Related to Our Dependence on Third Parties

We may not be successful in establishing new product collaborations, which could adversely affect our ability to develop and commercialize our future product candidates. If we are unsuccessful in maintaining or forming alliances on favorable terms, our business may not succeed.

We may seek to enter into additional product collaborations in the future, including alliances with other biotechnology or pharmaceutical companies, to enhance and accelerate the development and commercialization of our future product candidates. We face significant competition in seeking appropriate collaborators and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish other product collaborations or other alternative arrangements for any future product candidates and programs because our research and development pipeline may be insufficient, our product candidates and programs may be deemed to be at too early of a stage of development for collaborative effort and/or third parties may not view our product candidates and programs as having the requisite potential to demonstrate safety and efficacy. Even if we are successful in our efforts to establish product collaborations, the terms that we agree upon may not be favorable to us and we may not be able to maintain such product collaborations if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing.

If either of our existing collaboration agreements is terminated, or if we determine that entering into other product collaborations is in our best interest but we either fail to enter into, delay in entering into or fail to maintain such collaborations:

- the development of certain of our current or future product candidates may be terminated or delayed;
- our cash expenditures related to development of certain of our future product candidates would increase significantly and we may need to seek additional financing;

- we may be required to hire additional employees or otherwise develop expertise, such as clinical, regulatory, sales and marketing expertise, which we do not currently have;
- we will bear all of the risk related to the development of any such product candidates; and
- the competitiveness of any product candidate that is commercialized could be reduced.

We intend to rely on third-party manufacturers to produce our clinical product candidate supplies and any commercial supplies of any approved future product candidates. Any failure by a third-party manufacturer to produce acceptable supplies for us may delay or impair our ability to initiate or complete our clinical trials or sell any resulting product.

We do not currently own or operate any manufacturing facilities. We plan to work with third-party contract manufacturers to produce sufficient quantities of any future product candidates for preclinical testing, clinical trials and commercialization. If we are unable to arrange for such a third-party manufacturing source, or fail to do so on commercially reasonable terms, we may not be able to successfully produce, develop and market our future product candidates, or we may be delayed in doing so.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates ourselves, including reliance on the third party for regulatory compliance and quality control and assurance, volume production, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control (including a failure to synthesize and manufacture our product candidates in accordance with our product specifications) and the possibility of termination or nonrenewal of the agreement by the third party at a time that is costly or damaging to us. In addition, the FDA and other regulatory authorities require that our product candidates be manufactured according to cGMP and similar foreign standards. Pharmaceutical manufacturers and their subcontractors are required to register their facilities and/or products manufactured at the time of submission of the marketing application and then annually thereafter with the FDA and certain state and foreign agencies. They are also subject to periodic unannounced inspections by the FDA, state and other foreign authorities. Any subsequent discovery of problems with a product, or a manufacturing or laboratory facility used by us or our collaborators, may result in restrictions on the product or on the manufacturing or laboratory facility, including marketed product recall, suspension of manufacturing, product seizure, or a voluntary withdrawal of the drug from the market. Any failure by our third-party manufacturers to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates.

We plan to rely on third-party manufacturers to purchase from third-party suppliers the materials necessary to produce our future product candidates for our clinical studies. There are a small number of suppliers for certain capital equipment and materials that we plan to use to manufacture our drugs. Such suppliers may not sell these materials to our manufacturers at the times we need them or on commercially reasonable terms. Moreover, we currently do not have any agreements for the production of these materials. Although we do not intend to begin a clinical trial unless we believe we have a sufficient supply of a product candidate to complete the clinical trial, any significant delay in the supply of a product candidate or the material components thereof for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical studies, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenue from the sale of our product candidates.

Contract manufacturers may not be able to manufacture our product candidates at a cost or in quantities or in a timely manner necessary to develop and commercialize them. If we successfully commercialize any of our product candidates, to meet our projected needs we may need to find third parties that will increase their scale of production, or we may have to establish or access large-scale commercial manufacturing capabilities. We may require additional funds, personnel and other resources to build, lease or operate any manufacturing facility.

Because a portion of our manufacturing of certain key intermediates used in the manufacture of the active pharmaceutical ingredients for our future product candidates is expected to take place in China through third-party manufacturers, a significant disruption in the operation of those manufacturers or political unrest in China could materially adversely affect our business, financial condition and results of operations.

Although manufacturing for each of our lead product candidates, namely ABT-450 and EDP-239, is being conducted by our collaborators, we have relied on third parties located in China to manufacture and supply certain key intermediates used in the manufacture of our active pharmaceutical ingredients, or API, for our research product candidates, and we expect to continue to use such third party manufacturers for such intermediates for any future product candidates we develop independently, including EDP-788. Any disruption in production or inability of our manufacturers in China to produce adequate quantities to meet our needs, whether as a result of a natural disaster or other causes, could impair our ability to operate our business on a day-to-day basis and to continue our research and development of our future product candidates. Furthermore, since these manufacturers are located in China, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the Chinese government, political unrest or unstable economic conditions in China. Any of these matters could materially and adversely affect our business and results of operations. Any recall of the manufacturing lots or similar action regarding our API used in clinical trials could delay the trials or detract from the integrity of the trial data and its potential use in future regulatory filings. In addition, manufacturing interruptions or failure to comply with regulatory requirements by any of these manufacturers could significantly delay clinical development of potential products and reduce third-party or clinical researcher interest and support of proposed trials. These interruptions or failures could also impede commercialization of our future product candidates and impair our competitive position. Further, we may be exposed to fluctuations in the value of the local currency in China. Future appreciation of the local currency could increase our costs. In addition, our labor costs could continue to rise as wage rates increase due to increased demand for skilled laborers and the availability of skilled labor declines in China.

We will rely on third parties to monitor, support, conduct and/or oversee clinical trials of our future product candidates that we develop independently and, in some cases, to maintain regulatory files for those product candidates. If we are not able to maintain or secure agreements with such third parties on acceptable terms, if these third parties do not perform their services as required, or if these third parties fail to timely transfer any regulatory information held by them to us, we may not be able to obtain regulatory approval for, or commercialize, our product candidates.

We will rely on academic institutions, CROs, hospitals, clinics and other third-party collaborators who are outside our control to monitor, support, conduct and/or oversee preclinical and clinical studies of our future product candidates. We will also rely on third parties to perform clinical trials on our future product candidates when they reach that stage. As a result, we have less control over the timing and cost of these studies and the ability to recruit trial subjects than if we conducted these trials wholly by ourselves. If we are unable to maintain or enter into agreements with these third parties on acceptable terms, or if any such engagement is terminated, we may be unable to enroll patients on a timely basis or otherwise conduct our trials in the manner we anticipate. In addition, there is no guarantee that these third parties will devote adequate time and resources to our studies or perform as required by a contract or in accordance with regulatory requirements, including maintenance of clinical trial information regarding our future product candidates. If these third parties fail to meet expected deadlines, fail to timely transfer to us any regulatory information, fail to adhere to protocols or fail to act in accordance with regulatory requirements or our agreements with them, or if they otherwise perform in a substandard manner or in a way that compromises the quality or accuracy of their activities or the data they obtain, then clinical trials of our future product candidates may be extended, delayed or terminated, or our data may be rejected by the FDA or regulatory agencies.

To the extent we elect to enter into additional licensing or collaboration agreements to partner our future product candidates, our dependence on such relationships may adversely affect our business.

Our commercialization strategy for some of our future product candidates may depend on our ability to enter into collaboration agreements with other companies to obtain assistance and funding for the development and potential commercialization of these product candidates, similar to what we have done with AbbVie and Novartis. Supporting diligence activities conducted by potential collaborators and negotiating the financial and other terms of a collaboration agreement are long and complex processes with uncertain results. Even if we are successful in entering into one or more additional collaboration agreements, collaborations can involve greater uncertainty for us, as we may have limited or no control over certain aspects of our collaborative programs. We may determine that continuing a collaboration under the terms provided is not in our best interest, and we may terminate the collaboration. Our collaborators could delay or terminate their agreements with us, and our product candidates subject to collaborative arrangements may never be successfully commercialized.

Further, our collaborators may develop alternative products or pursue alternative technologies either on their own or in collaboration with others, including our competitors, and the priorities or focus of our collaborators may shift such that our programs receive less attention or resources than we would like, or they may be terminated altogether. Any such actions by our collaborators may adversely affect our business prospects and ability to earn revenue. In addition, we could have disputes with our collaborators, such as the interpretation of terms in our agreements. Any such disagreements could lead to delays in the development or commercialization of any potential products or could result in time-consuming and expensive litigation or arbitration, which may not be resolved in our favor.

Even with respect to programs that we intend to commercialize ourselves, we may enter into agreements with collaborators to share in the burden of conducting clinical trials, manufacturing and marketing our product candidates or products. In addition, our ability to apply our proprietary technologies to develop proprietary compounds will depend on our ability to establish and maintain licensing arrangements or other collaborative arrangements with the holders of proprietary rights to such compounds. We may not be able to establish such arrangements on favorable terms or at all, and our collaborative arrangements may not be successful.

Risks Related to Our Intellectual Property Rights

We could be unsuccessful in obtaining or maintaining adequate patent protection for one or more of our product candidates.

Our commercial success will depend, in large part, on our ability to obtain and maintain patent and other intellectual property protection with respect to our product candidates. We cannot be certain that patents will be issued or granted with respect to our patent applications that are currently pending, or that issued or granted patents will not later be found to be invalid and/or unenforceable, be interpreted in a manner that does not adequately protect our products, or otherwise provide us with any competitive advantage. The patent position of biotechnology and pharmaceutical companies is generally uncertain because it involves complex legal and factual considerations. The standards applied by the United States Patent and Trademark Office and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology and pharmaceutical patents. Consequently, patents may not issue from our pending patent applications. As such, we do not know the degree of future protection that we will have on our proprietary products and technology, if any, and a failure to obtain adequate intellectual property protection with respect to our product candidates and proprietary technology could have a material adverse impact on our business.

In addition, certain of our activities have been funded, and may in the future be funded, by the United States federal government. For example, the preclinical and early clinical development of EDP-788, our lead candidate for the treatment of MRSA, is currently funded under a contract with the NIAID, an entity of the United States

federal government. When new technologies are developed with United States federal government funding, the government obtains certain rights in any resulting patents, including a nonexclusive license authorizing the government to use the invention for non-commercial purposes. These rights may permit the government to disclose our confidential information to third parties and to exercise "march-in" rights to use or allow third parties to use our patented technology. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the United States government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations or to give preference to United States industry. In addition, United States government-funded inventions must be reported to the government and United States government funding must be disclosed in any resulting patent applications. In addition, our rights in such inventions are subject to certain requirements to manufacture products in the United States.

Issued patents covering one or more of our product candidates could be found invalid or unenforceable if challenged in court.

Despite measures we take to obtain patent and other intellectual property protection with respect to our product candidates and proprietary technology, any of our intellectual property rights could be challenged or invalidated. For example, if we were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the United States and in some other jurisdictions, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the United States Patent and Trademark Office, or the applicable foreign counterpart, or made a misleading statement, during prosecution. Although we believe that we have conducted our patent prosecution in accordance with the duty of candor and in good faith, the outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on a product candidate. Even if a defendant does not prevail on a legal assertion of invalidity and/or unenforceability, our patent claims may be construed in a manner that would limit our ability to enforce such claims against the defendant and others. Any loss of patent protection could have a material adverse impact on one or more of our product candidates and our business.

Enforcing our intellectual property rights against third parties may also cause such third parties to file other counterclaims against us, which could be costly to defend and could require us to pay substantial damages, cease the sale of certain products or enter into a license agreement and pay royalties (which may not be possible on commercially reasonable terms or at all). Any efforts to enforce our intellectual property rights are also likely to be costly and may divert the efforts of our scientific and management personnel.

Claims that our product candidates or the sale or use of our future products infringe the patent or other intellectual property rights of third parties could result in costly litigation or could require substantial time and money to resolve, even if litigation is avoided.

Our commercial success depends upon our ability to develop, manufacture, market and sell our product candidates and use our proprietary technology without infringing the intellectual property rights of others. We cannot guarantee that our product candidates or any uses of our product candidates do not and will not in the future infringe third-party patents or other intellectual property rights. Third parties might allege that we or our collaborators are infringing their patent rights or that we have misappropriated their trade secrets, or that we are otherwise violating their intellectual property rights, whether with respect to the manner in which we have conducted our research or to the composition, use or manufacture of the compounds we have developed or are

developing with our collaborators. Such third parties might resort to litigation against us or other parties we have agreed to indemnify, which litigation could be based on either existing intellectual property or intellectual property that arises in the future.

It is also possible that we failed to identify, or may in the future fail to identify, relevant patents or patent applications held by third parties that cover our product candidates. For example, applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Other patent applications in the United States and several other jurisdictions are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Furthermore, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Therefore, we cannot be certain that we or our collaborators were the first to invent, or the first to file patent applications on, our product candidates or for their uses, or that our product candidates will not infringe patents that are currently issued or that are issued in the future. In the event that a third party has also filed a patent application covering one of our product candidates or a similar invention, we may have to participate in an adversarial proceeding, known as an interference, declared by the U.S. Patent and Trademark Office or its foreign counterpart to determine priority of invention. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our products or their use.

In order to avoid or settle potential claims with respect to any patent or other intellectual property rights of third parties, we may choose or be required to seek a license from a third party and be required to pay license fees or royalties or both, which could be substantial. These licenses may not be available on acceptable terms, or at all. Even if we or any future collaborators were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced, by court order or otherwise, to cease some or all aspects of our business operations, if, as a result of actual or threatened patent or other intellectual property claims, we are unable to enter into licenses on acceptable terms. Further, we could be found liable for significant monetary damages as a result of claims of intellectual property infringement. For example, we have received, and may in the future receive, offers to license and demands to license from third parties claiming that we are infringing their intellectual property or owe license fees and, even if such claims are without merit, there can be no assurance that we will successfully avoid or settle such claims.

In addition, we are aware of patents needed to use the replicon assay, which is an *in vitro* test for determining potency of an active compound in reducing HCV replication and is commonly used by us and others engaged in HCV research. We have a license to the relevant patents for one of our HCV programs and are negotiating a license for our other HCV inhibitor programs, which is expected to include up to $5 million in clinical milestone payments, as well as low single-digit royalties on sales, for each HCV inhibitor product developed by us. Although the patent owner has granted licenses under the relevant patents to others, we cannot provide any assurances that we will be able to obtain one on the expected terms, on terms that are acceptable to us, or at all. If we do not obtain such a license, or if the license we obtain is not broad enough to cover all of our activities, and if a legal action based on such patents were to be brought against us, we cannot provide any assurances that we would prevail or that we have sufficient resources to defend such claims and the additional risks described above could materialize. If AbbVie and Novartis license or otherwise acquire rights to intellectual property controlled by a third party in various circumstances, for example, where a product could not be legally developed or commercialized in a country without the third-party intellectual property right or, in the case of the Novartis agreement, where it is decided that it would be useful to acquire such third-party right to develop or commercialize the product, they are entitled under our collaboration agreements to decrease payments payable to us on a product-by-product basis and, in certain cases, on a country-by-country basis. Any of the foregoing events could harm our business significantly.

Defending against claims of patent infringement, misappropriation of trade secrets or other violations of intellectual property rights could be costly and time consuming, regardless of the outcome. Thus, even if we were

to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs. In addition, litigation or threatened litigation could result in significant demands on the time and attention of our management team, distracting them from the pursuit of other company business. Claims that our product candidates or the sale or use of our future products infringe, misappropriate or otherwise violate third-party intellectual property rights could therefore have a material adverse impact on our business.

Unfavorable outcomes in intellectual property litigation could limit our research and development activities and/or our ability to commercialize certain products.

If third parties successfully assert their intellectual property rights against us, we might be barred from using certain aspects of our technology, or barred from developing and commercializing certain products. Prohibitions against using certain technologies, or prohibitions against commercializing certain products, could be imposed by a court or by a settlement agreement between us and a plaintiff. In addition, if we are unsuccessful in defending against allegations that we have infringed, misappropriated or otherwise violated patent or other intellectual property rights of others, we may be forced to pay substantial damage awards to the plaintiff. There is inevitable uncertainty in any litigation, including intellectual property litigation. There can be no assurance that we would prevail in any intellectual property litigation, even if the case against us is weak or flawed. If litigation leads to an outcome unfavorable to us, we may be required to obtain a license from the intellectual property owner in order to continue our research and development programs or to market any resulting product. It is possible that the necessary license will not be available to us on commercially acceptable terms, or at all. Alternatively, we may be required to modify or redesign our products in order to avoid infringing or otherwise violating third-party intellectual property rights. This may not be technically or commercially feasible, may render our products less competitive, or may delay or prevent the entry of our products to the market. Any of the foregoing could limit our research and development activities, our ability to commercialize one or more product candidates, or both.

Most of our competitors are larger than we are and have substantially greater resources. They are, therefore, likely to be able to sustain the costs of complex intellectual property litigation longer than we could. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to conduct our clinical trials, continue our internal research programs, in-license needed technology, or enter into strategic partnerships that would help us bring our product candidates to market.

In addition, any future intellectual property litigation, interference or other administrative proceedings will result in additional expense and distraction of our personnel. An adverse outcome in such litigation or proceedings may expose us or any future strategic partners to loss of our proprietary position, expose us to significant liabilities, or require us to seek licenses that may not be available on commercially acceptable terms, if at all, each of which could have a material adverse effect on our business.

Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our common stock to decline.

During the course of any intellectual property litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our products, programs or intellectual property could be diminished. Accordingly, the market price of our common stock may decline. Such announcements could also harm our reputation or the market for our future products, which could have a material adverse effect on our business.

Confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of trade secrets and other proprietary information.

In addition to patents, we rely on trade secrets, technical know-how and proprietary information concerning our business strategy and product candidates in order to protect our competitive position in the field of HCV and

anti-infectives. In the course of our research and development activities and our business activities, we often rely on confidentiality agreements to protect our proprietary information. Such confidentiality agreements are used, for example, when we talk to vendors of laboratory or clinical development services or potential strategic partners. In addition, each of our employees is required to sign a confidentiality agreement and invention assignment agreement upon joining our company. We take steps to protect our proprietary information, and our confidentiality agreements and invention assignment agreements are carefully drafted to protect our proprietary interests. Nevertheless, there can be no guarantee that an employee or an outside party will not make an unauthorized disclosure of our proprietary confidential information. This might happen intentionally or inadvertently. It is possible that a competitor will make use of such information, and that our competitive position will be compromised, in spite of any legal action we might take against persons making such unauthorized disclosures. In addition, to the extent that our employees, consultants or contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, business partners or outside scientific collaborators might intentionally or inadvertently disclose our trade secret information to competitors or our trade secrets may otherwise be misappropriated. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States sometimes are less willing than United States courts to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

Our collaborators may have rights to publish data and other information to which we have rights. In addition, we sometimes engage individuals or entities to conduct research relevant to our business. The ability of these individuals or entities to publish or otherwise publicly disclose data and other information generated during the course of their research is subject to certain contractual limitations. These contractual provisions may be insufficient or inadequate to protect our confidential information. If we do not apply for patent protection prior to such publication, or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized, which could adversely affect our business.

Intellectual property rights do not necessarily protect us from all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of the patents that we or our collaborators own or have exclusively licensed;
- we or our collaborators or any future collaborators might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or may in the future exclusively license, which could result in the patent applications not issuing or being invalidated after issuing;
- we or our collaborators or any future collaborators might not have been the first to file patent applications covering certain of our inventions, which could result in the patent applications not issuing or being invalidated after issuing;
- the ownership of the intellectual property arising out of our collaborations is subject to complex legal and factual issues, and in certain circumstances our collaborators may own or jointly own important intellectual property relating to our product candidates. Although we have rights to such intellectual property under our collaboration agreements, such rights could potentially be lost or diminished if the

applicable collaboration agreement is terminated, which could affect our ability to commercialize our product candidates;

- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors; we may obtain patents for certain compounds many years before we obtain marketing approval for products containing such compounds, and because patents have a limited life, which may begin to run prior to the commercial sale of the related product, the commercial value of our patents may be limited;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may fail to develop additional proprietary technologies that are patentable;
- the laws of certain foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States, or we may fail to apply for or obtain adequate intellectual property protection in all the jurisdictions in which we operate; and
- the patents of others may have an adverse effect on our business, for example by preventing us from marketing one or more of our product candidates for one or more indications.

Any of the aforementioned threats to our competitive advantage could have a material adverse effect on our business.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with many other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining, maintaining and enforcing patents in the biopharmaceutical industry involves both technological complexity and legal complexity. Therefore, obtaining, maintaining and enforcing biopharmaceutical patents is costly, time-consuming and inherently uncertain. In addition, recent legislative and judicial developments in the United States and elsewhere have in some cases narrowed the protection afforded to patent owners, made patents more difficult to obtain, or increased the uncertainty regarding the ability to obtain, maintain and enforce patents. For example, Congress recently passed patent reform legislation, and may pass patent reform legislation in the future. The United States Supreme Court has ruled on several patent cases in recent years, and in certain circumstances has narrowed the scope of patent protection available or otherwise weakened the rights of patent owners. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions and actions by the United States Congress, the federal courts, the United States Patent and Trademark Office, and their respective foreign counterparts, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to maintain and enforce our existing patents and patents that we might obtain in the future.

Risks Related to Industry

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

As has been widely reported, global credit and financial markets have been experiencing extreme disruptions over the past several years, including severely diminished liquidity and credit availability, declines in consumer

confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by the recent economic downturn and volatile business environment and continued unpredictable and unstable market conditions, particularly for securities of biotechnology companies such as our common stock. There is a possibility that our stock price may decline, due in part to the volatility of the stock market and any general economic downturn. If the current equity and credit markets become more volatile, deteriorate or do not improve, it may make any necessary debt or equity financing more difficult to secure, more costly and/or more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon our business and clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates, and we will face an even greater risk if we commercialize any product candidates. For example, we may be sued if any of our product candidates, including any that are developed in combination therapies, allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. There is also risk that third parties we have agreed to indemnify could incur liability.

Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product candidates or any resulting products;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management’s time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- the inability to commercialize our product candidates; and
- a decline in our stock price.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We currently carry product liability insurance covering our clinical studies in the amount of $5.0 million in the aggregate. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by

a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

Our relationships with customers and third-party payors in the United States and elsewhere will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval. Restrictions under applicable federal, state and foreign healthcare laws and regulations include the following:

- the federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid;
- the federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or *qui tam* actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the federal transparency requirements under the Patient Protection and Affordable Care Act of 2010 requires manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests;
- analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures; and
- analogous anti-kickback, fraud and abuse and healthcare laws and regulations in foreign countries.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil,

criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, which could have a material adverse effect on our business. If any of the physicians or other providers or entities with whom we expect to do business, including our collaborators, are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs, which could also materially affect our business.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials or our or third parties' disposal of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

We may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials. This insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of hazardous or radioactive materials.

Risks Related to Our Common Stock

Our executive officers, directors and principal stockholders own a significant percentage of our stock and will be able to exercise control over all matters submitted to stockholders for approval.

Our executive officers and directors and stockholders holding more than 5% of our outstanding common, in the aggregate, beneficially own shares representing approximately 66.76% of our outstanding capital stock. As a result, if these stockholders were to choose to act together, they would be able to control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. The interests of this group of stockholders may not always coincide with our corporate interests or the interests of other stockholders, and they may act in a way in which you may not agree with or in a way that may not be in the best interests of other stockholders. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which they might otherwise receive a premium for their shares.

These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified or staggered board of directors such that not all members of the board are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- provide our board of directors with the authority to designate the terms of and issue a new series of preferred stock without stockholder approval, which could be used to institute a “poison pill” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 66 2/3% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibit a person who owns 15% or more of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. Any provision in our corporate charter or our bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

Our employment agreements with our named executive officers may require us to pay severance benefits to any of those persons who are terminated in connection with a change of control of us, which could harm our financial condition or results.

Our named executive officers are parties to employment agreements that provide for aggregate cash payments of up to approximately $2.1 million for severance and other benefits and acceleration of vesting of stock options in the event of a termination of employment in connection with a change of control of our company. Based on the March 31, 2013 closing price of our common stock at $18.20 per share, the aggregate intrinsic value of unvested stock options subject to accelerated vesting upon these events was $1.1 million as of March 31, 2013. The accelerated vesting of options could result in dilution to our stockholders and harm the market price of our common stock. The payment of these severance benefits could harm our financial condition and results. In addition, these potential severance payments may discourage or prevent third parties from seeking a business combination with us.

We incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. We are subject to the reporting and other requirements of the Securities Exchange Act of 1934, as

amended, known as the Exchange Act, portions of the Sarbanes-Oxley Act of 2002, as well as rules subsequently adopted by the Securities and Exchange Commission, or SEC, and The NASDAQ Stock Market, or NASDAQ. These rules and regulations require, among other things, that we file annual, quarterly and current reports with respect to our business and financial condition and establish and maintain effective disclosure and financial controls and corporate governance practices. These rules and regulations substantially increase our legal and financial compliance costs and make some activities more time-consuming and costly, and we expect that this our legal and financial compliance costs will further increase after we are no longer an "emerging growth company" as defined in the recently enacted Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Our management and other personnel devote a substantial amount of time to these compliance initiatives. We estimate that incremental annual compliance costs associated with these reporting obligations will initially approximate $1.0 million.

We are an "emerging growth company," and we cannot be certain if the reduced reporting requirements applicable to "emerging growth companies" will make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. For as long as we continue to be an "emerging growth company," we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As an "emerging growth company" we are required to report periodic financial results and selected financial data related to two fiscal years compared to three and five years, respectively, for comparable data required to be reported by other public companies in selected SEC reports. We may take advantage of these exemptions until we are no longer an "emerging growth company." We could be an "emerging growth company" for up to five years, although circumstances could cause us to lose that status earlier, including if the market value of our common stock held by non-affiliates exceeds $700 million as of any March 31 (the end of our second fiscal quarter) before that time, in which case we would no longer be an "emerging growth company" as of the following September 30 (our fiscal year end). We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, "emerging growth companies" can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption to delay the adoption of new or revised accounting standards and, therefore, will be subject to adopting new or revised accounting standards at the same time as other public companies that are not "emerging growth companies."

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act of 2002, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

We will be required to disclose changes made in our internal controls and procedures on a quarterly basis and our management will be required to assess the effectiveness of these controls annually. However, for as long as we are an "emerging growth company" under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. We could be an "emerging growth company" for up to five years. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

Our stock price is likely to be volatile, and thus our stockholders could incur substantial losses.

Our stock price is likely to be volatile. The stock market in general and the market for biopharmaceutical companies, and for those developing potential therapies for HCV in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above your purchase price, if at all. The market price for our common stock may be influenced by many factors, including:

- actions by any of our collaborators regarding our product candidates they are developing, including announcements regarding clinical or regulatory developments or our collaboration;
- results from or delays of clinical trials of our product candidates, as well as results of regulatory reviews relating to the approval of our product candidates;
- new products, product candidates or new uses for existing products or technologies introduced or announced by our competitors and the timing of these introductions or announcements;
- our or our collaborators' decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- the results of our efforts to discover or develop additional product candidates;
- our dependence on third parties, including our collaborators, CROs, clinical trial sponsors and clinical investigators;
- regulatory or legal developments in the United States or other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key scientific or management personnel;
- our ability to commercialize our future product candidates we develop independently, if approved;
- the level of expenses related to any of our product candidates or clinical development programs;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- sales of common stock by us or our stockholders in the future, as well as the overall trading volume of our common stock;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies; and
- the other factors described in this "Risk Factors" section.

We do not anticipate paying any cash dividends on our capital stock in the foreseeable future.

We do not currently intend to pay any cash dividends on our common stock in the foreseeable future. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. As of March 31, 2013, we had outstanding 17,818,796 shares of common stock, of which 13,096,595 shares (exclusive of shares purchased in our initial public offering) are currently restricted as a result of securities laws or lock-up agreements. We intend to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements.

If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If too few securities or industry analysts cover our company, the trading price for our stock would likely be negatively impacted. In the event that one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Unregistered Sales of Equity Securities

From January 1, 2013 through March 31, 2013, we granted options to our employees and directors for the purchase of an aggregate of 206,153 shares of our common stock at a weighted-average exercise price of $14.01, pursuant to our 1995 Equity Incentive Plan. During this period, we issued an aggregate of 382,235 shares of our common stock at prices ranging from $0.73 to $11.77 per share to certain of our employees and directors pursuant to the exercise of stock options under the 1995 Equity Incentive Plan for an aggregate purchase price of $349,838. These securities were issued pursuant to written compensatory plans or arrangements with our employees and directors in reliance on the exemption provided by Rule 701 promulgated under Section 3(b) of the Securities Act, or pursuant to Section 4(2) under the Securities Act, relative to transactions by an issuer not involving any public offering, to the extent an exemption from such registration was required.

Use of Proceeds from the Sale of Registered Securities

On March 20, 2013, the Securities and Exchange Commission declared effective our registration statement on Form S-1 (File No. 333-184779), as amended, filed in connection with the initial public offering of our common stock. Pursuant to the registration statement, we registered the offer and sale of shares of our common stock with an aggregate offering price of up to $73.6 million. On March 26, 2013, 4,600,000 shares of common stock were sold on our behalf by J.P. Morgan Securities LLC and Credit Suisse Securities (USA) LLC, as managing underwriters, including 600,000 shares of common stock that were sold in connection with the exercise of the underwriters' over-allotment option, at an initial public offering price of $14.00 per share, for aggregate gross proceeds of $64.4 million. Following the sale of the 4,600,000 shares of common stock, the offering terminated.

We paid to the underwriters underwriting discounts and commissions of approximately $4.5 million in connection with the offering. In addition, we incurred expenses of approximately $4.6 million in connection with the offering, which when added to the underwriting discounts and commissions paid by us, amounts to total expenses of approximately $9.1 million. Thus, the net offering proceeds to us, after deducting underwriting discounts and commissions and offering expenses, were approximately $55.3 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

The net proceeds from the offering have been invested in cash and cash equivalents. There has been no material change in the expected use of the net proceeds from our initial public offering as described in our registration statement on Form S-1.

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.	8-K	03/28/2013	3.2	001-35839	
4.1	Specimen certificate evidencing shares of common stock.	S-1/A	02/05/2013	4.1	333-184779	
10.1	Form of Indemnification Agreement for directors and officers.	S-1/A	02/05/2013	10.7	333-184779	
10.2†	Amendment No. 1, dated March 28, 2013, to that certain Collaboration and License Agreement between Enanta Pharmaceuticals, Inc. and Novartis Institutes for BioMedical Research, Inc.	—	—	—	—	X
10.3	Amended and Restated 1995 Equity Incentive Plan.	S-1/A	03/05/2013	10.8	333-184779	
10.4	Form of Non-Statutory Stock Option Certificate for directors under Amended and Restated 1995 Equity Incentive Plan.	S-1/A	03/05/2013	10.11	333-184779	
10.5	2012 Equity Incentive Plan.	S-1/A	02/05/2013	10.12	333-184779	
10.6	Form of Incentive Stock Option Agreement under 2012 Equity Incentive Plan.	S-1/A	03/05/2013	10.13	333-184779	
10.7	Form of Non-Statutory Stock Option Agreement under 2012 Equity Incentive Plan.	S-1/A	03/05/2013	10.14	333-184779	
10.8	Form of Non-Statutory Stock Option Certificate for directors under 2012 Equity Incentive Plan.	S-1/A	03/05/2013	10.15	333-184779	
10.9	Employee Stock Purchase Plan.	S-1/A	02/05/2013	10.16	333-184779	
10.10	Amended and Restated Employment Agreement between Enanta Pharmaceuticals, Inc. and Jay R. Luly, Ph.D., dated as of March 4, 2013.	S-1/A	03/05/2013	10.5	333-184779	
10.11	Form of Amended and Restated Employment Agreement for Executive Officers other than Chief Executive Officer.	S-1/A	03/05/2013	10.17	333-184779	
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

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	Date	Exhibit Number	File Number	
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 materials from the Quarterly Report of Enanta Pharmaceuticals, Inc. on Form 10-Q for the quarter ended March 31, 2013, formatted in XBRL (eXtensible Business Reporting Language): (i) Balance Sheets as of March 31, 2013 and September 30, 2012 of Enanta Pharmaceuticals, Inc., (ii) Statements of Operations for the three months and six months ended March 31, 2013 and 2012 of Enanta Pharmaceuticals, Inc., (iii) Statements of Cash Flows for the six months ended March 31, 2013 and 2012 of Enanta Pharmaceuticals, Inc., and (iv) Notes to Financial Statements of Enanta Pharmaceuticals, Inc.††					X

† This Exhibit has been filed separately with the Commission pursuant to an application for confidential treatment. The confidential portions of this Exhibit have been omitted and are marked by asterisks.

†† Pursuant to Rule 406T of Regulation S-T, the Interactive Data Files in Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.

ENANTA PHARMACEUTICALS, INC.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ENANTA PHARMACEUTICALS, INC.

Date: May 14, 2013

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

ENANTA PHARMACEUTICALS, INC.

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Exhibit 10.2

AMENDMENT NO. 1 TO
COLLABORATION AND LICENSE AGREEMENT

This Amendment No. 1 to Collaboration and License Agreement (this "Amendment No. 1") is executed as of March 28, 2013, but effective as of February 16, 2013 (the "Amendment No. 1 Effective Date") by and between Enanta Pharmaceuticals, Inc. ("Enanta") and Novartis Institutes for BioMedical Research, Inc. ("Novartis").

WHEREAS, Enanta and Novartis are parties to that certain Collaboration and License Agreement, effective as of February 16, 2012 (the "Agreement"); and

WHEREAS, Enanta and Novartis wish to amend the Agreement to extend the Research Term in the Agreement to support [*****] ([*****]) FTEs for an additional six (6) months as set forth herein, effective without interruption.

NOW, THEREFORE, in consideration of the foregoing and the covenants and promises contained in this Amendment, the parties agree as follows:

1. Section 2.3 is hereby deleted, and in its place, the following is hereby inserted:

   Term and Scope of Research Program. The Research Program shall commence on the Effective Date and shall continue for 18 months from the Effective Date (the "Research Term"). No later than [*****] days prior to expiration of the Research Term, the Parties may agree to extend the Research Term and shall discuss, in good faith, the scope of additional research funding to be provided to Enanta by Novartis and the proposed Research Plan. In the event of a Change of Control, Novartis may terminate the Research Program by providing thirty (30) days' prior written notice to Enanta.

2. An amended Research Plan is attached hereto as Exhibit B, which shall, as of the Amendment No. 1 Effective Date, replace in its entirety any previous version thereof.

3. Any initially capitalized terms not otherwise defined herein shall have the meanings given in the Agreement.

4. Except as expressly amended hereby, all terms of the Agreement shall remain unchanged and in full force and effect.

5. This Amendment No. 1 may be executed in multiple counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the Parties have duly executed this Amendment as of the Amendment No. 1 Effective Date.

NOVARTIS INSTITUTES FOR BIOMEDICAL RESEARCH, INC.

By: /s/ Charles Winslow
Name: Dr. Charles Winslow
Title: Vice President, Global Head Strategic Alliances

ENANTA PHARMACEUTICALS, INC.

By: /s/ Jay R. Luly
Name: Jay R. Luly, Ph.D.
Title: President and CEO

[Signature Page to Amendment No. 1 to Enanta Collaboration and License Agreement]

Confidential materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote such omission.

AMENDED EXHIBIT B

RESEARCH PLAN

[*****]

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 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)) 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) 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

   (c) 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 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: May 14, 2013

/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 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)) 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) 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

   (c) 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 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: May 14, 2013

/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 three months ended March 31, 2013 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: May 14, 2013

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

Dated: May 14, 2013

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