ENANTA PHARMACEUTICALS INC
Form 10-Q
August 10, 2015
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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, 2015

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 July 31, 2015, was 18,713,976 shares.

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ENANTA PHARMACEUTICALS, INC.

FORM 10-Q Quarterly Report

For the Quarterly Period Ended June 30, 2015

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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, 2015	September 30, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 19,844	$ 30,699
Short-term marketable securities	134,442	60,065
Accounts receivable	11,724	1,724
Unbilled receivables	1,376	2,770
Deferred tax assets	1,757	11,123
Prepaid expenses and other current assets	3,497	1,594
Total current assets	172,640	107,975
Property and equipment, net	2,582	1,803
Long-term marketable securities	57,657	41,003
Deferred tax assets	4,287	4,198
Restricted cash	608	436
Total assets	$ 237,774	$ 155,415
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 1,614	$ 1,874
Accrued expenses	3,469	2,872
Income taxes payable	2,229	
Total current liabilities	7,312	4,746
Warrant liability	1,457	1,584
Series 1 nonconvertible preferred stock	185	202
Other long-term liabilities	538	229
Total liabilities	9,492	6,761

Commitments and contingencies (Note 11)		
Stockholders equity:		
Common stock; $0.01 par value; 100,000,000 shares authorized at June 30, 2015 and September 30, 2014; 18,916,750 and 18,803,390 shares issued, and 18,707,934 and 18,594,574 shares outstanding, at June 30, 2015 and September 30, 2014, respectively	189	188
Additional paid-in capital	228,001	221,580
Treasury stock, at par value; 208,816 shares at June 30, 2015 and September 30, 2014	(2)	(2)
Accumulated other comprehensive loss	(74)	(100)
Retained earnings (deficit)	168	(73,012)
Total stockholders equity	228,282	148,654
Total liabilities and stockholders equity	$ 237,774	$ 155,415

The accompanying notes are an integral part of these interim 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,	
	2015	2014	2015	2014
Revenue	$ 11,599	$ 42,051	$ 146,464	$ 45,104
Operating expenses:				
Research and development	6,253	4,553	16,140	13,538
General and administrative	3,643	2,603	9,850	7,255
Total operating expenses	9,896	7,156	25,990	20,793
Income from operations	1,703	34,895	120,474	24,311
Other income (expense):				
Interest income	304	106	660	329
Interest expense	(2)	(5)	(6)	(14)
Change in fair value of warrant liability and Series 1 nonconvertible preferred stock	(15)	(65)	144	(268)
Total other income, net	287	36	798	47
Income before income taxes	1,990	34,931	121,272	24,358
Income tax benefit (expense)	428	15,122	(48,092)	15,122
Net income	$ 2,418	$ 50,053	$ 73,180	$ 39,480
Net income per share:				
Basic	$ 0.13	$ 2.70	$ 3.92	$ 2.16
Diluted	$ 0.13	$ 2.61	$ 3.80	$ 2.06
Weighted average common shares outstanding:				
Basic	18,697,104	18,528,833	18,659,742	18,275,831
Diluted	19,277,966	19,203,270	19,276,767	19,168,368

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

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ENANTA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(unaudited)

(in thousands)

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2015	2014	2015	2014
Net income	$ 2,418	$ 50,053	$ 73,180	$ 39,480
Other comprehensive income (loss):				
Net unrealized gains (losses) on marketable securities, net of tax of $40, $0, $18 and $0	(57)	(65)	26	(2)
Total other comprehensive income (loss)	(57)	(65)	26	(2)
Comprehensive income	$ 2,361	$ 49,988	$ 73,206	$ 39,478

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

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ENANTA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

(in thousands)

	Nine Months Ended June 30,	
	2015	**2014**
Cash flows from operating activities		
Net income	$ 73,180	$ 39,480
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization expense	435	242
Non-cash interest expense	6	14
Change in fair value of warrant liability and Series 1 nonconvertible preferred stock	(144)	268
Stock-based compensation expense	4,041	1,887
Gain on sale of fixed assets	(21)	
Gain on sale of marketable securities	(4)	
Premium on marketable securities	(2,063)	(1,824)
Amortization of premium on marketable securities	1,651	1,636
Deferred income taxes	11,076	(15,228)
Income tax benefit from exercise of stock options	(1,817)	(105)
Changes in operating assets and liabilities:		
Accounts receivable	(10,000)	409
Unbilled receivables	1,394	(1,475)
Prepaid expenses and other current assets	(1,108)	161
Accounts payable	(332)	(190)
Accrued expenses	391	(200)
Income taxes payable	2,229	
Deferred revenue		(10)
Other long-term liabilities	134	46
Net cash provided by operating activities	79,048	25,111
Cash flows from investing activities		
Purchases of property and equipment	(756)	(543)
Increase in restricted cash	(172)	
Purchases of marketable securities	(155,583)	(85,750)
Sales of marketable securities	2,210	7,413
Maturities of marketable securities	62,017	70,164
Net cash used in investing activities	(92,284)	(8,716)

Cash flows from financing activities		
Proceeds from exercise of stock options	564	1,015
Income tax benefit from exercise of stock options	1,817	105
Net cash provided by financing activities	2,381	1,120
Net increase (decrease) in cash and cash equivalents	(10,855)	17,515
Cash and cash equivalents at beginning of period	30,699	8,859
Cash and cash equivalents at end of period	$ 19,844	$ 26,374
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	$ 39,566	$
Non-cash items:		
Fixed assets purchased through capital lease	$ 175	$

The accompanying notes are an integral part of these interim 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 chemistry-driven approach and drug discovery capabilities to create small molecule drugs for the treatment of viral infections and liver diseases. The Company has developed novel protease and NS5A inhibitors for treatment of hepatitis C virus (HCV) infection. The Company also has programs to develop cyclophilin and nucleotide polymerase inhibitors targeted against HCV and also recently announced a new focus area in non-alcoholic steatohepatitis (NASH). Additionally, the Company has programs to discover new chemical entities for the treatment of other diseases.

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 for financial resources to fund research and development activities. 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, 2014 was derived from the 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, 2015 and for the three and nine months ended June 30, 2015 and 2014 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 note 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 fiscal year ended September 30, 2014 included in the Company s Annual Report on Form 10-K for that fiscal year.

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, 2015 and results of operations for the three and nine months ended June 30, 2015 and 2014 and cash flows for the nine months ended June 30, 2015 and 2014 have been made. The results of operations for the three and nine months ended June 30, 2015 are not necessarily indicative of the results of operations that may be expected for subsequent quarters or the year ending September 30, 2015.

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

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, fair value of investments, valuation of warrants, Series 1 nonconvertible preferred stock and stock-based awards; the useful lives of property and equipment; and the accounting for income taxes, including uncertain tax positions. 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 has been 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

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(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 agreements entered into prior to October 1, 2011, the Company evaluated license agreements with multiple deliverables to determine if the deliverable elements could be recognized separately by considering (i) if the delivered elements (typically the license) had standalone value to the customer, (ii) if the fair value of any undelivered elements (typically the research and development services and the steering committee activities) could be determined based on vendor-specific objective evidence (VSOE) or vendor objective evidence (VOE), and (iii) if the arrangement included a general right of return relative to the delivered item, the delivery or performance of the undelivered item was considered probable and substantially within the control of the Company. VSOE of fair value was based on the consistent price of a deliverable when the Company regularly sold it on a standalone basis. Alternatively, VOE was based upon third-party objective evidence of fair value. If the delivered elements had value on a standalone basis and the fair value of the undelivered elements could be determined based on VSOE or VOE, revenues of such elements were then accounted for separately as delivered with arrangement consideration allocated to the delivered elements based on the residual value method. If either (i) the delivered elements were considered to not have standalone value or (ii) VSOE or VOE of fair value for any of the undelivered elements could not be determined, the arrangement was accounted for as a single unit of accounting and all payments received were recognized as revenue over the estimated period of performance of the entire arrangement.

On October 1, 2011, the Company adopted Accounting Standards Update No. 2009-13, *Multiple-Deliverable Revenue Arrangements* (ASU 2009-13). This guidance, which applies to multiple-element arrangements entered into or materially modified on or after October 1, 2011, amends the criteria for separating and allocating consideration in a multiple-element arrangement by modifying the fair value requirements for revenue recognition and eliminating the use of the residual value method. 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 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. The Company elected to adopt ASU 2009-13 prospectively as of October 1, 2011.

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.

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

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performance model as of each reporting period. Alternatively, if the Company cannot make reasonably reliable estimates of 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.

Royalty revenue 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.

During the three and nine months ended June 30, 2015 and 2014, the Company also generated revenue from a government contract, under which the Company is reimbursed 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 expenses in the statements of operations.

Amounts received prior to satisfying all revenue recognition criteria are recorded as deferred revenue in the accompanying consolidated balance sheets. Amounts not expected to be recognized as revenue within the next twelve months of the consolidated 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 Accounting Pronouncements

In May, 2014, the Financial Accounting Standards Board (the FASB) issued Accounting Standard Update (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 July 2015, the FASB decided to delay the effective date of the new revenue standard by one year. The new standard 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.

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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, 2015 and September 30, 2014 and indicate the fair value hierarchy of the valuation inputs utilized to determine such fair value:

	Fair Value Measurements as of June 30, 2015 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market fund	$ 16,472	$	$	$ 16,472
Commercial paper		12,495		12,495
Corporate bonds		144,958		144,958
U.S. Agency bonds		34,646		34,646
	$ 16,472	$ 192,099	$	$ 208,571
Liabilities:				
Warrant liability	$	$	$ 1,457	$ 1,457
Series 1 nonconvertible preferred stock			185	185
	$	$	$ 1,642	$ 1,642

	Fair Value Measurements as of September 30, 2014 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market fund	$ 30,239	$	$	$ 30,239
Commercial paper		7,499		7,499
Corporate bonds		88,056		88,056
U.S. Agency bonds		5,513		5,513
	$ 30,239	$ 101,068	$	$ 131,307
Liabilities:				
Warrant liability	$	$	$ 1,584	$ 1,584
Series 1 nonconvertible preferred stock			202	202
	$	$	$ 1,786	$ 1,786

During the three and nine months ended June 30, 2015 and 2014, there were no transfers between Level 1, Level 2 and Level 3.

As of June 30, 2015 and September 30, 2014, the warrant liability was comprised of the values 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. The fair value of warrants to purchase our Series 1 nonconvertible preferred stock was $1,457 and $1,584, at June 30, 2015 and September 30, 2014, respectively. The fair value of Series 1 nonconvertible preferred stock was $185 and $202 as of June 30, 2015 and September 30, 2014, respectively. Changes in the fair value of the warrant liability and Series 1 nonconvertible preferred stock are recognized in the consolidated statements of operations.

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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	Range (Weighted Average)
Warrant liability and Series 1 nonconvertible preferred stock	Probabilities of payout	0% - 88%
	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, 2014	$ 1,584	$ 202
Decrease in fair value	(127)	(17)
Balance, June 30, 2015	$ 1,457	$ 185

4. Marketable Securities

As of June 30, 2015 and September 30, 2014, the fair value of available-for-sale marketable securities by type of security was as follows:

	June 30, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial paper	$ 12,495	$	$	$ 12,495
Corporate bonds	145,029	47	(118)	144,958
U.S. Agency bonds	34,631	21	(6)	34,646
	$ 192,155	$ 68	$ (124)	$ 192,099

September 30, 2014

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial paper	$ 7,499	$	$	$ 7,499
Corporate bonds	88,156	14	(114)	88,056
U.S. Agency bonds	5,513			5,513
	$ 101,168	$ 14	$ (114)	$ 101,068

As of June 30, 2015, marketable securities consisted of investments that mature within one year, with the exception of certain corporate bonds, which have maturities within two years and an aggregate fair value of $57,657.

As of September 30, 2014, marketable securities consisted of investments that mature within one year, with the exception of certain corporate bonds and U.S. Agency bonds, which have maturities within three years and an aggregate fair value of $41,003.

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5. Accrued Expenses and Other Long-Term Liabilities

Accrued expenses (current) and other long-term liabilities consisted of the following as of June 30, 2015 and September 30, 2014:

	June 30, 2015	September 30, 2014
Accrued expenses:		
Accrued payroll and related expenses	$ 1,165	$ 1,275
Accrued preclinical and clinical expenses	656	493
Accrued vendor manufacturing expenses	733	116
Accrued third-party license fees	198	240
Accrued professional fees	372	436
Accrued other	345	312
	$ 3,469	$ 2,872
Other long-term liabilities:		
Accrued rent expense	$ 265	$ 153
Capital lease liability	175	
Asset retirement obligation	98	76
	$ 538	$ 229

6. Collaboration Agreements

AbbVie Collaboration

On November 27, 2006, the Company entered into a Collaborative Development and License Agreement (the AbbVie Agreement) with Abbott Laboratories to identify, develop and commercialize HCV NS3 and NS3/4A protease inhibitor compounds, including paritaprevir (previously known as ABT-450). The agreement, which was amended in January and December 2009, was assigned by Abbott to AbbVie Inc. on January 1, 2013 in connection with Abbott s transfer of its research-based pharmaceuticals business to AbbVie. The agreement was subsequently amended further in October 2014 and March 2015.

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 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 net sales by AbbVie allocated to the collaboration s protease inhibitors. Under the terms of the agreement, as amended in October 2014, 30% of net sales of a 3-DAA regimen containing paritaprevir will be allocated to paritaprevir, and 45% of net sales of a 2-DAA regimen containing paritaprevir will be allocated to paritaprevir. For ABT-493, 50% of net sales of a 2-DAA regimen containing ABT-493 will be allocated to ABT-493, and 33 ⅓ % of net sales of a 3-DAA regimen containing ABT-493 will be allocated to ABT-493. If there is any active ingredient other than DAA s in any ABT-493-containing regimen sold by AbbVie, there will be a further adjustment to net sales based on the relative value of the non-DAA ingredient.

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 service obligations under the agreement as of June 2011. All milestone payments received after June 2011 are recognized as revenue when the respective milestone is achieved by AbbVie.

Through September 30, 2014, the Company had received upfront license payments, proceeds from a sale of preferred stock, research funding payment, and milestone payments totaling $160,000 from AbbVie.

In December 2014, the Company earned and recognized as revenue a $75,000 milestone amount due from AbbVie as a result of U.S. regulatory approval by the FDA for AbbVie s first treatment regimen containing a collaboration compound. In January 2015, the Company earned and recognized as revenue a $50,000 milestone payment from AbbVie upon commercialization regulatory approval of VIEKIRAX in Europe.

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As a result, during the three and nine months ended June 30, 2015, the Company recognized milestone revenue of $0 and $125,000, respectively. The Company s first product, paritaprevir, was a part of AbbVie s new treatment regimen for HCV approved by the FDA on December 19, 2014. During the three and nine months ended June 30, 2015, the Company recognized royalty revenue of $11,390 and $19,743, respectively.

As of June 30, 2015, the Company was eligible to receive additional milestone payments totaling up to $30,000 upon AbbVie s achievement of commercialization regulatory approval of a paritaprevir-containing regimen in Japan. The Company is also eligible to receive additional milestone payments totaling up to $80,000 upon AbbVie s achievement of similar commercialization regulatory approval milestones in the U.S. and other selected world markets for each additional protease inhibitor commercialized by AbbVie.

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.

On September 30, 2014 the Company entered into an amendment to its 2012 collaboration and license agreement with Novartis to return to the Company full rights to its NS5A inhibitor program, including EDP-239, and to transition the proof-of-concept study to the Company. The Company owes no future payments to Novartis in connection with this transfer except for any unused drug product or ingredients that the Company may choose to buy from Novartis.

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 contract provided for up to $42,700 in potential development funding to the Company over a five-year period. Under this contract NIAID has funded the preclinical and clinical development of a bridged bicyclic antibiotic to be used as a medical countermeasure against multiple biodefense Category A and B bacteria.

In December 2014, the company communicated to NIAID its strategic decision not to continue commercial development of the antibiotic candidate for non-biodefense indications. In February 2015, NIAID and the Company amended the contract to decrease the total committed funding to $21,000, of which the Company has received $18,268 through June 30, 2015. The contract is expected to be completed in August 2015 upon the Company s delivery of the study report for the Phase 1 clinical study.

The Company recognizes revenue under this contract as development services are performed in accordance with its terms. During the three months ended June 30, 2015 and 2014, revenue of $209 and $2,051, respectively, was recognized under this contract. During the nine months ended June 30, 2015 and 2014, the Company recognized revenue of $1,721 and $5,104, respectively.

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) in the consolidated statement of operations. On February 5, 2014, 225,408 warrants were exercised resulting in the net issuance of 223,153 shares of Series 1 nonconvertible preferred stock. As of June 30, 2015 and September 30, 2014, the total fair value of the Series 1 nonconvertible preferred stock was $185 and $202, respectively. As of June 30, 2015 and September 30, 2014, the total fair value of the Series 1 nonconvertible preferred stock warrants was $1,457 and $1,584, respectively.

8. Stock-Based Awards

2012 Equity Incentive Plan

The Company s 2012 Equity Incentive Plan (the 2012 Plan) permits 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, 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 number of shares of common stock that may be issued under the 2012 Plan is subject to increase by the number of

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shares forfeited under any options terminated and not exercised under the 2012 Plan or the previous plan, known as the 1995 Equity Incentive Plan, as well as by a number of additional shares automatically on the first day of each fiscal year equal to the lowest amount among the following: (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) a lower amount determined by the board of directors. On October 1, 2014, the number of shares of common stock that may be issued under the 2012 Plan was increased by 557,863. As of June 30, 2015, 455,136 shares remained available for future grant.

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. To date the Company lacks sufficient company-specific historical volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a selected group of 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 June 30,		Nine Months Ended June 30,	
	2015	2014	2015	2014
Risk-free interest rate	1.84%	1.93%	1.85%	1.89%
Expected term (in years)	6.10	6.10	6.03	6.06
Expected volatility	70%	76%	74%	75%
Expected dividend yield	0%	0%	0%	0%

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 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. The Company bases fair value of its common stock on the quoted market price.

The following table summarizes stock option activity during the nine months ended June 30, 2015:

	Shares Issuable Under Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value

Outstanding as of September 30, 2014	1,389,437	$ 15.39	7.2	$ 33,573
Granted	513,355	42.33		
Exercised	(113,360)	4.88		
Expired	(39,485)	32.47		
Outstanding as of June 30, 2015	1,749,947	$ 23.59	7.4	$ 37,517
Options vested and expected to vest as of June 30, 2015	1,566,662	$ 24.22	7.4	$ 32,250
Options exercisable as of June 30, 2015	794,816	$ 13.17	5.7	$ 25,288

In March 2013, the Company granted certain executives a total of 167,052 options that vest upon the achievement of certain performance-based targets. The grant date fair value of these options was $2,479. During the three and nine months ended June 30, 2015, the Company recorded no compensation expense related to these options as none of the remaining performance-based targets were considered probable of being achieved during these periods. During the nine months ended June 30, 2014, one performance-based target was achieved and the Company recorded compensation expense of $206 related to that target.

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Market and Performance-based Stock Unit Awards

In February 2015, the Company awarded certain executive officers a total of 41,800 share units consisting of 20,900 performance share units, or PSUs, and 20,900 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, 2016. The aggregate grant date fair value of the 20,900 PSUs ranges between $0 and $1,501. During the three months ended June 30, 2015, the Company recorded no compensation expense related to the PSU awards as none of the performance-based targets were 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 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 grant-date fair value of the rTSRUs was $554. The table below sets forth the assumptions used to value the awards and the estimated grant-date fair value:

Risk-free interest rate	0.61%
Dividend yield	0%
Expected volatility	55.66%
Remaining performance period (years)	1.86
Estimated fair value per share of rTSRUs granted	$ 26.51

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.

Stock-Based Award Expense

The Company recorded stock-based compensation expense for the three and nine months ended June 30, 2015 and 2014 in the following expense categories:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2015	2014	2015	2014
Research and development	$ 468	$ 196	$ 1,106	$ 562
General and administrative	1,116	580	2,935	1,325
	$ 1,584	$ 776	$ 4,041	$ 1,887

As of June 30, 2015, the Company had an aggregate of $19,557 of unrecognized stock-based compensation cost, which is expected to be recognized over a weighted average period of 3.0 years.

Employee Stock Purchase Plan

Under the Employee Stock Purchase Plan (the ESPP), a total of 185,614 shares of common stock were reserved for issuance. As of June 30, 2015, the Company has not commenced any offering under the ESPP and no shares have been issued.

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9. Net Income Per Share

Basic and diluted net income per share attributable to common stockholders was calculated as follows for the three and nine months ended June 30, 2015 and 2014:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2015	2014	2015	2014
Basic net income per share:				
Numerator:				
Net income	$ 2,418	$ 50,053	$ 73,180	$ 39,480
Denominator:				
Weighted average common shares outstanding basic	18,697,104	18,528,833	18,659,742	18,275,831
Net income per share basic	$ 0.13	$ 2.70	$ 3.92	$ 2.16
Diluted net income per share:				
Numerator:				
Net income	$ 2,418	$ 50,053	$ 73,180	$ 39,480
Denominator:				
Weighted average common shares outstanding basic	18,697,104	18,528,833	18,659,742	18,275,831
Dilutive effect of common stock equivalents	580,862	674,437	617,025	892,537
Weighted average common shares outstanding diluted	19,277,966	19,203,270	19,276,767	19,168,368
Net income per share diluted	$ 0.13	$ 2.61	$ 3.80	$ 2.06

Stock options for the purchase of 700,679 and 433,535 weighted average shares were excluded from the computation of diluted net income per share for the three months ended June 30, 2015 and 2014, respectively, because those options had an anti-dilutive impact due to either the net loss attributable to common stockholders incurred for the period or 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 559,384 and 300,428 weighted average shares were excluded from the computation of diluted net income per share for the nine months ended June 30, 2015 and 2014, respectively, because those options had an anti-dilutive impact due to either the net loss attributable to common stockholders incurred for the period or 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.

10. Income Taxes

For the three months ended June 30, 2015 and 2014, the Company recorded income tax benefits of $428 and $15,122, respectively. The income tax benefit for the three months ended June 30, 2015 was attributable to research and development credits offset by federal and state taxes on the earnings of the Company s operations, all of which are domestic. During the quarter ended June 30, 2015, the Company performed a research and development tax credit study and recognized the incremental benefit upon its completion in June 2015. During the three months ended June 30, 2015, the gross deferred tax assets increased by $726 primarily as a result of the research and development credits recognized during the period. During the three months ended June 30, 2014, the net income tax benefit resulted in an increase in the gross deferred tax assets of $15,228 due to the release by the Company of a valuation allowance against its deferred tax assets.

For the nine months ended June 30, 2015 and 2014, the Company recorded an income tax provision of $48,092 and a tax benefit of $15,122, respectively. During the nine months ended June 30, 2015, the gross deferred tax assets decreased by $9,277 primarily as a result of the utilization of net operating loss carryforwards to offset income before income taxes generated during the period. No provision for income tax was recorded for the nine months ended June 30, 2014, as the Company used net operating loss carryforwards to offset its income before income taxes. The net income tax benefit during the 2014 period was due to the Company s release of its valuation allowance against its deferred tax assets during the period.

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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 2007 to the present. Earlier years may be examined to the extent that tax credit or net operating loss carryforwards are used in future periods.

The Company recognizes and measures uncertain tax positions using a two-step approach. The first step is to evaluate the tax position for recognition by determining if, based on the technical merits, it is more likely than not that the position will be sustained upon audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit at the largest amount that is more than 50% likely of being realized upon ultimate settlement. The Company reevaluates these uncertain tax positions on a quarterly basis. This evaluation is based on factors including, but not limited to, changes in facts or circumstances, changes in tax laws, effectively settled issues under audit and new audit activity. Any changes in these factors could result in the recognition of a tax benefit or an additional charge to the tax provision. When applicable, the Company accrues for the effects of uncertain tax positions and the related potential penalties and interest through income tax expense.

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. As of June 30, 2015, the Company had unrecognized tax benefits of $0.1 million. As of September 30, 2014, the Company had no unrecognized tax benefits.

11. Commitments and Contingencies

Leases

In March 2015 the Company amended its lease for office and laboratory space to expand the rented space and extend the lease term beginning in the fourth fiscal quarter of 2015. As amended, the lease 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 $341 and $237 for the three months ended June 30, 2015 and 2014, respectively, and $821 and $711 for the nine months ended June 30, 2015 and 2014, respectively.

Future minimum lease payments for operating leases as of June 30, 2015 are as follows:

Year ending September 30,	
2015	$ 382
2016	1,958
2017	2,010
2018	2,062
2019	2,117
Thereafter	6,494
Total	$ 15,023

In connection with the amended lease, the Company has outstanding a $608 and $436 letter of credit, collateralized by a money market account, as of June 30, 2015 and September 30, 2014, respectively. The Company classified such amounts as restricted cash.

Additionally the amended lease included approximately $600 in a tenant improvement allowance from the landlord, which allowance will be 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 $200 in fiscal 2015 and (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.

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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, 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 made and such expenditures can be reasonably estimated.

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, 2014 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 its robust chemistry-driven approach and drug discovery capabilities to create small molecule drugs for the treatment of viral infections and liver diseases. Through our collaboration with AbbVie (formerly Abbott Laboratories), we have discovered protease inhibitors designed for use against the hepatitis C virus, referred to as HCV, including:

- Paritaprevir, the protease inhibitor contained in AbbVie s all-oral, interferon-free VIEKIRA PAK HCV treatment regimen, which was approved and first sold in the U.S. in December 2014 for genotype 1 HCV. VIEKIRAX , another paritaprevir-containing HCV treatment, was approved in the EU in January 2015.

ABT-493, our next-generation protease inhibitor, which is being developed by AbbVie in combination with its next-generation NS5A inhibitor, ABT-530, as a pan-genotypic, once daily oral treatment regimen for HCV. This combination of two direct-acting antivirals, or DAAs, is completing Phase 2 clinical trials in 2015. AbbVie plans to initiate Phase 3 trials before the end of 2015 and has a target date for approval in the U.S. in 2017.

In our fiscal 2015 through June 30, 2015, we have received $125 million in milestone payments for paritaprevir, and earned $20 million in royalties. We have $212 million in cash and marketable securities at June 30, 2015. With these resources, we are continuing to invest in research into inhibitors that attack other mechanisms necessary for replication and survival of HCV, particularly mechanisms such as cyclophilin inhibitors and nucleotide polymerase inhibitors that we expect will have high barriers to resistance and may be able to overcome emerging HCV resistance to the current approved therapies.

The reported worldwide sales of the new oral therapies for HCV totaled approximately $15 billion in 2014. We believe that aggregate annual worldwide sales of HCV therapies could increase during the next few years, and that the share of those sales represented by VIEKIRA PAK and other paritaprevir-containing regimens should increase our royalties as AbbVie s HCV regimens continue to be introduced in more markets and for treatment of other HCV subpopulations.

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We are also using our financial resources to build our internal research capabilities to advance several early stage programs to discover new chemical entities for the treatment of other diseases with significant unmet medical need, including our recently announced new focus area in non-alcoholic steatohepatitis, or NASH. We have utilized our internal chemistry and drug discovery capabilities and our collaborations to generate all of our development-stage programs, and we have active research efforts to broaden our drug pipeline. Our internal and external research expenses are increasing, as we expand our research effort.

The following table summarizes our product development pipeline in HCV antivirals and liver disease:

Our HCV portfolio includes inhibitors of four fundamental, validated HCV targets. Our first product, paritaprevir, previously known as ABT-450, is a protease inhibitor that was discovered through our collaboration with AbbVie. During the nine months ended June 30, 2015, we earned and recognized as revenue milestone payments from AbbVie totaling $125.0 million as a result of regulatory approvals in the U.S. and EU for the first regimens containing paritaprevir. On July 24, 2015 the FDA approved a paritaprevir-containing regimen for genotype 4 HCV patients. Additional regulatory reviews for paritaprevir-containing regimens are ongoing, including a priority review in Japan for a ribavirin-free regimen for genotype 1 HCV patients in that country. To date 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 paritaprevir, ABT-493 and any other follow-on products worldwide.

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Our independent HCV research activities are focused on our cyclophilin inhibitor program, which is in preclinical development, as well as our NS5A inhibitor assets and our small-molecule drug discovery effort underway for nucleotide polymerase inhibitors. We are currently funding all research and development for our cyclophilin inhibitor, NS5A inhibitor and nucleotide polymerase inhibitor programs. We have prioritized our cyclophilin and nucleotide polymerase inhibitor-driven programs because we believe that high-barrier-to-resistance mechanisms are going to be increasingly important for the treatment of HCV patients, including those who have failed on current DAA therapies. We expect to incur substantially greater expenses if we advance any of these programs into clinical development.

In addition to our HCV and NASH programs, we used our internal research capabilities to discover a new class of antibiotics called Bicyclolides, which we were developing for the treatment of multi-drug resistant bacteria. For the periods included in this report this program has been funded under a September 2011 contract 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 develop our lead bicyclolide for biodefense purposes. After we communicated to NIAID our strategic decision to discontinue commercial development of this antibiotic candidate for non-biodefense indications, we and NIAID amended our contract in February 2015 to change its completion date to August 2015 upon our delivery of the study report for our Phase 1 study. Accordingly we do not expect to earn any significant additional revenue under this contract.

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. For the periods included in this report we have funded our operations primarily through payments received under our collaborations and a 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.

As of June 30, 2015, we had $211.9 million in cash, cash equivalents and short-term and long-term marketable securities.

Our revenue from our collaboration agreements has resulted in our reporting net income in each of our past five fiscal years and in the nine months ended June 30, 2015. We expect that our revenue in the near term will continue to be dependent on our collaboration with AbbVie, including its commercialization of paritaprevir-containing regimens and its continued advancement of the related development programs for paritaprevir and ABT-493. 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 AbbVie s regimen, we cannot be certain as to the extent of royalty payments related to paritaprevir or when or whether we will receive further milestone payments under this collaboration or whether we will report continuing net income in future years.

Financial Operations Overview

Revenue

For the periods included in this report, our revenue has been derived from two primary sources: collaboration agreements with pharmaceutical companies and one government research and development contract. For the nine months ended June 30, 2015, we generated royalty revenue from AbbVie s net sales allocable to paritaprevir, which is part of AbbVie s new treatment regimens for HCV launched in the United States after its approval by the FDA in December 2014 and the EMA in January 2015. We have entered into three significant collaboration agreements since 2006 when we entered into our collaboration agreement with AbbVie. Our second collaboration was with Novartis, from February 2012 through September 2014, and since September 2011, we have had a contract with NIAID, which has funded the preclinical and early clinical development of our bicyclolide antibiotic product candidate since that

time.

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The following table is a summary of revenue recognized from our collaboration agreements and government contract for the three and nine months ended June 30, 2015 and 2014:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2015	2014	2015	2014
	(in thousands)			
AbbVie agreement:				
Milestone payments	$	$ 40,000	$ 125,000	$ 40,000
Royalties	11,390		19,743	
NIAID contract	209	2,051	1,721	5,104
Total revenue	$ 11,599	$ 42,051	$ 146,464	$ 45,104

AbbVie Agreement

Each milestone payment received after we concluded our research obligations under the AbbVie agreement in June 30, 2011 has been recognized as revenue upon achievement of the milestone by AbbVie. During the year ended September 30, 2014, we earned and recognized as revenue a total of $40.0 million in milestone payments as a result of U.S. and EU regulatory filings by AbbVie for the first protease inhibitor product resulting from our collaboration with AbbVie. During the nine months ended June 30, 2015, we earned and recognized as revenue a total of $125.0 million of milestone payments related to AbbVie s U.S. and EU regulatory approvals of combination treatment regimens containing paritaprevir. Under the terms of the AbbVie agreement, we are eligible to receive an additional future milestone payment of $30.0 million if AbbVie achieves commercialization regulatory approval in Japan of the first HCV treatment regimen incorporating one of our collaboration s protease inhibitors. We expect to earn this payment in the quarter ending December 31, 2016. We are also eligible to receive annually tiered, double-digit royalties per product on AbbVie s net sales, if any, 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 a 3-DAA regimen containing paritaprevir and 45% of net sales of a 2-DAA regimen containing paritaprevir will be allocated to paritaprevir. For ABT-493, 50% of net sales of a 2-DAA regimen containing ABT-493 and 33 ⅓% of net sales of a 3-DAA regimen containing ABT-493 will be allocated to ABT-493. If there is any active ingredient other than DAA s in any ABT-493-containing regimen sold by AbbVie, there will be a further adjustment to net sales based on the relative value of the non-DAA ingredient.

NIAID Contract

In December 2014, we communicated to NIAID our strategic decision not to continue commercial development of the antibiotic candidate for non-biodefense indications. In February 2015 we and NIAID amended our contract to decrease the total committed funding to a total of $21.0 million, of which we have received $18.3 million through June 30, 2015. We expect the contract to be completed in August 2015 upon our delivery of the study report for the Phase 1 clinical study.

We recognize revenue under this contract as research and development services are performed. We recognized revenue of $0.2 million and $2.1 million under this contract during the three months ended June 30, 2015 and 2014, respectively, and $1.7 million and $5.1 million during the nine months ended June 30, 2015 and 2014, respectively.

Operating Expenses

The following table summarizes our operating expenses for the three and nine months ended June 30, 2015 and 2014:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2015	2014	2015	2014
	(in thousands)			
Research and development	$ 6,253	$ 4,553	$ 16,140	$ 13,538
General and administrative	3,641	2,603	9,848	7,255
Total operating expenses	$ 9,894	$ 7,156	$ 25,988	$ 20,793

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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 research and development efforts in HCV, NASH and other areas.

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, 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, and professional fees for auditing, tax and legal services, including legal expenses to pursue patent protection of our intellectual property.

Other Income (Expense)

Interest income. Interest income consists of interest earned on our cash equivalents and marketable securities balances.

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 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).

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Income Tax Expense

Income tax expense is based on our best estimate of applicable rates applied to pre-tax profit reported during the 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 assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions and conditions. See also Note 2 to our consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the fiscal year ended September 30, 2014 (referred to as our 2014 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

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, 2014. For further information, please see the discussion of critical accounting policies included in our Form 10-K.

Results of Operations

Comparison of Three Months Ended June 30, 2015 and 2014

	Three Months Ended June 30,	
	2015	**2014**

		(in thousands)
Revenue	$ 11,599	$ 42,051
Research and development expenses	6,253	4,553
General and administrative expenses	3,641	2,603
Other income (expense):		
Interest income	304	106
Interest expense	(2)	(5)
Change in fair value of warrant liability and Series 1 preferred stock	(17)	(65)
Income tax benefit	428	15,122

Revenue.

	Three Months Ended June 30,	
	2015	2014
	(in thousands)	
AbbVie agreement:		
Milestone payments	$	$ 40,000
Royalties	11,390	
NIAID contract	209	2,051
Total revenue	$ 11,599	$ 42,051

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We recognized revenue of $11.6 million during the three months ended June 30, 2015, as compared to $42.1 million during the three months ended June 30, 2014. In December 2014, the FDA approved AbbVie s new treatment regimen for HCV, containing our first product paritaprevir. During the three months ended June 30, 2015, revenue primarily consisted of royalties of $11.4 million on the portion of AbbVie s net sales of its HCV treatment regimen allocable to paritaprevir. During the three month ended June 30, 2014, we received and recognized as revenue a total of $40.0 million in milestone payments from AbbVie as a result of its U.S. and European Union regulatory filings for the first regimen containing a collaboration compound. During the three months ended June 30, 2015, revenue related to our performance of services under our contract with NIAID was $0.2 million, compared to $2.1 million in the comparable quarter in 2014. The decrease in revenue from NIAID was due to our nearing completion of the contract, which we expect to complete in August 2015.

Research and development expenses.

	Three Months Ended June 30,	
	2015	2014
	(in thousands)	
Development programs:		
Antibiotic	$ 157	$ 1,468
Research and drug discovery	6,096	3,085
Total research and development expenses	$ 6,253	$ 4,553

Research and development expenses were $6.3 million in the three months ended June 30, 2015, as compared to $4.6 million for the same period in 2014. The $1.7 million increase was due primarily to a $3.0 million increase in expenses related to our early stage drug discovery programs, partially offset by a decrease in our NIAID antibiotic program of $1.3 million. We incurred increased research expenses in the second quarter of fiscal 2015 as compared to the 2014 quarter in our early stage drug discovery programs due to an increase in internal spending related to these programs, primarily due to increased headcount related to these programs.

General and administrative expenses. General and administrative expenses increased by $1.0 million from $2.6 million in the three months ended June 30, 2014 to $3.6 million for the same period in 2015. The increase was primarily due to increased stock-based compensation expense related to additional employee stock options and a higher value of our common stock, as well as additional expense to support our expanding operations.

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

Interest income. The increase in interest income for the three months ended June 30, 2015, as compared to the three months ended June 30, 2014, was due to higher average investment balances in the third fiscal quarter of 2015 as compared to 2014 primarily due to the receipt of a total of $125.0 million of milestone payments from AbbVie in the second fiscal quarter of 2015.

Change in fair value of warrant liability and Series 1 nonconvertible preferred stock. During the three months ended June 30, 2015, we recorded an immaterial expense due to an increase in the fair value of our warrant liability and Series 1 nonconvertible preferred stock as a result of the remeasurement of our warrant liability and Series 1 nonconvertible preferred stock.

Income tax benefit (expense). For the three months ended June 30, 2015 and 2014, we recorded an income tax benefit of $0.4 million and $15.1 million, respectively. The income tax benefit for the three months ended June 30, 2015 was primarily attributable to the research and development credits recognized during the period. During the quarter ended June 30, 2015, we performed a research and development tax credit study and recognized the incremental benefit upon completion in June 2015. During the three months ended June 30, 2015, the gross deferred tax assets increased by $0.7 million primarily as a result of the research and development credits recorded during the period. For the three months ended June 30, 2014, we used net operating loss carryforwards to offset our income before income taxes. The net income tax benefit during the 2014 period was due to our release of our valuation allowance which we maintained against our deferred tax assets.

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Comparison of Nine Months Ended June 30, 2015 and 2014

	Nine Months Ended June 30,	
	2015	2014
	(in thousands)	
Revenue	$ 146,464	$ 45,104
Research and development expenses	16,140	13,538
General and administrative expenses	9,848	7,255
Other income (expense):		
Interest income	660	329
Interest expense	(6)	(14)
Change in fair value of warrant liability and Series 1 preferred stock	142	(268)
Income tax benefit (expense)	(48,092)	15,122

Revenue.

	Nine Months Ended June 30,	
	2015	2014
	(in thousands)	
AbbVie agreement:		
Milestone payments	$ 125,000	$ 40,000
Royalties	19,743	
NIAID contract	1,721	5,104
Total revenue	$ 146,464	$ 45,104

We recognized revenue of $146.5 million during the nine months ended June 30, 2015, as compared to $45.1 million during the nine months ended June 30, 2014. During the nine months ended June 30, 2015, we earned and recognized as revenue $125.0 million in milestone payments under our collaboration with AbbVie as a result of U.S. and EU regulatory approvals for AbbVie s paritaprevir-containing regimens, as well as royalties of $19.7 million on the portion of AbbVie s net sales of its HCV treatment regimen allocable to paritaprevir. During the nine months ended June 30, 2014, we received and recognized as revenue a total of $40.0 million in milestone payments from AbbVie as a result of its U.S. and European Union regulatory filings for the first regimen containing a collaboration compound. Our government contract revenue was $1.7 million and $5.1 million during the nine months ended June 30, 2015 and 2014, respectively, under our contract with NIAID. The decrease in revenue from NIAID was due to our nearing completion of the contract which is expected in August 2015.

Research and development expenses.

	Nine Months Ended June 30,	
	2015	2014
	(in thousands)	
Development programs:		
Antibiotic	$ 1,291	$ 3,842
Research and drug discovery	14,849	9,696
Total research and development expenses	$ 16,140	$ 13,538

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Research and development expenses were $16.1 million in the nine months ended June 30, 2015, as compared to $13.5 million for the same period in 2014. The increase of $2.6 million from 2014 to 2015 was due primarily to a $5.2 million increase in preclinical expenses for our early stage drug discovery programs partially offset by a decrease of $2.5 million in our expenses for our NIAID program. We incurred increased research expenses in our early stage drug discovery programs due to an increase in internal spending related to these programs primarily due to increased headcount related to these programs.

General and administrative expenses. General and administrative expenses were $9.8 million during the nine months ended June 30, 2015 and $7.3 million during the nine months ended June 30, 2014. The increase of $2.5 million during the nine months ended June 30, 2015 was related primarily to an increase in stock-based compensation expense related to amortization of additional stock option grants to employees and a higher Black-Scholes value for these options granted in the later period due to the higher value of our common stock, as well as to an increase in insurance expense and additional expense to support our expanding operations.

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

Interest income. The increase in interest income for the nine months ended June 30, 2015, as compared to the nine months ended June 30, 2014, was due to higher average investment balances in the third fiscal quarter of 2015 as compared to 2014 primarily due to the receipt of $125.0 million in milestone payments from AbbVie in the second fiscal quarter of 2015.

Change in fair value of warrant liability and Series 1 nonconvertible preferred stock. We account for our outstanding warrants for our Series 1 nonconvertible 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 nine months ended June 30, 2014, we recorded income due to a decrease in the fair value of our warrant liability during the nine months ended June 30, 2014 as a result of the remeasurement of the fair value of warrants for Series 1 nonconvertible preferred stock. During the nine months ended June 30, 2015 we recorded an expense of $0.2 million due to an increase in the fair value of our warrant liability and Series 1 nonconvertible preferred stock. In February 2014, 225,408 warrants were exercised resulting in net issuance of 223,153 shares of Series 1 nonconvertible preferred stock.

Income tax benefit (expense). For the nine months ended June 30, 2015, we recorded an income tax provision of $48.1 million and income tax benefit of $15.1 million in the 2014 period. The income tax provision for the nine months ended June 30, 2015 was primarily attributable to the tax provision on the earnings of our operations, all of which are domestic. During the nine months ended June 30, 2015, we performed a research and development tax credit study and recognized the incremental benefit upon completion in June 2015. During the nine months ended June 30, 2015, the gross deferred tax assets decreased by $9.3 million primarily as a result of their utilization against tax liability on income before income taxes generated during the period. For the nine months ended June 30, 2014, we used net operating loss carryforwards to offset our income before income taxes. The net income tax benefit during the 2014 period was due to our release of our valuation allowance which we had previously maintained against our deferred tax assets.

Liquidity and Capital Resources

At June 30, 2015, our principal sources of liquidity were cash, cash equivalents and marketable securities totaling $211.9 million.

During the nine months ended June 30, 2015, we generated $79.0 million in cash from our operating activities. The following table shows a summary of our cash flows for the nine months ended June 30, 2015 and 2014.

	Nine Months Ended June 30,	
	2015	2014
	(in thousands)	
Cash provided by (used in):		
Operating activities	$ 79,048	$ 25,111
Investing activities	$ (92,284)	$ (8,716)
Financing activities	$ 2,381	$ 1,120

Net cash provided by operating activities

During the nine months ended June 30, 2015, operating activities provided $79.0 million of cash. Cash provided by operating activities primarily resulted from our net income of $73.3 million and net non-cash charges of $13.2 million, partially offset by the net

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change in operating assets and liabilities of $7.3 million. Our net income in the period was primarily due to normal operating expenses and revenue consisting of $125.0 million in milestone payments received and $19.7 million in royalties from AbbVie and $1.7 million of reimbursement under our NIAID contract. Our net non-cash charges in the period primarily consisted of change in deferred tax assets of $11.1 million, $4.0 million of stock-based compensation expense and $1.7 million related to amortization of the premium on our marketable securities, which were partially offset by $1.8 million income tax benefit from exercise of stock options and premium on marketable securities of $2.1 million. The $8.6 million increase in accounts receivable and unbilled receivables was due to timing of our billings under the NIAID contract and royalty payments from AbbVie. The $2.2 million increase in accrued taxes payable is a result of the current tax provision on pretax income during the period offset by the use of deferred tax assets.

During the nine months ended June 30, 2014, operating activities provided $25.1 million of cash primarily due to our net income of $39.5 million partially reduced by non-cash items of $13.0 million and changes in our operating assets and liabilities of $1.3 million. Our net income in the period was primarily due to the milestone payments we earned and received during the third quarter of fiscal 2014. Non-cash items affecting income from operations during the nine months ended June 30, 2014 consisted primarily of benefit from deferred income taxes of $15.2 million and premium on marketable securities of $1.8 million, partially offset by stock-based compensation of $1.9 million and amortization of premium on marketable securities of $1.6 million, depreciation expense of $0.2 million and change in fair value of warrant and preferred stock liability of $0.3 million. The changes in our operating assets and liabilities resulted from in an increase in accounts receivable and unbilled receivables of $1.1 million, decrease in prepaid expenses of $0.2 million and decrease in accounts payable and accrued expenses of $0.4 million.

Net cash used in investing activities

During the nine months ended June 30, 2015, net cash used in investing activities was $92.3 million. Net cash used in investing activities during the period consisted primarily of $155.6 million used to purchase marketable securities offset by cash received from sales of marketable securities of $2.2 million and from maturities of marketable securities of $62.0 million.

During the nine months ended June 30, 2014, net cash used in investing activities was $8.7 million. Net cash used in investing activities during the period consisted primarily of $85.8 million of cash used for purchases of marketable securities, partially offset by $70.2 million of maturities and $7.4 million of sales of marketable securities.

Net cash provided by financing activities

Net cash provided by financing activities during the nine months ended June 30, 2015 was $2.4 million and consisted of income tax benefit from exercise of stock options of $1.8 million and proceeds from exercise of stock options of $0.6 million.

Net cash provided by financing activities during the nine months ended June 30, 2014 consisted of proceeds received from the exercise of stock options of $1.0 million and income tax benefit from the exercise of stock options of $0.1 million.

Funding requirements

As of June 30, 2015, we had $211.9 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, 2015, will be sufficient to meet our anticipated cash requirements for the forseeable 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:

- 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;
- whether we in-license or otherwise acquire additional assets for development;
- whether our existing collaboration generates significant royalties and potential milestone payments to us;
- the timing of, and the costs involved in, obtaining regulatory approvals for any future product candidates we develop independently;

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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, 2014, 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, 2015 except for those related to our amended lease agreement as disclosed in Note 11 to our consolidated financial statements included in this Quarterly Report on Form 10-Q.

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Future minimum lease payments for operating leases as of June 30, 2015 are as follows:

Year ending September 30,	
2015	$ 382
2016	1,958
2017	2,010
2018	2,062
2019	2,117
Thereafter	6,494
Total	$ 15,023

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 July 2015, the FASB decided to delay the effective date of the new revenue standard by one year. The new standard will be effective for us October 1, 2018. We are currently evaluating the potential impact that Topic 606 may have on our financial position and results of operations.

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 $211.9 million at June 30, 2015, which consisted 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, 2015.

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.

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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 paritaprevir, ABT-493 (our next-generation protease inhibitor in clinical development) and any other protease inhibitors we discover, 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 potential commercialization of paritaprevir or 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 any such combination therapies against alternative products and therapies for HCV;
- may have to comply with additional requests and recommendations from the FDA, including additional clinical trials for paritaprevir or ABT-493;
- may not make all regulatory filings and obtain all necessary approvals from the FDA and similar foreign regulatory agencies, and all necessary reimbursement approvals;

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

may not commit sufficient resources to the development or regulatory approval of 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 our product candidates 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 our products or product candidate 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 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 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

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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 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), as well as other liver and viral diseases, which may result in others discovering, developing or commercializing products before ours 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 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, some combination of these factors, in order to overcome price competition and to be commercially successful.

We expect our current and future product candidates to face intense and increasing competition as new products 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 in combination with interferon and ribavirin, which in combination 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. A third protease inhibitor, simeprevir (Olysio) from Janssen Therapeutics, was approved by the FDA in November 2013 for use in genotype 1 HCV patients only when used in combination with pegylated interferon and ribavirin. 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 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 and sofusbuvir for genotype 1 HCV patients. In December 2014, AbbVie s Viekira Pak treatment regimen containing our collaboration s paritaprevir was approved by the FDA. Other all-oral, next-generation treatment regimens are under development and may obtain regulatory approvals in other settings for the treatment of HCV. These other potential new treatment regimens may render AbbVie s treatment regimens containing any of our HCV product candidates noncompetitive. In particular, regimens containing our HCV product

candidates may not be able to compete successfully with other products and regimens in development involving multiple classes of inhibitors of HCV, including protease inhibitors, polymerase inhibitors (nucleoside and non-nucleoside), NS5A inhibitors, and others, under development by companies such as Achillion, Bristol-Myers Squibb, Gilead, Johnson & Johnson, Medivir, Merck, Regulus and Roche, as well as by our collaborator AbbVie.

Competitive products in the form of other treatment methods or a vaccine for HCV 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 agreement with AbbVie face competition from generic products, the collaboration agreement provides 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 collaborator 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.

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Though there is currently no approved treatment for NASH, we expect significant competition from other companies in the development of new treatments for NASH and related conditions. We are aware of several companies with programs that are significantly more advanced than ours, including companies with compounds in Phase 2 or later stage clinical trials for NASH or related conditions. These companies include Alberio, Conatus, Galectin, Galmed, Genfit, Gilead, GSK, Intercept, NGM, Novo Nordisk, Raptor, Tobira and Shire. A significant number of other companies are conducting earlier clinical trials that may be applicable in NASH and other cholestatic diseases, including AstraZeneca, Boehringer Ingelheim, Cymabay, Durect, Islet, Medicnova, Nimbus, and Viking, and there are additional companies conducting preclinical studies in these disease areas.

If we are not able to develop new products that can 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 not developed independently any approved products and we have limited 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 paritaprevir and ABT-493 protease inhibitor product candidates. We have not yet demonstrated an ability to successfully address 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 any combinations of any of our cyclophilin inhibitors, NS5A inhibitors and nucleotide polymerase inhibitors for HCV, as well as for any of our research programs beyond HCV, we will need to successfully:

- execute clinical development of our future product candidates and demonstrate acceptable safety and efficacy for them alone and, at least in the case of HCV, in combination with other drugs or drug 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;
- obtain and maintain patent protection for our product candidates and freedom from infringement of intellectual property of others;
- establish acceptable commercial manufacturing arrangements with third-party manufacturers;
- 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 among physicians, payers and patients; 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.

If we are not successful in discovering further product candidates in addition to paritaprevir and ABT-493, our ability to expand our business and achieve our strategic objectives will be impaired.

Most of our internal research programs are at preclinical stages. 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 less commercially viable or obsolete;

competitors may obtain intellectual property protection that effectively prevents us from developing a potential product candidate;

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.

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Additional drug candidates that we may develop will require significant research, preclinical and clinical studies, regulatory approvals and commitments of resources before they can be commercialized. We cannot give assurance that our research will lead to discovery of any additional drug candidates that will generate additional revenue for us. 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 or she 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 fields 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 may encounter difficulties in managing our growth and expanding our operations successfully.

As we expand our research efforts and 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.

Expenses associated with development of our product candidates may cause our earnings to fluctuate from period to period.

Many of the preclinical and clinical development activities required for our product candidates will have to be contracted out to CROs at significant expense. It is difficult to accurately predict the timing of these expenses, and we expect that they will vary from quarter to quarter. In addition, the FDA or other regulatory agencies may require more preclinical or clinical testing than we originally anticipated for any of our drug candidates. We may also be required to purchase expensive competitor drugs for use in our trials, either to demonstrate potential treatment combinations or as comparators to our product candidates. As a result, the expenses of our development programs and our operating results may fluctuate significantly from quarter to quarter, and our stock price may be adversely affected.

To date, our principal sources of revenue have been our collaboration agreements, including our current agreement with AbbVie and our prior agreement with Novartis, and future milestone payments and the level of royalties under the AbbVie agreement are uncertain. We have had no products approved for commercial sale by us. Therefore, it is possible that we may incur operating losses in one or more years in the future, and our ability to achieve sustained profitability is unproven.

In each of our 2012, 2013 and 2014 fiscal years, our net income resulted primarily from license payments, including milestone payments we earned from AbbVie and/or Novartis. There is no assurance, however, that we will report net income in subsequent years. To date, we have not commercialized any products ourselves and we have not yet generated substantial revenue from product sales by AbbVie.

Our principal source of revenue has been our collaboration agreements, including our current agreement with AbbVie. Future milestone payments are uncertain because AbbVie may choose not to continue research or development activities for our ABT-493 product candidate. For example, under our previous collaboration with Novartis for the development of our NS5A inhibitor, Novartis

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decided in September 2014 not to pursue further development of the licensed product candidate in light of its decision that HCV was no longer a strategic focus of Novartis, which resulted in the NS5A inhibitor program being transferred back to us and 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 any more of our product candidates, either alone or with our collaborators, or if any such product candidate or paritaprevir does not achieve market acceptance, we may never generate sufficient product royalties or product sales. In addition, for any of our product candidates other than paritaprevir or ABT-493 included in a treatment regimen with more than one active compound, it would be uncertain what portion of net sales of the regimen would be allocated to our product candidate. The existence of multiple active compounds in the regimen or an unfavorable allocation to our product candidate could adversely affect our royalty revenue. Even if we do generate significant product royalties or product sales, we may not be able to sustain profitability on a quarterly or annual basis. Our failure to sustain profitability would depress the market price of our common stock and ultimately 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 require substantial additional financing in the longer term to achieve our goals if the further commercialization of paritaprevir is delayed or curtailed or if the development of ABT-493 is terminated. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate some or all of 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 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. For the foreseeable future, we expect to incur substantial additional costs associated with research and development for our internally developed programs, exclusive of costs incurred by our collaborator in developing our licensed product candidates paritaprevir and ABT-493. In addition, we may seek opportunities to in-license or otherwise acquire new therapeutic candidates and therapies.

Our future capital requirements depend on many factors, including:

- 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, including 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, including manufacturing for clinical development;

- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patents, including litigation costs and the outcome of such litigation;

- the level of future sales of paritaprevir-containing regimens and the resulting levels of annually tiered royalties on paritaprevir, as well as the level of potential sales, if any, of ABT-493-containing regimens.

Additional funds may not be available if and 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.

Our government funded contract for our antibiotic program, which is being concluded in fiscal 2015, is subject to audit and adjustments that could affect our previously reported revenues.

Our contract 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, is scheduled to be completed in fiscal 2015. 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

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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 reported revenue.

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. None of our product candidates in our pipeline other than paritaprevir has yet advanced beyond Phase 2 clinical trials. Any future clinical trials of our other product candidates 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, compete successfully against other HCV therapies 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, including guidelines specifically addressing requirements for the development of DAAs for the treatment of HCV;

program discontinuations or clinical holds for a program of a competitor, which could increase the level of regulatory scrutiny or delay data review or other response times by regulators with respect to one of our programs in the same class as the competitor s program; or

varying interpretations of data by the FDA, the EMA and similar foreign regulatory agencies.

The results of any Phase 3 clinical trial may not be adequate to support marketing approval for one of AbbVie s regimens containing a protease inhibitor. These clinical trials are lengthy and usually involve from many hundreds to thousands of patients. In addition, if the FDA or the EMA disagrees with AbbVie 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 or the EMA, or both, may refuse to approve AbbVie s product candidate. The FDA or the EMA also may require additional clinical trials as a condition for approving any of these product candidates. AbbVie estimates that it will likely be 2017 before an NDA for one of AbbVie s HCV treatment regimens containing one of our product candidates other than paritaprevir could be approved by the FDA or the EMA.

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, the EMA 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

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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. 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.

Any product candidate in our current NASH program may have undesirable side effects which may delay or prevent marketing approval, or, if approval is received, require our product candidates to be taken off the market, require them to include safety warnings or otherwise limit their sales.

In our NASH program we are developing an agonist of the farnesoid X receptor, or FXR, that is designed to bind to that receptor and then trigger a response from it. With the exception of one drug approved to treat cholesterol gallstone dissolution and a rare lipid storage disease, there are no approved FXR agonists and the adverse effects from long-term exposure to this drug class are unknown. Unforeseen side effects from any of our product candidates could arise either during clinical development or, if approved, after the approved product has been marketed. The range and potential severity of possible side effects from systemic therapies like FXR agonists is significant.

In addition, our drug candidates for NASH will be developed as a potential treatment for a severe disease that commonly occurs in patients with other serious conditions, including metabolic syndrome and diabetes. Any clinical trials in NASH will necessarily be conducted in patient population that will be more prone than the general population to exhibit certain disease states or adverse events. It may be difficult to discern whether certain events or symptoms observed during our trials were due to our drug candidates or placebo, resulting in our company and our development programs being negatively affected even if such events or symptoms are ultimately determined to be unlikely related to our drug candidates.

If any of our product candidates receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by such products:

- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- we may be required to change instructions regarding the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;

regulatory authorities may require us to take our approved product off the market;

we may be subject to litigation or product liability claims; and

our reputation may suffer.

Any of these events could prevent us or our potential future collaborators from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from the sale of any product we develop for NASH.

If we, or AbbVie in the case of our protease inhibitor product candidates, 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 AbbVie are required to conduct studies on the long-term effects associated with the use of such product candidates, efforts to commercialize such 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 AbbVie 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

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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, AbbVie or regulatory authorities, such as the FDA or EMA, to interrupt, delay or halt clinical trials of our product candidates and could result in the FDA or EMA 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 AbbVie from commercializing our product candidates.

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-493, EDP-239 or any of our future product candidates, may not be predictive of the results of later-stage clinical trials. In addition, results of Phase 3 clinical trials in one or more ethnic groups are not necessarily indicative of results in other ethnic groups. 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 early and 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, the EMA and other 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 approvals are unpredictable and depend 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 comparable application to other regulatory authorities. Neither we nor our collaborator 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, the EMA or other 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, the EMA or other 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, the EMA or other 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, the EMA or other 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 submissions or to obtain regulatory approval in the United States or elsewhere;

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- 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 of any of our product candidate; and

- the approval policies or regulations of the FDA, the EMA or other 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