ENANTA PHARMACEUTICALS INC
Form 10-Q
August 09, 2016
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

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

For the quarterly period ended June 30, 2016

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 x 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 x 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 x
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 x

The number of shares of the registrant s Common Stock, $0.01 par value, outstanding as of August 1, 2016, was 19,035,910 shares.

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ENANTA PHARMACEUTICALS, INC.

FORM 10-Q Quarterly Report

For the Quarterly Period Ended June 30, 2016

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PART I FINANCIAL INFORMATION

ITEM 1. CONSOLIDATED FINANCIAL STATEMENTS

ENANTA PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

(unaudited)

(in thousands, except share and per share amounts)

	June 30, 2016	September 30, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 24,789	$ 21,726
Short-term marketable securities	193,676	123,479
Accounts receivable	13,978	15,289
Unbilled receivables		433
Deferred tax assets	1,147	1,447
Prepaid expenses and other current assets	8,200	8,267
Total current assets	241,790	170,641
Property and equipment, net	7,499	5,886
Long-term marketable securities	26,194	64,238
Deferred tax assets	5,843	4,640
Restricted cash	608	608
Total assets	$ 281,934	$ 246,013
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 2,044	$ 1,543
Accrued expenses and other current liabilities	4,583	3,962
Income taxes payable	2,942	1,199
Total current liabilities	9,569	6,704
Warrant liability	1,237	1,276
Series 1 nonconvertible preferred stock	158	163
Other long-term liabilities	1,963	1,713
Total liabilities	12,927	9,856
Commitments and contingencies (Note 11)		
Stockholders equity:		

Common stock; $0.01 par value, 100,000,000 shares authorized; 19,035,763 and 18,716,834 shares issued and outstanding at June 30, 2016 and September 30, 2015, respectively;	190	187
Additional paid-in capital	239,252	229,957
Accumulated other comprehensive income	117	33
Retained earnings	29,448	5,980
Total stockholders equity	269,007	236,157
Total liabilities and stockholders equity	$ 281,934	$ 246,013

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

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ENANTA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited)

(in thousands, except share and per share amounts)

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2016	2015	2016	2015
Revenue				
Milestones	$	$	$ 30,000	$ 125,000
Royalties	13,978	11,390	44,851	19,743
Other		209	576	1,721
Total revenue	$ 13,978	$ 11,599	$ 75,427	$ 146,464
Operating expenses:				
Research and development	10,785	6,253	28,961	16,140
General and administrative	4,282	3,643	12,526	9,850
Total operating expenses	15,067	9,896	41,487	25,990
Income (loss) from operations	(1,089)	1,703	33,940	120,474
Other income (expense):				
Interest income	474	304	1,238	660
Interest expense	(11)	(2)	(34)	(6)
Change in fair value of warrant liability and Series 1 nonconvertible preferred stock	(16)	(15)	44	144
Total other income (expense), net	447	287	1,248	798
Income (loss) before income taxes	(642)	1,990	35,188	121,272
Income tax (expense) benefit	(434)	428	(11,720)	(48,092)
Net income (loss)	$ (1,076)	$ 2,418	$ 23,468	$ 73,180
Net income (loss) per share:				
Basic	$ (0.06)	$ 0.13	$ 1.24	$ 3.92
Diluted	$ (0.06)	$ 0.13	$ 1.22	$ 3.80
Weighted average shares outstanding:				
Basic	18,982,825	18,697,104	18,892,627	18,659,742
Diluted	18,982,825	19,277,966	19,223,359	19,276,767

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

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ENANTA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(unaudited)

(in thousands)

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2016	2015	2016	2015
Net income (loss)	$ (1,076)	$ 2,418	$ 23,468	$ 73,180
Other comprehensive income (loss):				
Net unrealized gains (losses) on marketable securities, net of tax of $185, ($40), $50 and $18	(84)	(57)	84	26
Total other comprehensive income (loss)	(84)	(57)	84	26
Comprehensive income (loss)	$ (1,160)	$ 2,361	$ 23,552	$ 73,206

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

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ENANTA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

(in thousands)

	Nine Months Ended June 30,	
	2016	**2015**
Cash flows from operating activities		
Net income	$ 23,468	$ 73,180
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization expense	1,206	435
Non-cash interest expense		6
Change in fair value of warrant liability and Series 1 nonconvertible preferred stock	(44)	(144)
Stock-based compensation expense	6,844	4,041
Gain on sale of fixed assets		(21)
Premium on marketable securities	(130)	(2,063)
Gain on sale of marketable securities		(4)
Amortization of premium on marketable securities	1,304	1,651
Deferred income taxes	546	11,076
Income tax benefit from the exercise of stock options	(1,749)	(1,817)
Change in operating assets and liabilities:		
Accounts receivable	1,311	(10,000)
Unbilled receivables	433	1,394
Prepaid expenses and other current assets	67	(1,108)
Accounts payable	677	(332)
Accrued expenses	1,946	391
Income taxes payable	1,754	2,229
Other long-term liabilities	302	134
Net cash provided by operating activities	37,935	79,048
Cash flows from investing activities		
Purchase of property and equipment	(4,323)	(756)
Purchase of marketable securities	(150,490)	(155,583)
Sale of marketable securities		2,210
Maturities of marketable securities	117,297	62,017
Increase in restricted cash		(172)
Net cash used in investing activities	(37,516)	(92,284)
Cash flows from financing activities		
Proceeds from exercise of stock options	945	564

Payments of capital lease obligations	(50)	
Income tax benefit from the exercise of stock options	1,749	1,817
Net cash provided by financing activities	2,644	2,381
Net increase (decrease) in cash and cash equivalents	3,063	(10,855)
Cash and cash equivalents at beginning of period	21,726	30,699
Cash and cash equivalents at end of period	$ 24,789	$ 19,844
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	$ 9,116	$ 39,566

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

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ENANTA PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED 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 robust chemistry-driven approach and drug discovery capabilities to create small molecule drugs primarily for the treatment of viral infections and liver diseases. The Company s research and development is currently focused on four disease targets: hepatitis C virus (HCV); hepatitis B virus (HBV); non-alcoholic steatohepatitis (NASH); and respiratory syncytial virus (RSV).

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, the uncertainties of research and development, competition from technological innovations of others, dependence on collaborative arrangements, protection of proprietary technology, dependence on key personnel, 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.

Unaudited Interim Financial Information

The consolidated balance sheet at September 30, 2015 was derived from audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the United States of America (GAAP). The accompanying unaudited consolidated financial statements as of June 30, 2016 and for the three and nine months ended June 30, 2016 and 2015 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 included in the Company s Annual Report on Form 10-K for the year ended September 30, 2015.

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 June 30, 2016 and results of operations for the three and nine months ended June 30, 2016 and 2015 and cash flows for the nine months ended June 30, 2016 and 2015 have been made. The results of operations for the three and nine months ended June 30, 2016 are not necessarily indicative of the results of operations that may be expected for subsequent quarters or the year ending September 30, 2016.

The accompanying consolidated financial statements have been prepared in conformity with GAAP. All dollar amounts in the consolidated 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

For the Company s Significant Accounting Policies refer to its Annual Report on Form 10-K for the fiscal year ended September 30, 2015.

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenues and expenses during the reporting period. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, management s judgments of separate units of accounting and best estimate of selling price of those units of accounting within its revenue arrangements; valuation of 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.

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Recently Issued Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (the FASB) issued ASU No. 2014-09, *Revenue from Contracts with Customers* (Topic 606), which supersedes all existing revenue recognition requirements, including most industry-specific guidance. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. In March 2016, the FASB issued ASU No. 2016-08, *Revenue from Contracts with Customers: Principal versus Agent Considerations*. The amendment includes indicators to assist an entity in determining whether it controls a specified good or service before it is transferred to the customers. In April 2016, the FASB issued ASU No. 2016-10, *Revenue from Contracts with Customers: Identifying Performance Obligations and Licensing* in April 2016 to clarify guidance from ASU 2014-09. Specifically, this amendment addresses an entity s identification of its performance obligations in a contract, as well as an entity s evaluation of the nature of its promise to grant a license of intellectual property and whether or not that revenue is recognized over time or at a point in time. The FASB also issued ASU No. 2016-12 *Revenue from Contracts with Customers: Narrow-Scope Improvements and Practical Expedients*, in May 2016. This amendment addresses collectability, non-cash consideration, presentation of sales tax and transitioning to the new standard. These new standards will be effective for the Company on October 1, 2018. The Company is currently evaluating the potential impact that Topic 606 may have on its financial position and results of operations.

In November 2015, the FASB issued ASU No. 2015-17, *Balance Sheet Classification of Deferred Taxes* (ASU 2015-17), which simplifies the presentation of deferred income taxes by eliminating the need for entities to separate deferred income tax liabilities and assets into current and noncurrent amounts in a classified statement of financial position. This amendment is effective for the Company in the fiscal year beginning October 1, 2017, but early adoption is permissible. The Company is currently evaluating the potential impact that ASU 2015-17 may have on its financial position.

In February 2016, the FASB issued ASU No. 2016-02, *Leases* (ASU 2016-02), which will replace the existing guidance in ASC 840, Leases. The updated standard aims to increase transparency and comparability among organizations by requiring lessees to recognize lease assets and lease liabilities on the balance sheet and requiring disclosure of key information about leasing arrangements. This amendment is effective for the Company in the fiscal year beginning October 1, 2019, but early adoption is permissible. The Company is currently evaluating the potential impact that ASU 2016-02 may have on its financial position and results of operations.

In March 2016, the FASB issued ASU No. 2016-09, *Improvements to Employee Share-Based Payment Accounting* (ASU 2016-09), which intends to simplify several aspects of accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, an option to recognize gross stock compensation expense with actual forfeitures recognized as they occur, as well as certain classifications on the statement of cash flows. This amendment is effective for the Company in the fiscal year beginning October 1, 2017, but early adoption is permissible. The Company is currently evaluating the potential impact that ASU 2016-09 may have on its financial position and results of operations.

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

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3. Fair Value of Financial Assets and Liabilities

The following tables present information about the Company s financial assets and liabilities that were subject to fair value measurement on a recurring basis as of June 30, 2016 and September 30, 2015 and indicate the fair value hierarchy of the valuation inputs utilized to determine such fair value:

	Fair Value Measurements at June 30, 2016 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
U.S. Treasury notes	$ 62,658	$	$	$ 62,658
Cash equivalents	20,534			20,534
Corporate bonds		79,326		79,326
Commercial paper		46,819		46,819
U.S. Agency bonds		31,067		31,067
	$ 83,192	$ 157,212	$	$ 240,404
Liabilities:				
Warrant liability	$	$	$ 1,237	$ 1,237
Series 1 nonconvertible preferred stock			158	158
	$	$	$ 1,395	$ 1,395

	Fair Value Measurements at September 30, 2015 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	$ 21,327	$	$	$ 21,327
Corporate bonds		151,020		151,020
U.S. Agency bonds		36,697		36,697
	$ 21,327	$ 187,717	$	$ 209,044
Liabilities:				
Warrant liability	$	$	$ 1,276	$ 1,276
Series 1 nonconvertible preferred stock			163	163
	$	$	$ 1,439	$ 1,439

During the three and nine months ended June 30, 2016 and 2015, there were no transfers between Level 1, Level 2 and Level 3.

As of June 30, 2016 and September 30, 2015, respectively, the warrant liability was comprised of the value of warrants for the purchase of Series 1 nonconvertible preferred stock measured at fair value. The outstanding Series 1 nonconvertible preferred stock was also measured at fair value. The fair value of both of these instruments was based on significant inputs not observable in the market, which represented a Level 3 measurement within the fair value hierarchy. The Company utilized a probability-weighted valuation model which takes into consideration various

outcomes that may require the Company to transfer assets upon exercise. Changes in the fair value of the warrant liability and Series 1 nonconvertible preferred stock are recognized in the consolidated statements of operations.

As of June 30, 2016 and September 30, 2015, the recurring Level 3 fair value measurements of the Company s warrant liability and Series 1 nonconvertible preferred stock using probability-weighted discounted cash flow include the following significant unobservable inputs:

	Unobservable Input	June 30, 2016 Range (Weighted Average)
Warrant liability and Series 1 nonconvertible preferred stock	Probabilities of payout	0% - 60%
	Periods in which payout is expected to occur	2016 2017
	Discount rate	4.50%

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	Unobservable Input	September 30, 2015 Range (Weighted Average)
Warrant liability and Series 1 nonconvertible preferred stock	Probabilities of payout	5% - 60%
	Periods in which payout is expected to occur	2016 2017
	Discount rate	4.25%

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

	Warrant Liability	Series 1 Nonconvertible Preferred Stock
Balance, September 30, 2015	$ 1,276	$ 163
Decrease in fair value	(39)	(5)
Balance, June 30, 2016	$ 1,237	$ 158

4. Marketable Securities

As of June 30, 2016 and September 30, 2015, the fair value of available-for-sale marketable securities by type of security was as follows:

	June 30, 2016			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate bonds	$ 79,259	$ 75	$ (8)	$ 79,326
U.S. Treasury notes	62,558	100		62,658
Commercial paper	46,819			46,819
U.S. Agency bonds	31,047	20		31,067
	$ 219,683	$ 195	$ (8)	$ 219,870

	September 30, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate bonds	$ 151,012	$ 77	$ (69)	$ 151,020

U.S. Agency bonds	36,652	45		36,697
	$ 187,664	$ 122	$ (69)	$ 187,717

As of June 30, 2016, marketable securities consisted of investments that mature within one year, with the exception of certain corporate bonds, which have maturities within three years and an aggregate fair value of $26,194.

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5. Accrued Expenses and Other Long-Term Liabilities

Accrued expenses and other current liabilities as well as other long-term liabilities consisted of the following as of June 30, 2016 and September 30, 2015:

	June 30, 2016	September 30, 2015
Accrued expenses:		
Accrued preclinical and clinical expenses	$ 1,696	$ 237
Accrued payroll and related expenses	1,661	1,622
Accrued professional fees	517	338
Accrued other	419	371
Accrued vendor manufacturing	219	18
Capital lease obligation	71	69
Accrued fixed assets		1,307
	$ 4,583	$ 3,962
Other long-term liabilities:		
Accrued rent expense	$ 682	$ 628
Uncertain tax positions	668	448
Capital lease obligation	478	529
Asset retirement obligation	135	108
	$ 1,963	$ 1,713

6. Ongoing Collaboration Agreements

AbbVie Collaboration

The Company has a Collaborative Development and License Agreement (the AbbVie Agreement), as amended, with AbbVie Inc. to identify, develop and commercialize HCV NS3 and NS3/4A protease inhibitor compounds, including paritaprevir, under which it has received license payments, proceeds from a sale of preferred stock, research funding payments, milestone payments and royalties totaling $380,000 through June 30, 2016. As of June 30, 2016 the Company is eligible to receive additional milestone payments totaling up to $80,000 upon AbbVie s achievement of commercialization regulatory approval in the U.S. and other selected world markets for any additional protease inhibitor commercialized by AbbVie. Since the Company completed all its performance obligations under the AbbVie Agreement by the end of fiscal 2011, any milestone payments received since then have been and will be recognized as revenue when the milestones are achieved by AbbVie. The Company is also receiving annually 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 calendar year net sales by AbbVie allocated to the collaboration s protease inhibitors. Beginning with each January 1, the cumulative net sales of a given royalty-bearing product start at zero for purposes of calculating the tiered royalties.

During the three and nine months ended June 30, 2016, the Company earned and recognized milestone revenue of $0 and $30,000 respectively, upon AbbVie s achievement of commercialization regulatory approval of a

paritaprevir-containing regimen in Japan in November 2015. During the three and nine months ended June 30, 2015, the Company earned and recognized milestone revenue of $0 and $125,000 respectively, upon AbbVie s achievement of commercialization regulatory approval of VIEKIRAX in Europe in January 2015 and VIEKIRA PAK in the U.S in December 2014.

7. Warrants to Purchase Series 1 Nonconvertible Preferred Stock and Series 1 Nonconvertible Preferred Stock

In October and November 2010, the Company issued warrants to purchase up to a total of 1,999,989 shares of Series 1 nonconvertible preferred stock, which 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. 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), net, in the consolidated statement of operations.

8. Stock-Based Awards

The Company may grant stock-based awards under its existing 2012 Equity Incentive Plan (the 2012 Plan) and its Employee Stock Purchase Plan (the ESPP). The Company also has outstanding stock-based awards under its 1995 Equity Incentive Plan (the 1995

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Plan), but is no longer granting awards under this plan. As of June 30, 2016, 491,511 shares of common stock are available for issuance under the 2012 Plan. As of June 30, 2016, a total of 185,614 shares of common stock are available for issuance under the ESPP. As of June 30, 2016, the Company had not commenced any offering under the ESPP and no shares have been issued.

The Company applies the fair value recognition provisions for all stock-based awards granted or modified in accordance with authoritative guidance. Under this guidance the Company records compensation costs over the requisite service period of the award based on the grant-date fair value. The straight-line method is applied to all grants with service conditions, while the graded vesting method is applied to all grants with both service and performance conditions.

In March 2013, the Company granted to certain executive officers 167,052 options that vest upon achievement of certain performance-based targets. The aggregate fair value of these performance options ranges between $0 and $2,479. During the three and nine months ended June 30, 2016, certain performance-based targets were achieved and the Company recorded compensation expense of $206 and $412, respectively, in the consolidated statements of operations.

	Shares Issuable Under Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in years	Aggregate Intrinsic Value
Outstanding as of September 30, 2015	1,752,010	$ 23.76	7.2	$ 25,093
Granted	495,780	30.52		
Exercised	(318,929)	3.21		
Forfeited	(38,530)	32.17		
Outstanding, June 30, 2016	1,890,331	$ 28.81	7.8	$ 4,989
Options vested and expected to vest as of June 30, 2016	1,751,653	$ 29.84	7.9	$ 3,979
Options exercisable as of June 30, 2016	836,313	$ 25.01	7.0	$ 3,894

In December 2015, the Company awarded certain executive officers a total of 50,000 share units consisting of 25,000 performance share units, or PSUs, and 25,000 relative total shareholder return units, or rTSRUs. The number of units represents the target number of shares of common stock that may be earned; however, the actual number of shares that may be earned ranges from 0% to 200% of the target number. The PSUs will vest and result in issuance, or settlement, of common shares, based upon continued employment and achievement of specified research and development milestones on or before December 31, 2017. The aggregate grant date fair value of the 25,000 PSUs ranges between $0 and $1,602. During the three and nine months ended June 30, 2016, the Company recorded no compensation expense related to the PSU awards as none of the performance-based targets was probable of being achieved during this period.

The rTSRUs will vest and result in the issuance of common stock based on continuing employment and the relative ranking of the total shareholder return, or TSR, of the Company s common stock in relation to the TSR of the component companies in the NASDAQ Biotech Index over a two-year period based on a comparison of average closing stock prices in November 2015 and December 2017. The number of market-based rTSRUs awarded represents the target number of shares of common stock that may be earned; however, the actual number of shares that may be earned ranges from 0% to 200% of the target number.

The Company used a Monte Carlo simulation model to estimate that the aggregate grant-date fair value of the rTSRUs was $942. The table below sets forth the assumptions used to value the awards and the estimated grant-date fair value:

Risk-free interest rate	0.97%
Dividend yield	0%
Expected volatility	63.95%
Remaining performance period (years)	2.03
Estimated fair value per share of rTSRUs granted	$ 37.67

The fair value related to the rTSRUs will be recorded as compensation expense over the period from date of grant to December 2017 regardless of whether the target relative total shareholder returns are reached.

In addition, in December 2015, the Company awarded an executive officer 5,250 share units consisting of 2,625 PSUs and 2,625 rTSRUs. The number of units represents the target number of shares of common stock that may be earned; however, the actual number of shares that may be earned ranges from 0% to 200% of the target number.

The PSUs will vest and result in issuance, or settlement, of common shares, based upon continued employment and achievement of specified research and development milestones on or before December 31, 2016. The aggregate grant date fair value of the 2,625 PSUs ranges between $0 and $168. During the three and nine months ended June 30, 2016, the Company recorded no compensation expense related to the PSU awards as none of the performance-based targets was probable of being achieved during this period.

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The rTSRUs will vest and result in the issuance of common stock based on continuing employment and the relative ranking of the total shareholder return, or TSR, of the Company s common stock in relation to the TSR of the component companies in the NASDAQ Biotech Index over a two-year period based on a comparison of average closing stock prices in December 2014 and December 2016. The number of market-based rTSRUs awarded represents the target number of shares of common stock that may be earned; however, the actual number of shares that may be earned ranges from 0% to 200% of the target number.

The Company used a Monte Carlo simulation model to estimate that the aggregate grant-date fair value of the rTSRUs was $44. The table below sets forth the assumptions used to value the awards and the estimated grant-date fair value:

Risk-free interest rate	0.65%
Dividend yield	0%
Expected volatility	72.30%
Remaining performance period (years)	1.03
Estimated fair value per share of rTSRUs granted	$ 16.90

The fair value related to the rTSRUs will be recorded as compensation expense over the period from date of grant to December 2016 regardless of whether the target relative total shareholder returns are reached.

The Company recognized stock-based compensation expense on all awards in the following expense categories:

	Three Months ended June 30,		Nine Months ended June 30,	
	2016	2015	2016	2015
Research and development	$ 790	$ 468	$ 2,092	$ 1,106
General and administrative	1,680	1,116	4,752	2,935
	$ 2,470	$ 1,584	$ 6,844	$ 4,041

As of June 30, 2016, the Company had an aggregate of $24,680 unrecognized stock-based compensation cost, which is expected to be recognized over a weighted average period of 2.4 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 nine months ended June 30, 2016 and 2015:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2016	2015	2016	2015
Basic net income (loss) per share:				
Numerator:				
Net income (loss)	$ (1,076)	$ 2,418	$ 23,468	$ 73,180
Denominator:				
Weighted average common shares outstanding basic	18,982,825	18,697,104	18,892,627	18,659,742
Net income (loss) per share allocable to common shareholders basic	$ (0.06)	$ 0.13	$ 1.24	$ 3.92
Diluted net income (loss) per share:				
Numerator:				
Net income (loss)	$ (1,076)	$ 2,418	$ 23,468	$ 73,180
Denominator:				
Weighted average common shares outstanding basic	18,982,825	18,697,104	18,892,627	18,659,742
Dilutive effect of common stock equivalents		580,862	330,732	617,025
Weighted average common shares outstanding diluted	18,982,825	19,277,966	19,223,359	19,276,767
Net income (loss) per share allocable to common shareholders diluted	$ (0.06)	$ 0.13	$ 1.22	$ 3.80
Antidilutive common stock equivalents excluded from above	1,619,987	700,679	1,250,330	599,384

The impact of certain common stock equivalents were excluded from the calculation of diluted net income (loss) per share for the three months ended June 30, 2016 because the impact would have been anti-dilutive for the period. The impact of dilutive common stock equivalents of 237,796 were excluded from the calculation of diluted earnings per share for the three months ended June 30, 2016 as the effect would be anti-dilutive.

As of June 30, 2016 the Company excluded 97,050 and 125,291 of unvested restricted stock units and performance based options, respectively, from the calculation of diluted net income per share attributable to common stockholders as these awards contain performance and market conditions that would not have been achieved as of June 30, 2016 had the measurement period been as of that date.

10. Income Taxes

For the three months ended June 30, 2016 and 2015, the Company recorded an income tax (expense) benefit of $(434) and $428 respectively. The income tax (expense) benefit for the three months ended June 30, 2016 and 2015 was primarily attributable to the Company s domestic operations. During the three months ended June 30, 2016, the Company increased its estimate of its annual effective tax rate, which resulted in an income tax expense despite a pre-tax loss for the quarter. For the three months ended June 30, 2015, the Company s effective tax rate of 21.5% differs from the statutory rate of 35.0% primarily due to a research and development tax credit study performed in the quarter which resulted in an incremental tax benefit upon its completion in June 2015.

For the nine months ended June 30, 2016 and 2015, the Company recorded an income tax (expense) of $(11,720) and $(48,092), respectively, representing an effective tax rate of 33.3% and 39.7%, respectively. For the nine months ended June 30, 2016, the Company s effective tax rate differs from the statutory rate of 35.0% primarily due to reinstatement of the federal research and development tax credits which are included in the Company s annual effective tax rate. For the nine months ended June 30, 2015, the Company s effective tax rate differs from the statutory rate of 35.0% primarily due to state income taxes and certain expenditures which are permanently not deductible for tax purposes.

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. There are currently no pending income tax examinations. The Company s tax years are still open under statute from 2008 to the present. Earlier years may be examined to the extent that tax credit or net operating loss carryforwards are used in future periods.

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The Company had an unrecognized tax benefit of $668 and $448 as of June 30, 2016 and September 30, 2015, respectively. Unrecognized tax benefits represent tax positions for which reserves have been established. The Company s policy is to record interest and penalties related to uncertain tax positions as part of its income tax provision.

11. Commitments and Contingencies

Leases

The Company has an office and laboratory lease that expires in September 2022. Payment escalation as specified in the lease agreement is accrued such that rent expense is recognized on a straight-line basis over the term of occupancy. The Company recorded rent expense of $506 and $341 for the three months ended June 30, 2016 and 2015, respectively, and $1,519 and $821 for the nine months ended June 30, 2016 and 2015, respectively.

In connection with the lease, the Company has outstanding a $608 letter of credit, collateralized by a money market account. As of June 30, 2016 and September 30, 2015, the Company classified the $608 related to the letter of credit as restricted cash. Additionally, the lease, as amended, included a $598 tenant improvement allowance from the landlord, which allowance is accounted for as a capital lease obligation.

Intellectual Property Licenses

The Company has a non-exclusive intellectual property license agreement with a third party, under which the Company is required to pay (1) annual maintenance fees of $105 for each year that the agreement remains in effect, commencing on the first anniversary of the agreement, 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.

The Company also has a non-exclusive license with respect to patents it uses in its HCV research. Under the license, the Company is obligated to pay milestones totaling up to $5,000 plus low single digit royalties, for the development and regulatory approval of each HCV product outside of the Company s collaboration with AbbVie and any other collaboration it may enter into in the future with a partner that has already licensed these patents. During the nine months ended June 30, 2016, the Company made a $500 milestone payment under this license agreement upon its filing to commence clinical development of its cyclophilin inhibitor candidate. During the three and nine months ended June 30, 2015, no events triggering such payment occurred.

Litigation and Contingencies Related to Use of Intellectual Property

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

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 and its executive officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. In addition, the Company maintains officers and directors insurance coverage. The Company does not believe that the outcome of any claims under indemnification arrangements will have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its financial statements as of June 30, 2016.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the unaudited consolidated financial statements and notes thereto included elsewhere in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto for our fiscal year ended September 30, 2015 included in our Annual Report on Form 10-K for that fiscal year. 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 our robust chemistry-driven approach and drug discovery capabilities to create small molecule drugs primarily for the treatment of viral infections and liver diseases. Our research and development is currently focused on four disease targets: hepatitis C virus, or HCV; hepatitis B virus, or HBV; non-alcoholic steatohepatitis, or NASH; and respiratory syncytial virus, or RSV. Our lead product, paritaprevir, a protease inhibitor designed for use against HCV, is a key compound in AbbVie s marketed HCV treatment regimens. We also have a second HCV protease inhibitor in phase 3 development with AbbVie, as well as a wholly-owned HCV program using a different class of molecules known as cyclophilin inhibitors, one of which is now in phase 1 development. In addition, we have a program in NASH, with a lead candidate, EDP-305, which we plan to take into clinical trials in the second half of calendar 2016. EDP-305 may have utility in primary biliary cholangitis, or PBC, as well. We also have research programs targeting HBV and RSV.

Our HCV protease inhibitors have been discovered and developed through our collaboration with AbbVie (formerly Abbott Laboratories), including:

Paritaprevir: Paritaprevir is the protease inhibitor contained in VIEKIRA PAK® and AbbVie s other all-oral, interferon-free HCV treatment regimens currently marketed in the U.S., EU, Japan and other countries around the world. VIEKIRA PAK was approved and first sold in the U.S. in December 2014 for treatment of genotype 1 HCV, the most prevalent genotype of HCV in the U.S., EU and Japan. A regimen containing paritaprevir and only one other direct-acting antiviral, or DAA, is now approved in Japan (VIEKIRAX®, September 2015) for the treatment of genotype 1 HCV and in the U.S. (TECHNIVIE , July 2015), EU (VIEKIRAX, January 2015) and other countries for the treatment of genotype 4 HCV.

ABT-493: Our second protease inhibitor, ABT-493, is being developed by AbbVie in combination with its next-generation NS5A inhibitor, ABT-530, as a pan-genotypic, once daily, all oral, fixed-dose combination treatment for HCV. AbbVie is now conducting a series of Phase 2 and 3 registrational trials with this investigational combination treatment, which will investigate 8-week and 12-week courses of this once-daily 2-DAA combination against all six major genotypes of HCV as well as subpopulations of patients with cirrhosis, renal impairment or failure on prior treatment regimens. AbbVie is planning for the first approval of this treatment in the U.S. in calendar 2017. AbbVie has completed several Phase 2 clinical studies of this investigational 2-DAA treatment and has most recently reported the following results from its Surveyor 1 and 2 studies:

After 8 weeks of treatment with doses at or closest to the Phase 3 clinical dose, SVR_{12} rates were 97-98% in genotype 1, 2 or 3 HCV patients without cirrhosis.

100% percent SVR_{12} rates were achieved within 12 weeks of treatment in genotype 3 patients with compensated cirrhosis (Child-Pugh A) new to therapy.

100% percent SVR_{12} rates were achieved within 12 weeks of treatment in genotypes 4, 5 or 6 patients without cirrhosis; a study of 8-week treatment duration in patients with these genotypes is ongoing.

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In the first nine months of fiscal 2015, we received $125.0 million in milestone payments for commercialization regulatory approvals of paritaprevir, and we earned $19.7 million in royalties on the portion of AbbVie s net sales of its HCV regimens allocated to paritaprevir. In the first nine months of our fiscal 2016, we received a $30.0 million milestone payment for the November 2015 reimbursement approval of paritaprevir in Japan, and earned $44.9 million in royalties on the portion of AbbVie s net sales of its HCV regimens allocated to paritaprevir. We earned $14.0 million of those royalties in the three months ended June 30, 2016. We had $244.7 million in cash and marketable securities at June 30, 2016, exclusive of the $14.0 million in royalty receivables due to us from AbbVie at that date. These existing resources will allow us to continue to invest for the foreseeable future in our current research and development programs in virology, namely HCV, HBV and RSV, and in liver disease (non-virology), namely NASH and PBC:

EDP-494: We have a cyclophilin inhibitor, EDP-494, for which we initiated clinical studies in the first quarter of calendar 2016, including a proof-of-concept study in HCV patients, to demonstrate its potential benefit as a host-targeted antiviral, or HTA. Cyclophilin is a protein in the human body that has been shown to be involved in HCV replication. By focusing on this human, or host, target rather than a viral target, we have selected a mechanism shown to be less susceptible to the HCV resistance that can occur due to viral mutation in response to therapy. We believe that cyclophilin inhibitors will be particularly valuable in the setting of resistance associated variants, or RAVs, of HCV. The presence of pre-treatment, or baseline, RAVs in treatment-naïve patients, and the emergence of treatment emergent RAVs in treatment-experienced patients, can result in reduced ability to eradicate the HCV virus. Since cyclophilin is a human host target, and not a viral target, cyclophilin inhibitors are not affected by changes in the virus and, therefore, use of this class of inhibitor may provide a unique solution for a subset of hard-to-treat HCV patients. We plan to develop EDP-494 for use in combination with one or more DAAs for the treatment of any emerging HCV resistance to currently approved therapies and other therapies under development for HCV that use DAAs. It is also possible that an EDP-494-containing regimen may find utility in other hard-to-treat subpopulations of HCV patients.

EDP-305: We are also working on multiple compounds that selectively bind to and activate the farnesoid X receptor, referred to as FXR agonists, which we plan to develop for use in the treatment of NASH, and possibly PBC, both of which are liver diseases with very few therapeutic options. We plan to initiate clinical trials of our lead FXR agonist candidate, EDP-305, in the second half of calendar 2016.

HBV and RSV: We also have programs to discover and develop new chemical entities for the treatment of HBV and RSV. In HBV, our initial focus is on core inhibitors, a mechanism with early clinical validation. In RSV, our initial efforts are concentrated on non-fusion inhibitors. To develop successful therapies for both HBV and RSV, we believe that it may be necessary to utilize more than one compound/mechanism and therefore are pursuing multiple approaches in those programs. We intend to advance a candidate compound into the clinic in at least one of these programs in calendar 2017.

We have utilized our internal chemistry and drug discovery capabilities to generate all of our development-stage programs.

We are currently funding all research and development for our internal programs. We have prioritized our cyclophilin program because we believe that high-barrier-to-resistance mechanisms are going to be increasingly important for the treatment of HCV patients, including those that have failed on current DAA therapies. We expect to incur

substantially greater expenses as we continue to advance our cyclophilin inhibitor, EDP-494, through Phase 1 clinical development, which began in January 2016. We are also funding our FXR agonist program, including substantial preclinical development work, which we expect will enable us to initiate clinical development of our lead candidate, EDP-305, in the second half of calendar 2016. In addition, we have increased expenses in fiscal 2016 as we advance other compounds into substantial preclinical development.

Since commencing our operations in 1995, we have devoted substantially all of our resources to the discovery and development of novel compounds for the treatment of infectious diseases and liver diseases. For the periods included in this report we have funded our operations primarily through payments received under our collaborations and a NIAID government contract, as well as net proceeds of approximately $59.9 million that we received from our March 2013 IPO, after deducting underwriting discounts and commissions.

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Our revenue from our collaboration agreements has resulted in our reporting net income in each of our past five fiscal years. We expect that our revenue in the near term will continue to be dependent on our collaboration with AbbVie, including royalties from sales of paritaprevir-containing regimens and potential milestone payments and royalties from the development program for ABT-493, our second protease inhibitor being developed with AbbVie. Given the schedule of potential milestone payments and the uncertainties due to the nature and timing of clinical development and regulatory approval and market acceptance of any AbbVie regimen containing ABT-493, as well as uncertainty regarding the extent of royalty payments related to paritaprevir, we cannot be certain as to when or whether we will receive further milestone payments or the extent of our royalty revenues under this collaboration or whether we will continue to report net income in future full-year periods.

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 entered into three significant collaboration agreements and contracts since 2006, the most significant of which is our collaboration agreement with AbbVie. Our second collaboration was with Novartis, from February 2012 through September 2014. In addition, from September 2011 through August 2015, we had a contract with NIAID, which funded the preclinical and early clinical development of an antibiotic product candidate for potential use in biodefense.

Beginning in our fiscal year ended September 30, 2015, we generated royalty revenue from AbbVie s net sales allocable to paritaprevir, which is part of AbbVie s treatment regimens for HCV approved in the U.S. in December 2014, in the EU in January 2015 and in dozens of other countries since then. AbbVie received reimbursement approval for paritaprevir in Japan in November 2015.

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The following table is a summary of revenue recognized from our collaboration agreement and our government contract for three and nine months ended June 30, 2016 and 2015:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2016	2015	2016	2015
	(in thousands)			
AbbVie agreement:				
Milestone payments	$	$	$ 30,000	$ 125,000
Royalties	13,978	11,390	44,851	19,743
NIAID contract:		209	576	1,721
Total revenue	$ 13,978	$ 11,599	$ 75,427	$ 146,464

AbbVie Agreement

Since all of our research obligations under the AbbVie agreement were concluded by June 30, 2011, all milestone payments received since then have been recognized as revenue upon achievement of each milestone by AbbVie. During the nine months ended June 30, 2016 we earned and recognized as revenue a $30.0 million milestone payment upon AbbVie s achievement of commercialization regulatory approval of a paritaprevir-containing regimen in Japan. During the nine months ended June 30, 2015, we earned and recognized as revenue a $75.0 million milestone payment related to AbbVie s FDA approval of a combination containing paritaprevir. We also earned and recognized as revenue a $50.0 million milestone payment from AbbVie upon commercialization regulatory approval of a similar regimen in Europe during that same period in 2015. Under the terms of the AbbVie agreement, we are eligible to receive additional future milestone payments from AbbVie totaling up to $80.0 million related to the successful commercialization regulatory approvals in major markets of the first HCV treatment regimen incorporating another of our collaboration s protease inhibitors.

We also receive annually tiered, double-digit royalties per product on AbbVie s net sales allocable to any one of our collaboration s protease inhibitors. Under the terms of our agreement, as amended in October 2014, 30% of net sales of 3-DAA regimens containing paritaprevir and 45% of net sales of 2-DAA regimens containing paritaprevir are allocated to paritaprevir for purposes of calculating our annually tiered royalties. Beginning with each January 1, the cumulative net sales of a given royalty-bearing product start at zero for purposes of calculating the tiered royalties.

Operating Expenses

The following table summarizes our operating expenses for the three and nine months ended June 30, 2016 and 2015:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2016	2015	2016	2015
	(in thousands)			

Research and development	$ 10,785	$ 6,253	$ 28,961	$ 16,140
General and administrative	4,282	3,643	12,526	9,850
Total operating expenses	$ 15,067	$ 9,896	$ 41,487	$ 25,990

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;

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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 continue to increase in the future as we advance our cyclophilin inhibitor program for HCV and our research and development efforts in NASH, HBV and RSV.

Our research and drug discovery programs are at early stages; therefore, the successful development of our product candidates is highly uncertain and may not result in approved products. Completion dates and completion costs can vary significantly for each product candidate and are difficult to predict. Given the uncertainty associated with clinical trial enrollments and the risks inherent in the development process, we are unable to determine the duration and completion costs of the current or future clinical trials of our product candidates or if, or to what extent, we will generate revenue from the commercialization and sale of any of our product candidates. We anticipate that we will make determinations as to which development programs to pursue and how much funding to direct to each program on an ongoing basis in response to the preclinical and clinical success of each product candidate, as well as ongoing assessments of the commercial potential of each product candidate.

General and Administrative Expenses

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

Other Income (Expense)

Interest income. Interest income consists of interest earned on our cash equivalents and short-term and long-term marketable securities balances

Interest expense. Interest expense consists of interest expense related to our capital lease obligation and to the value of accrued third-party license fees.

Change in fair value of warrant liability and Series 1 nonconvertible preferred stock. We have issued warrants for the purchase of our Series 1 nonconvertible preferred stock and we have issued Series 1 nonconvertible preferred stock, both of which we believe are financial instruments that may require a transfer of assets because of the liquidation preference features of the underlying stock. Therefore, we have classified these warrants and Series 1 nonconvertible

preferred stock as liabilities that we remeasure to fair value at each reporting period and we record the changes in the fair value of the warrants and Series 1 nonconvertible preferred stock as a component of other income (expense).

Income Tax (Expense) Benefit

Income tax expense is based on our best estimate of applicable income tax rates for the entire fiscal year applied to pre-tax profit reported for the year to date period.

Critical Accounting Policies

Our consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amount of assets, liabilities, revenue, costs and expenses, and related disclosures. We believe that the estimates and assumptions involved in the accounting policies described below may have the greatest potential impact on our consolidated financial statements and, therefore, consider these to be our critical accounting policies. We evaluate our estimates and

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assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions and conditions. See also our Annual Report on Form 10-K for the fiscal year ended September 30, 2015 (referred to as our 2015 Form 10-K) 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;

Stock-based compensation; and

Fair value of warrants and related preferred stock.

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, 2015. For further information, please see the discussion of critical accounting policies included in our 2015 Form 10-K.

Results of Operations

Comparison of three months ended June 30, 2016 and 2015

	Three Months Ended June 30,	
	2016	2015
	(in thousands)	
Revenue	$ 13,978	$ 11,599
Research and development	10,785	6,253
General and administrative	4,282	3,643
Other income (expense), net:		
Interest income	474	304
Interest expense	(11)	(2)
Change in fair value of warrant liability and Series 1 nonconvertible preferred stock, net	(16)	(15)
Income tax (expense) benefit	(434)	428

Revenue.

	Three Months Ended June 30,	
	2016	2015
	(in thousands)	
AbbVie agreement:		
Royalties	$ 13,978	$ 11,390
Milestones		
NIAID contract:		209
Total revenue	$ 13,978	$ 11,599

We recognized revenue of $14.0 million during the three months ended June 30, 2016 as compared to $11.6 million during three months ended June 30, 2015. During the three months ended June 30, 2016, revenue consisted of royalties on the portion of AbbVie s net sales of its HCV treatment regimens allocable to paritaprevir. During the three months ended June 30, 2015, revenue consisted of royalties on the portion of AbbVie s net sales of its HCV treatment regimen allocable to paritaprevir, and $0.2 million of revenue earned under our contract with NIAID.

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Research and development expenses.

	Three Months Ended June 30,	
	2016	2015
	(in thousands)	
R&D programs:		
Virology	$ 6,033	$ 2,398
Liver disease	4,619	3,197
Other	133	658
Total research and development expenses	$ 10,785	$ 6,253

Research and development expenses increased $4.5 million for the three months ended June 30, 2016 as compared to the same period in 2015. The increase was primarily due to progression of preclinical and clinical activities in our virology and liver disease programs. Increases were driven by an increase in headcount to support our preclinical activities, expansion of our research facility and an increase in external costs for clinical and preclinical activities.

General and administrative expenses. General and administrative expenses increased by $0.6 million for the three months ended June 30, 2016 as compared to the same period in 2015. The increase was primarily due to an increase in stock-based compensation expense related to an increase in headcount, additional stock option grants to employees, and achievement of performance-based option milestones granted to management.

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

Interest income. The increase in interest income for the three months ended June 30, 2016 as compared to the same period in 2015 was due to higher average investment balances in the third fiscal quarter of 2016 as compared to the same period in 2015.

Change in fair value of warrant liability and Series 1 nonconvertible preferred stock. The expense recorded during the three months ended June 30, 2016 was due to an increase in the fair value of the warrant liability and Series 1 nonconvertible preferred stock as a result of the remeasurement of these instruments from quarter to quarter.

Income tax (expense) benefit. For the three months ended June 30, 2016 and 2015, we recorded an income tax (expense) benefit of $(0.4) million and $0.4 million, respectively. For the three months ended June 30, 2016 we increased our estimate of our annual effective tax rate, which resulted in an income tax expense despite a pre-tax loss for the quarter. For the three months ended June 30, 2015, a research and development tax credit study performed in the quarter resulted in an incremental tax benefit upon its completion in June 2015, despite pre-tax income for the quarter.

Comparison of nine months ended June 30, 2016 and 2015

	Nine Months Ended June 30,	
	2016	2015
	(in thousands)	
Revenue	$ 75,427	$ 146,464
Research and development	28,961	16,140
General and administrative	12,526	9,850
Other income (expense), net:		
Interest income	1,238	660
Interest expense	(34)	(6)
Change in fair value of warrant liability and Series 1 nonconvertible preferred stock, net	44	144
Income tax (expense) benefit	(11,720)	(48,092)

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Revenue.

	Nine Months Ended June 30,	
	2016	2015
	(in thousands)	
AbbVie agreement:		
Royalties	$ 44,851	$ 19,743
Milestones	30,000	125,000
NIAID contract:	576	1,721
Total revenue	$ 75,427	$ 146,464

We recognized revenue of $75.4 million during the nine months ended June 30, 2016, as compared to $146.5 million during the nine months ended June 30, 2015. During the nine months ended June 30, 2016 and 2015, we recognized $30.0 million and $125.0 million, respectively, in milestone payments under our collaboration with AbbVie as a result of regulatory approvals for AbbVie s paritaprevir-containing regimens in Japan and the U.S. and EU, respectively. We earned royalties of $44.9 million and $19.7 million during the nine months ended June 30, 2016 and 2015, respectively. The increase in royalty revenue was driven by an increase in net sales of AbbVie s paritaprevir-containing regimens in 2016 as compared to 2015. Government contract revenue was $0.6 million and $1.7 million during the nine months ended June 30, 2016 and 2015, respectively, based on final payments under our contract with NIAID which ended in fiscal 2015.

Research and development expenses.

	Nine Months Ended June 30,	
	2016	2015
	(in thousands)	
R&D programs:		
Virology	$ 15,049	$ 7,176
Liver disease	13,183	5,694
Other	729	3,270
Total research and development expenses	$ 28,961	$ 16,140

Research and development expenses increased $12.8 million for the nine months ended June 30, 2016 as compared to the same period in 2015. The increase was primarily due to progression of preclinical and clinical activities in our virology and liver disease programs. Increases were driven by an increase in headcount to support our preclinical activities, expansion of our research facility and an increase in external costs for clinical and preclinical activities. These increases were partially offset by a decrease in clinical expenses for our other programs, specifically our contract with NIAID which ended in fiscal 2015.

General and administrative expenses. General and administrative expenses increased by $2.7 million for the nine months ended June 30, 2016 as compared to the same period in 2015. The increase was primarily due to an increase in stock-based compensation expense as a result of an increase in headcount, additional stock option grants to employees, and achievement of performance-based option milestones granted to management.

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

Interest income. The increase in interest income for the nine months ended June 30, 2016 as compared to the same period in 2015 was due to higher average investment balances in the first nine months of 2016 as compared to the same period in 2015.

Change in fair value of warrant liability and Series 1 nonconvertible preferred stock. The credit recorded during nine months ended June 30, 2016 and 2015 was due to a decrease in the fair value of the warrant liability and Series 1 nonconvertible preferred stock as a result of the remeasurement of these instruments from year to year.

Income tax (expense) benefit. For the nine months ended June 30, 2016 and 2015, we recorded an income tax (expense) of $(11.7) million and $(48.1) million, respectively, representing an estimated annual effective tax rate of 33.3% and 39.7%, respectively. For the nine months ended June 30, 2016 our estimated annual effective tax rate was lower than in the comparable period of 2015 primarily due to Congress reinstatement of federal research and development tax credits during the most recent fiscal year which is included in the 2016 annual effective tax rate.

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Liquidity and Capital Resources

At June 30, 2016, our principal sources of liquidity were cash, cash equivalents and short-term and long-term marketable securities totaling $244.7 million.

Since our initial public offering in March 2013, we have financed our operations through contract payments under our collaborations, government research and development contracts and grants, and the net proceeds from our initial public offering of our equity. The following table shows a summary of our cash flows for the nine months ended June 30, 2016 and 2015:

	Nine Months Ended June 30,	
	2016	2015
Cash provided by (used in):		
Operating activities	$ 37,935	$ 79,048
Investing activities	$ (37,516)	$ (92,284)
Financing activities	$ 2,644	$ 2,381

Net cash provided by operating activities

The decrease in cash provided by operating activities of $41.1 million for the nine months ended June 30, 2016 as compared to the same period in 2015 is primarily driven by a decrease in our net income largely as a result of a reduction in cash receipts under our collaboration with AbbVie. We received $75.2 million in cash from AbbVie during the first nine months of fiscal 2016, including royalties and a $30.0 million milestone payment, compared to $133.4 million during the first nine months of fiscal 2015, including royalties and $125.0 in milestone payments from AbbVie. In addition, we increased cash spending on research and development, which was reflected in our net income, during the first nine months of 2016 compared to the same period in 2015 in order to progress clinical development and preclinical research in our proprietary programs. These decreases to cash used in operating activities were partially offset by a decrease of $30.5 million in income tax payments, which is reflected in our income tax expense, based on lower income before tax in 2016 as compared to 2015.

Net cash used in investing activities

The decrease in cash used in investing activities of $54.8 million for the nine months ended June 30, 2016 as compared to the same period in 2015 was driven by timing of purchases and maturities of marketable securities. During the nine months ended June 30, 2016, we utilized $150.5 million of cash to purchase marketable securities, offset by $117.3 million of cash received from the maturity of marketable securities, compared to $155.6 million of cash used to purchase marketable securities, offset by maturities of marketable securities of $62.0 million and sales of marketable securities of $2.2 million in the same comparable period in 2015. During the nine months ended June 30, 2016, we increased our capital asset outlay by $3.6 million compared to 2015 as a result of our expansion of our research facility.

Net cash provided by financing activities

The increase in net cash provided by financing activities of $0.3 million for the nine months ended June 30, 2016 as compared to the same period in 2015 was driven by a decrease in the excess tax benefits from the exercise of stock options of $0.1 million, partially offset by an increase in proceeds from exercises of stock options of $0.4 million.

Funding requirements

As of June 30, 2016, we had $244.7 million in cash, cash equivalents and short-term and long-term marketable securities. We believe that our existing cash, cash equivalents and marketable securities as of June 30, 2016, will be sufficient to meet our anticipated cash requirements for the foreseeable future. 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 significant royalties, to us;

whether we exercise any opt-in right under the AbbVie Agreement regarding any protease inhibitor other than paritaprevir or ABT-493;

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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, paritaprevir, ABT-493 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.

Contractual Obligations and Commitments

In our Annual Report on Form 10-K for the year ended September 30, 2015, Part II, Item 7, Management s Discussion and Analysis of Financial Conditions and Results of Operations, under the heading Contractual Obligations and Commitments , we have described our commitments and contingencies. There were no material changes in our commitments and contingencies during the nine months ended June 30, 2016

Recently Issued Accounting Pronouncements

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Interest Rate Sensitivity

We had cash, cash equivalents and short-term and long-term marketable securities of $244.7 million at June 30, 2016 consisting of cash, money market funds, commercial paper, corporate bonds and government securities. 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 June 30, 2016.

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.

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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.

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PART II OTHER INFORMATION

ITEM 1A. RISK FACTORS
RISK FACTORS

Our business faces significant risks and uncertainties. Certain factors may have a material adverse effect on our business prospects, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the 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 dependent upon the development and commercialization efforts of AbbVie for combination therapies incorporating the protease inhibitors paritaprevir or ABT-493 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 regimens containing paritaprevir or ABT-493 (our second protease inhibitor, in clinical development), 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 paritaprevir or ABT-493. Such success is subject to significant uncertainty, and we have no control over the resources, time and effort that AbbVie may devote to paritaprevir or ABT-493. Any of several events or factors could have a material adverse effect on our ability to generate revenue from AbbVie s commercialization of paritaprevir or potentially ABT-493 in combination therapies. For example, AbbVie:

- may not achieve satisfactory levels of market acceptance and reimbursement by physicians, patients and third-party payers for combination therapies incorporating one of our protease inhibitor product candidates in the various markets of the world where these therapies are being introduced and sold by AbbVie;
- may not compete successfully with its combination therapies against other products and therapies for HCV;
- may have to comply with additional requests and recommendations from the FDA, including label restrictions for paritaprevir or similar restrictions or additional clinical trials for ABT-493;
- may not make all regulatory filings and obtain all necessary approvals from the FDA and similar foreign regulatory agencies, and all commercially necessary reimbursement approvals;

may be unable to complete successfully the clinical development of an ABT-493-containing regimen;

may not commit sufficient resources to the development or regulatory approval of regimens containing ABT-493 or to the marketing and distribution of regimens containing paritaprevir or ABT-493, whether for competitive or 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 protease inhibitor candidates;

may not be able to manufacture paritaprevir or ABT-493 in compliance with requirements of the FDA and similar foreign regulatory agencies and in commercial quantities sufficient to meet market demand; and

may independently develop products that compete with regimens containing paritaprevir or ABT-493 in the treatment of HCV.

We do 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 for any marketed product, regulatory affairs, process development, manufacturing, marketing, sales and other areas known by AbbVie. Thus, our ability to keep our stockholders informed about the status of products and product candidates under our collaboration is 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 further development and global commercialization of paritaprevir and the clinical development, regulatory approval and commercialization efforts related to ABT-493 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, the

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relative values allocated to the pharmaceutically active ingredients, or the ownership of intellectual property developed during the course of our collaboration agreement. If AbbVie acts in a manner that is not in our best interest, then it could adversely affect our business and prospects.

We and AbbVie face substantial competition in the markets for HCV drugs, and there are many companies developing potential therapies for non-alcoholic steatohepatitis (NASH), hepatitis B virus (HBV) and respiratory syncytial virus (RSV), as well as other liver and viral diseases, which may result in others discovering, developing or commercializing products before we do or doing so more successfully than we or 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, NASH, HBV, RSV and other infectious diseases or liver diseases that we may target in the future.

Many of our competitors have substantially greater commercial infrastructure and greater 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 any collaborator of ours does 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 in one or more disease indications, our competitive position could be compromised because it may be more difficult for us to obtain marketing approval for that product candidate and market acceptance of that product candidate as a second competitor. In addition, any new product that competes with an approved product typically must demonstrate compelling advantages in efficacy, convenience, tolerability or safety, or some combination of these factors, in order to overcome price competition and be commercially successful.

We expect our product candidates to face intense and increasing competition as new products continue to enter the HCV and antiviral markets and advanced technologies become available, particularly in the case of HCV in combinations with existing products and other new products. First generation protease inhibitors, Incivek® (telaprevir) of Vertex and Victrelis® (boceprevir) of Merck, were approved in 2011 by the FDA for the treatment of HCV, which in combination with interferon and ribavirin, were the previous standard of care. However, by January 2015 both Vertex and Merck had announced they would discontinue the sale of these products, noting competing treatments and diminishing market demand. The evolving competitive landscape in HCV intensified in December 2013, when the FDA approved sofosbuvir (Sovaldi®), a nucleotide analogue inhibitor of the HCV NS5B polymerase enzyme from Gilead, for patients with genotype 2 or 3 HCV and no requirement for interferon (also approved for patients with genotypes 1 or 4 when combined with pegylated interferon and ribavirin). On July 9, 2014, Bristol-Myers Squibb gained approval in Japan for the NS5A/protease inhibitor combination daclatasvir/asunaprevir. In October 2014 the FDA approved Gilead s interferon-free Harvoni®, a fixed-dose combination of sofosbuvir and ledipasvir (a NS5A inhibitor) for patients with genotype 1 HCV. Also in November 2014 the FDA approved an interferon-free combination therapy of simeprevir (brand name Olysio®, from Janssen Therapeutics) and sofosbuvir for genotype 1 HCV patients. In December 2014, AbbVie s VIEKIRA PAK treatment regimen containing our collaboration s paritaprevir was approved by the FDA, and since then approvals of other paritaprevir-containing regimens and Harvoni followed in the EU and Japan. In July 2015, B