ENANTA PHARMACEUTICALS INC
Form 10-Q
May 10, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended March 31, 2018

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
Commission File Number 001-35839

ENANTA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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

500 Arsenal Street

Watertown, Massachusetts 02472

(617) 607-0800

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

Large accelerated filer		Accelerated filer
Non-accelerated filer	(Do not check if a small reporting company)	Smaller reporting company
Emerging growth company		

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

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

As of May 1, 2018, the registrant had 19,267,599 shares of common stock, $0.01 par value per share, outstanding.

ENANTA PHARMACEUTICALS, INC.

FORM 10-Q — Quarterly Report

For the Quarterly Period Ended March 31, 2018

TABLE OF CONTENTS

		Page
PART I—FINANCIAL INFORMATION		
Item 1.	Consolidated Financial Statements	3
	Unaudited Consolidated Balance Sheets	3
	Unaudited Consolidated Statements of Operations	4
	Unaudited Consolidated Statements of Comprehensive Income (Loss)	5
	Unaudited Consolidated Statements of Cash Flows	6
	Unaudited Notes to Consolidated Financial Statements	7
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	18
Item 3.	Quantitative and Qualitative Disclosures about Market Risk	28
Item 4.	Controls and Procedures	28
PART II—OTHER INFORMATION		
Item 1A.	Risk Factors	30
Item 6.	Exhibits	55
Signatures		56

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, or Form 10-Q, contains forward-looking statements concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business operations and financial performance and condition. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended. In some cases, you can identify forward-looking statements by terminology such as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "due," "estimate," "expect," "goal," "intend," "plan," "predict," "potential," "positioned," "seek," "should," "target," "will," "would," and other similar expressions that are p of or indicate future events and future trends, or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about overall trends, royalty revenue trends, research and clinical development plans, liquidity and capital needs and other statements of expectations, beliefs, future plans and strategies, anticipated events or trends and similar expressions. These forward-looking statements are based on our management's current expectations, estimates, forecasts and projections about our business and the industry in which we operate and our management's beliefs and assumptions. These forward-looking statements are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this Form 10-Q may turn out to be inaccurate. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under "Risk Factors" and discussed elsewhere in this Form 10-Q. These forward-looking statements speak only as of the date of this Form 10-Q. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future. You should, however, review the factors and risks we describe in the reports we will file from

time to time with the Securities and Exchange Commission (SEC) after the date of this Form 10-Q.

PART I—FINANCIAL INFORMATION

ITEM 1. CONSOLIDATED FINANCIAL STATEMENTS
ENANTA PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

(unaudited)

(in thousands, except per share amounts)

	March 31, 2018	September 30, 2017
Assets		
Current assets:		
Cash and cash equivalents	$66,926	$65,675
Short-term marketable securities	189,797	157,994
Accounts receivable	44,049	10,614
Prepaid expenses and other current assets	4,905	3,536
Total current assets	305,677	237,819
Long-term marketable securities	32,186	70,038
Property and equipment, net	8,616	8,049
Deferred tax assets	7,567	10,123
Restricted cash	608	608
Total assets	$354,654	$326,637
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$4,696	$3,714
Accrued expenses and other current liabilities	7,041	7,970
Income taxes payable	5,380	9,298
Total current liabilities	17,117	20,982
Warrant liability	—	807
Series 1 nonconvertible preferred stock	1,528	762
Other long-term liabilities	2,607	2,410
Total liabilities	21,252	24,961
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Common stock; $0.01 par value per share, 100,000 shares authorized; 19,260 and 19,120 shares issued and outstanding at March 31, 2018 and September 30, 2017, respectively	193	191
Additional paid-in capital	264,354	256,241
Accumulated other comprehensive loss	(794)	(112)
Retained earnings	69,649	45,356
Total stockholders' equity	333,402	301,676
Total liabilities and stockholders' equity	$354,654	$326,637

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

ENANTA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited)

(in thousands, except per share amounts)

	Three Months Ended March 31,		Six Months Ended March 31,	
	2018	2017	2018	2017
Revenue				
Royalties	$44,049	$8,959	$67,158	$19,376
Milestones	—	—	15,000	—
Total revenue	44,049	8,959	82,158	19,376
Operating expenses:				
Research and development	21,484	13,004	39,446	25,530
General and administrative	5,706	5,461	11,476	10,398
Total operating expenses	27,190	18,465	50,922	35,928
Income (loss) from operations	16,859	(9,506)	31,236	(16,552)
Other income (expense):				
Interest income (expense), net	1,077	564	1,996	1,101
Other income (expense), net	(11)	—	(11)	—
Change in fair value of warrant liability and Series 1 nonconvertible preferred stock	—	(15)	41	(28)
Income (loss) before income taxes	17,925	(8,957)	33,262	(15,479)
Income tax (expense) benefit	(5,370)	3,565	(9,014)	5,107
Net income (loss)	$12,555	$(5,392)	$24,248	$(10,372)
Net income (loss) per share:				
Basic	$0.65	$(0.28)	$1.27	$(0.54)
Diluted	$0.61	$(0.28)	$1.20	$(0.54)
Weighted average shares outstanding:				
Basic	19,206	19,047	19,167	19,042
Diluted	20,601	19,047	20,256	19,042

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

ENANTA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(unaudited)

(in thousands)

	Three Months Ended March 31,		Six Months Ended March 31,	
	2018	2017	2018	2017
Net income (loss)	$12,555	$(5,392)	$24,248	$(10,372)
Other comprehensive loss:				
Net unrealized losses on marketable securities, net of tax of ($128), ($13), ($235), ($76)	(336)	(23)	(682)	(127)
Total other comprehensive loss	(336)	(23)	(682)	(127)
Comprehensive income (loss)	$12,219	$(5,415)	$23,566	$(10,499)

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

ENANTA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

(in thousands)

	Six Months Ended March 31,	
	2018	2017
Cash flows from operating activities		
Net income (loss)	$24,248	$(10,372)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Stock-based compensation expense	7,710	6,759
Depreciation and amortization expense	1,200	1,021
Deferred income taxes	2,791	(5,437)
Income tax benefit from stock awards	1,984	—
Premium on marketable securities	(243)	(857)
Amortization of premium on marketable securities	110	406
Change in fair value of warrant liability and Series 1 nonconvertible preferred stock	(41)	28
Other non-cash items	(84)	—
Change in operating assets and liabilities:		
Accounts receivable	(33,435)	3,882
Prepaid expenses and other current assets	(1,369)	3,114
Accounts payable	565	688
Accrued expenses	(939)	562
Income taxes payable	(5,902)	—
Other long-term liabilities	236	349
Net cash provided by (used in) operating activities	(3,169)	143
Cash flows from investing activities		
Purchase of property and equipment	(1,256)	(1,531)
Purchase of marketable securities	(99,721)	(151,273)
Proceeds from maturities and sales of marketable securities	104,986	155,475
Net cash provided by investing activities	4,009	2,671
Cash flows from financing activities		
Proceeds from exercise of stock options	2,207	58
Payments of capital lease obligations	(39)	(36)
Payments for settlement of share-based awards	(1,757)	(202)
Net cash provided by (used in) financing activities	411	(180)
Net increase in cash and cash equivalents	1,251	2,634
Cash and cash equivalents at beginning of period	65,675	16,577
Cash and cash equivalents at end of period	$66,926	$19,211
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	$9,883	$1,022

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

ENANTA PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

(Amounts in thousands, except per share data)

1. Nature of the Business and Basis of Presentation

Enanta Pharmaceuticals, Inc. (the "Company"), incorporated in Delaware in 1995, is a biotechnology company that uses its robust, chemistry-driven approach and drug discovery capabilities to create small molecule drugs primarily for the treatment of viral infections and liver diseases. The Company discovered glecaprevir, the second of two protease inhibitors discovered and developed through its collaboration with AbbVie and marketed as part of AbbVie's new direct-acting antiviral (DAA) regimen under the tradenames MAVYRET™ (U.S.) or MAVIRET™ (ex-U.S.) (glecaprevir/pibrentasvir) for the treatment of chronic hepatitis C virus, or HCV. The other protease inhibitor under its HCV collaboration is part of AbbVie's initial DAA regimens for the treatment of chronic HCV marketed under the tradenames VIEKIRA PAK® (paritaprevir/ritonavir/ombitasvir/dasabuvir) (U.S.) or VIEKIRAX® (paritaprevir/ritonavir/ombitasvir) (ex-U.S.). Royalties from the Company's AbbVie collaboration and its existing financial resources provide funding to support its wholly-owned research and development programs, which are currently focused on the following disease targets: non-alcoholic steatohepatitis ("NASH"); primary biliary cholangitis ("PBC"); respiratory syncytial virus ("RSV") and hepatitis B virus ("HBV").

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 and compliance with government regulations and the need to obtain additional financing. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approvals, prior to commercialization. These efforts require significant amounts of capital, adequate personnel infrastructure, and extensive compliance reporting capabilities.

Unaudited Interim Financial Information

The consolidated balance sheet at September 30, 2017 was derived from audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the United States of America ("GAAP"). The accompanying unaudited consolidated financial statements as of March 31, 2018 and for the three and six months ended March 31, 2018 and 2017 have been prepared by the Company pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC") for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. These financial statements should be read in conjunction with the Company's audited financial statements and the notes thereto included in the Company's Annual Report on Form 10-K for the year ended September 30, 2017.

In the opinion of management, all adjustments, consisting of normal recurring adjustments necessary for a fair statement of the Company's financial position as of March 31, 2018 and results of operations for the three and six months ended March 31, 2018 and 2017 and cash flows for the six months ended March 31, 2018 and 2017, have been made. The results of operations for the six months ended March 31, 2018 are not necessarily indicative of the results of operations that may be expected for subsequent quarters or the year ending September 30, 2018.

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 per share amounts, are in thousands unless otherwise indicated. Certain reclassifications were made to non-operating income (expense) to net interest income and interest expense in the consolidated statements of operations and to net proceeds received from maturities and sales of marketable securities in the consolidated statements of cash flows to confirm the prior period presentation to the current period presentation.

2. Summary of Significant Accounting Policies

For the Company's Significant Accounting Policies, please refer to its Annual Report on Form 10-K for the fiscal year ended September 30, 2017. Other than the adoption of ASU 2016-09 as of October 1, 2017, there were no other significant changes to the Company's Significant Accounting Policies during the quarter.

ENANTA PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

(Amounts in thousands, except per share data)

Use of Estimates

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

Recently Issued Accounting Pronouncements

In March 2016, the FASB issued ASU No. 2016-09, Improvements to Employee Share-Based Payment Accounting ("ASU 2016-09"), which intends to simplify several aspects of accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, a choice to recognize gross stock compensation expense with actual forfeitures recognized as they occur, as well as certain classifications on the statement of cash flows. This amendment was effective for the Company in the fiscal year beginning October 1, 2017. As a result of the adoption, the Company changed its forfeiture rate policy to recognize forfeitures as they occur. Upon adoption, the cumulative impact of this change in policy on retained earnings and deferred tax assets in the consolidated balance sheet was not material. In addition, the consolidated statements of cash flows will present excess tax benefits, if any, as part of cash flows from operating activities. The Company elected to adopt this change on a prospective basis and, therefore, excess tax benefits from prior periods in the statement of cash flow were not restated. The adoption of the standard is also expected to create variability in the consolidated statements of operations in years in which the Company is expected to have taxable income, as the tax consequences of settled share-based payments will be recognized in income tax expense when share-based payment awards are settled.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606) ("ASU 2014-09") 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. The FASB has continued to issue accounting standards updates to clarify and provide implementation guidance related to Revenue from Contracts with Customers, including ASU 2016-08, Revenue from Contract with Customers: Principal versus Agent Considerations, ASU 2016-10, Revenue from Contracts with Customers: Identifying Performance Obligations and Licensing, and ASU 2016-12, Revenue from Contracts with Customers: Narrow-Scope Improvements and Practical Expedients. These amendments address a number of areas, including an entity's identification of its performance obligations in a contract, collectibility, non-cash consideration, presentation of sales tax and an entity's evaluation of the nature of its promise to grant a license of intellectual property and whether or not that revenue is recognized over time or at a point in time. The new guidance must be adopted using either a modified retrospective

approach or a full retrospective approach for all periods presented. Under the modified retrospective method, the cumulative effect of applying the new standard would be recognized at the adoption date in retained earnings on the consolidated balance sheet. Under the full retrospective approach, the new standard would be applied to each prior reporting period presented. These new standards will be effective for the Company beginning October 1, 2018. The Company is in process of determining the method of adoption of this standard, but under either method, the impact of adoption is not expected to have a material impact on the Company's consolidated financial statements. The AbbVie Agreement is the only revenue-generating arrangement outstanding. All performance obligations under the agreement have been achieved and the Company is earning annually tiered per-product royalties on the portion of AbbVie's net sales of its HCV regimens allocable to the protease inhibitor product in the regimen.

In November 2016, the FASB issued ASU No. 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash ("ASU 2016-18") that changes the presentation of restricted cash and cash equivalents on the statement of cash flows. Restricted cash and restricted cash equivalents will be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. This amendment is effective for the Company in the fiscal year beginning October 1, 2018, but early adoption is permissible. Upon adoption, the Company will adjust the presentation of the statement of cash flows to include restricted cash related to an outstanding letter of credit collateralized by a money market fund of $608 so that it is included in the beginning balance of cash and cash equivalents.

ENANTA PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

(Amounts in thousands, except per share data)

In May 2017, the FASB issued ASU No. 2017-09, Compensation—Stock Compensation (Topic 718) (“ASU 2017-09”) which provides updated guidance about changes to the terms or conditions of a share-based payment award that requires companies to apply modification accounting under Topic 718. This amendment is effective for the Company in the fiscal year beginning October 1, 2018, but early adoption is permissible. The Company does not expect the adoption of ASU 2017-09 to have a material impact on its consolidated financial statements.

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

In March 2017, the FASB issued ASU No. 2017-08, Receivables—Nonrefundable Fees and Other Costs (Subtopic 310-20): Premium Amortization on Purchased Callable Debt Securities (“ASU 2017-08”) which requires companies to amend the amortization period for premiums on debt securities with explicit call features to be the earliest call date rather than through the contractual life of the debt instrument. This amendment aims to more closely align the recognition of interest income with the manner in which market participants price such instruments. This amendment is effective for the Company in the fiscal year beginning October 1, 2019, but early adoption is permissible. The Company is currently evaluating the potential impact that ASU 2017-08 may have on its financial position and results of operations.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments—Credit Losses (“ASU 2016-13”), which introduces a new methodology for accounting for credit losses on financial instruments, including available-for-sale debt securities. The guidance establishes a new “expected loss model” that requires entities to estimate current expected credit losses on financial instruments by using all practical and relevant information. Any expected credit losses are to be reflected as allowances rather than reductions in the amortized cost of available-for-sale debt securities. This amendment is effective for the Company in the fiscal year beginning October 1, 2020. The Company is currently evaluating the potential impact that ASU 2016-13 may have on its financial position and results of operations.

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

3.Fair Value of Financial Assets and Liabilities

The following tables present information about the Company’s financial assets and liabilities that were subject to fair value measurement on a recurring basis as of March 31, 2018 and September 30, 2017 and indicate the fair value hierarchy of the valuation inputs utilized to determine such fair value:

ENANTA PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

(Amounts in thousands, except per share data)

	Fair Value Measurements at March 31, 2018 Using:			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets:				
Cash equivalents:				
Money market funds	$24,465	$—	$—	$24,465
U.S. Treasury notes	14,493	—	—	14,493
Commercial paper	—	9,980	—	9,980
Corporate bonds	—	2,594	—	2,594
Marketable securities:				
U.S. Treasury notes	32,633	—	—	32,633
Corporate bonds	—	162,037	—	162,037
Commercial paper	—	27,313	—	27,313
	$71,591	$201,924	$—	$273,515
Liabilities:				
Series 1 nonconvertible preferred stock	$—	$—	$1,528	$1,528
	$—	$—	$1,528	$1,528

	Fair Value Measurements at September 30, 2017 Using:			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets:				
Cash equivalents:				
Money market funds	$19,863	$—	$—	$19,863
Commercial paper	—	29,756	—	29,756
Corporate bonds	—	3,000	—	3,000
Marketable securities:				
U.S. Treasury notes	60,843	—	—	60,843
Corporate bonds	—	150,731	—	150,731
Commercial paper	—	12,458	—	12,458
U.S. Agency bonds	—	4,000	—	4,000
	$80,706	$199,945	$—	$280,651
Liabilities:				
Warrant liability	$—	$—	$807	$807

Series 1 nonconvertible preferred stock	—	—	762	762
	$—	$—	$1,569	$1,569

During the six months ended March 31, 2018 and 2017, there were no transfers between Level 1, Level 2 and Level 3.

As of September 30, 2017, the Company's warrant liability was comprised of the value of warrants for the purchase of its Series 1 nonconvertible preferred stock. These warrants were financial instruments that might have required a transfer of assets because of the liquidation features in the contract and were therefore recorded as liabilities and measured at fair value. These warrants expired on October 4, 2017, and are therefore no longer outstanding. The outstanding shares of Series 1 nonconvertible preferred stock are also measured at fair value. The fair value of both these instruments was based on significant inputs not observable in the market, which represented a Level 3 measurement within the fair value hierarchy. The Company utilized a probability-weighted valuation model which takes into consideration various outcomes that may require the Company to transfer assets upon exercise. Changes in the fair value of the warrant liability and Series 1 nonconvertible preferred stock are recognized in other income (expense), net in the consolidated statements of operations.

ENANTA PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

(Amounts in thousands, except per share data)

The recurring Level 3 fair value measurements of the Company's outstanding warrant liability and Series 1 nonconvertible preferred stock using probability-weighted discounted cash flow include the following significant unobservable inputs:

		Range (Weighted Average)	
	Unobservable Input	March 31, 2018	September 30, 2017
Warrant liability and Series 1 nonconvertible preferred stock	Probabilities of payout	0%-65%	0%-65%
	Discount rate	5.25%	5.25%

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, 2017	$ 807	$ 762
Warrants exercised	(766)	766
Warrants expired	(41)	—
Balance, March 31, 2018	$ —	$ 1,528

4. Marketable Securities

As of March 31, 2018 and September 30, 2017, the fair value of available-for-sale marketable securities, by type of security, was as follows:

	March 31, 2018	
	Amortized	Gross
		Gross

	Cost	Unrealized Gains	Unrealized Losses	Fair Value
	(in thousands)			
Corporate bonds	$162,981	$ —	$ (944)	$162,037
U.S. Treasury notes	32,785	—	(152)	32,633
Commercial paper	27,313	—	—	27,313
	$223,079	$ —	$ (1,096)	$221,983

	September 30, 2017			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(in thousands)			
Corporate bonds	$150,841	$ 9	$ (119)	$150,731
U.S. Treasury notes	60,908	—	(65)	60,843
Commercial paper	12,458	—	—	12,458
U.S. Agency bonds	4,004	—	(4)	4,000
	$228,211	$ 9	$ (188)	$228,032

As of March 31, 2018, marketable securities consisted of short-term marketable securities, which are investments that mature within one year, and long-term marketable securities, with an aggregate fair value of $32,186, which consist of certain U.S. Treasury notes and corporate bonds that have maturities of more than one year but not more than three years.

ENANTA PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

(Amounts in thousands, except per share data)

5. Accrued Expenses and Other Long-Term Liabilities

Accrued expenses and other current liabilities as well as other long-term liabilities consisted of the following as of March 31, 2018 and September 30, 2017:

	March 31, 2018	September 30, 2017
	(in thousands)	
Accrued expenses:		
Accrued preclinical and clinical expenses	$2,944	$ 3,156
Accrued vendor manufacturing	1,492	1,130
Accrued payroll and related expenses	1,431	2,829
Accrued professional fees	748	456
Accrued other	426	399
	$7,041	$ 7,970
Other long-term liabilities:		
Uncertain tax positions	$1,439	$ 1,175
Accrued rent expense	632	676
Capital lease obligation	337	379
Asset retirement obligation	199	180
	$2,607	$ 2,410

6. Ongoing Collaboration Agreements

AbbVie Collaboration

The Company has a Collaborative Development and License Agreement (as amended, the “AbbVie Agreement”), with AbbVie to identify, develop and commercialize HCV NS3 and NS3/4A protease inhibitor compounds, including paritaprevir and glecaprevir, under which the Company has received license payments, proceeds from a sale of preferred stock, research funding payments, milestone payments and royalties totaling approximately $548,000 through March 31, 2018. Since the Company completed all its performance obligations under the AbbVie Agreement by the end of fiscal 2011, all milestone payments received since then have been recognized as revenue when the milestones were achieved by AbbVie.

The Company is also receiving annually tiered royalties per Company protease 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 the portion of AbbVie’s calendar year net sales of each HCV regimen that is allocated to the protease inhibitor product in the regimen. Beginning with each January 1, the cumulative net sales of a given royalty-bearing protease inhibitor product

start at zero for purposes of calculating the tiered royalties on a product-by-product basis.

During the six months ended March 31, 2018, the Company earned and recognized milestone revenue of $15,000 upon AbbVie's achievement of commercialization regulatory approval in Japan for MAVIRET™.

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 2,000 shares of Series 1 nonconvertible preferred stock. As these warrants were financial instruments that might have required the Company to transfer assets, these instruments are classified as liabilities. The following table summarizes the activity of the warrants to purchase Series 1 nonconvertible preferred stock:

ENANTA PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

(Amounts in thousands, except per share data)

	Outstanding Warrants	Weighted Average Exercise Price Per Share
	(in thousands, except per share data)	
Outstanding as of September 30, 2017	1,030	$ 0.01
Exercised	(978)	$ 0.01
Expired	(52)	$ 0.01
Outstanding as of March 31, 2018	—	$ 0.01

As of March 31, 2018, 1,931 shares of Series 1 nonconvertible preferred stock were issued and outstanding. As this preferred stock may require the Company to transfer a fixed amount of assets, these shares are classified as liabilities.

8. Stock-Based Awards

The Company has granted stock-based awards, including stock options, restricted stock units, and performance share units, under its existing 2012 Equity Incentive Plan (the “2012 Plan”). The Company also has outstanding stock-based awards under its 1995 Equity Incentive Plan (the “1995 Plan”), but is no longer granting awards under this plan.

The following table summarizes stock option activity, including performance-based options, for the year-to-date period ending March 31, 2018:

	Shares Issuable Under Options	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
	(in thousands)		(in years)	(in thousands)
Outstanding as of September 30, 2017	2,298	$ 30.36	7.4	$ 37,821

Granted	536	$ 52.47		
Exercised	(94)	$ 23.39		
Forfeited	(24)	$ 39.44		
Outstanding as of March 31, 2018	2,716	$ 34.89	7.5	$ 125,041
Options exercisable as of March 31, 2018	1,517	$ 30.08	6.5	$ 77,113

Market and Performance-Based Stock Unit Awards

The Company awards both performance share units, or PSUs, and relative total stockholder return units, or rTSRUs, to its executive officers. The number of units 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 following table summarizes PSU and rTSRU activity (at target) for the year-to-date period ending March 31, 2018:

	PSUs		rTSRUs	
	Shares	Weighted Average Grant Date Fair Value Per Share	Shares	Weighted Average Grant Date Fair Value Per Share
	(in thousands, except per share data)			
Unvested at September 30, 2017	70	$ 34.51	70	$ 43.07
Granted	25	$ 77.93	25	$ 84.70
Vested	(20)	$ 32.04	(25)	$ 37.67
Cancelled	(5)	$ 32.04	—	$ —
Unvested at March 31, 2018	70	$ 50.97	70	$ 59.96

ENANTA PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

(Amounts in thousands, except per share data)

A total of 80% of the target PSUs and 192.91% of the target rTSRUs granted in December 2015 vested during the three months ended March 31, 2018, resulting in the issuance of an aggregate of 68 common shares, net of share withholding.

Restricted Stock Units

During the three months ended December 31, 2016, the Company awarded restricted stock units to its employees, which vest 50% in three years and 50% in four years, provided the employee remains employed with the Company at the time of vesting. The fair value of these awards is determined based on the intrinsic value of the stock on the date of grant and will be recognized as stock-based compensation expense over the requisite service period. The following table summarizes the restricted stock unit activity for the year-to-date period ending March 31, 2018:

	Restricted Stock Units	Weighted Average Grant Date Fair Value Per Share
	(in thousands, except per share data)	
Unvested at September 30, 2017	110	$ 30.00
Granted	—	$ —
Vested	—	$ —
Cancelled	—	$ —
Unvested at March 31, 2018	110	$ 30.00

Stock-Based Compensation Expense

During the three and six months ended March 31, 2018 and 2017, the Company recognized the following stock-based compensation expense:

	Three Months ended March 31,		Six Months Ended March 31,	
	2018	2017	2018	2017
	(in thousands)			
Research and development	$1,429	$1,044	$2,900	$2,008
General and administrative	2,161	2,448	4,810	4,751
	$3,590	$3,492	$7,710	$6,759

	Three Months ended March 31,		Six Months Ended March 31,	
	2018	2017	2018	2017
	(in thousands)			
Stock options	$3,030	$2,907	$5,978	$5,253
Performance stock units	35	43	641	667
rTSRUs	332	344	694	547
Restricted stock units	193	198	397	292
	$3,590	$3,492	$7,710	$6,759

During the six months ended March 31, 2018 and 2017, the Company recognized stock-based compensation expense for PSUs and performance-based options upon achievement of performance-based targets that occurred during their respective periods.

As discussed in Note 2, the Company adopted ASU 2016-09 during the three months ended December 31, 2017. ASU 2016-09 intends to simplify several aspects of accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity awards or liability awards, a choice to recognize gross stock compensation expense with actual forfeitures recognized as they occur, as well as certain classifications on the statement of cash flows. As a result of the adoption,

ENANTA PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

(Amounts in thousands, except per share data)

the Company changed its forfeiture rate policy to recognize forfeitures as they occur. Upon adoption, the cumulative impact of this change in policy on retained earnings and deferred tax assets in the consolidated balance sheet was not material. In addition, the consolidated statements of cash flows will present excess tax benefits, if any, as part of cash flows from operating activities. The Company elected to adopt this change on a prospective basis and, therefore, excess tax benefits from prior periods in the statement of cash flow were not retroactively restated. The adoption of the standard is also expected to create variability in the consolidated statements of operations in years in which the Company is expected to have taxable income, as the tax consequences of settled share-based payments will be recognized in income tax expense when share-based payment awards are settled.

As of March 31, 2018, the Company had an aggregate of $33,320 of unrecognized stock-based compensation cost, which is expected to be recognized over a weighted average period of 2.5 years.

9. Net Income (Loss) Per Share

Basic and diluted net income (loss) per share attributable to common stockholders for the three and six months ended March 31, 2018 and 2017 was calculated as follows:

	Three Months Ended March 31,		Six Months Ended March 31,	
	2018	2017	2018	2017
	(in thousands, except per share data)			
Basic net income (loss) per share:				
Numerator:				
Net income (loss)	$12,555	$(5,392)	$24,248	$(10,372)
Denominator:				
Weighted average common shares outstanding—basic	19,206	19,047	19,167	19,042
Net income (loss) per share common share—basic	$0.65	$(0.28)	$1.27	$(0.54)
Diluted net income (loss) per share:				
Numerator:				
Net income (loss)	$12,555	$(5,392)	$24,248	$(10,372)
Denominator:				
Weighted average common shares outstanding—basic	19,206	19,047	19,167	19,042
Dilutive effect of common stock equivalents	1,395	—	1,089	—
Weighted average common shares outstanding—diluted	20,601	19,047	20,256	19,042
Net income (loss) per share common share—diluted	$0.61	$(0.28)	$1.20	$(0.54)
Anti-dilutive common stock equivalents excluded from above	46	2,529	449	2,552

The impact of certain common stock equivalents was excluded from the computation of diluted net loss per share for the periods in which the Company incurred a net loss since the impact of such common stock equivalents would have been anti-dilutive.

10. Income Taxes

For the three months ended March 31, 2018, the Company recorded income tax expense of $(5,370) and for the comparable period in 2017, recorded an income tax benefit of $3,565, both of which were attributable to the Company's domestic operations. Income tax expense for the three months ended March 31, 2018 was driven by the Company's pre-tax income during the quarter which increased from the prior comparable quarter due to an increase in royalties earned from the AbbVie Agreement. During the three months ended March 31, 2017, the Company's income tax benefit was driven by the Company's pre-tax loss during the quarter.

ENANTA PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

(Amounts in thousands, except per share data)

For the six months ended March 31, 2018, the Company recorded income tax expense of $(9,014) and for the comparable period in 2017, recorded an income tax benefit of $5,107, representing effective tax rates of 27.1% and 33.0%, respectively. Income tax expense for the six months ended March 31, 2018, was driven by the Company's pre-tax income for the year which increased from the prior comparable period due to an increase in royalties earned under the AbbVie Agreement. The effective tax rate of 27.1% differs from the federal statutory rate of 21.0% due to the revaluation adjustment against deferred tax assets due to a decrease in the federal corporate income tax rate as enacted under the U.S. Tax Cuts and Jobs Act (the "Tax Act"), offset by federal research and development tax credits and excess tax benefits from stock option exercises and restricted stock units vesting during the first half of 2018. During the six months ended March 31, 2017, the Company's income tax benefit was driven by the Company's pre-tax loss during the first half of 2017. The effective tax rate of 33.0% differs from the prior year federal statutory rate of 35.0% due to federal research and development tax credits which reduced the Company's annual effective tax rate slightly below the statutory rate.

Estimates used to prepare our income tax expense are based on the Company's initial analysis of the Tax Act enacted in December 2017. Given the complexity of the act, anticipated guidance from the U. S. Treasury regarding implementation of the act, and potential for additional guidance from the SEC and the Financial Accounting Standards Board related to the act, these estimates may be adjusted during fiscal 2018 to reflect any such guidance provided. The effective tax rate in 2018 therefore could be affected by adjustments to the provisional amounts recorded under the guidance of SAB 118 for the revaluation of deferred tax assets and liabilities due to the U.S. statutory rate change in 2017. While we believe we have adequately provided for all tax positions, amounts asserted by taxing authorities could materially differ from our accrued positions as a result of uncertain and complex application of tax law and regulations. Additionally, the recognition and measurement of certain tax benefits include estimates and judgment by management. Accordingly, we could record additional provisions or benefits for U.S. federal and state tax matters in future periods as new information becomes available.

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. The Company's tax years are still open under statute from fiscal year 2014 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 is currently under examination by the Internal Revenue Service for the year ending September 30, 2016. No adjustments have been proposed to date. The Company has not received notice of examination by any other jurisdictions for any other tax year open under statute.

The Company had an unrecognized tax benefit of $1,439 and $1,175 as of March 31, 2018 and September 30, 2017, respectively. Unrecognized tax benefits represent tax positions for which reserves have been established. The Company's policy is to record interest and penalties related to uncertain tax positions as part of its income tax provision.

11. Commitments and Contingencies

Leases

The Company has an office and laboratory lease that expires in September 2022. Payment escalation as specified in the lease agreement is accrued such that rent expense is recognized on a straight-line basis over the term of occupancy. The Company recorded rent expense of $1,013 for both the six months ended March 31, 2018 and 2017.

In connection with the lease, the Company has outstanding a $608 letter of credit, collateralized by a money market account. As of March 31, 2018 and September 30, 2017, the Company classified the $608 related to the letter of credit as restricted cash. Additionally, the lease, as amended, included a $598 tenant improvement allowance from the landlord, which is accounted for as a capital lease obligation.

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 could 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

ENANTA PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

(Amounts in thousands, except per share data)

inability to obtain a necessary license, would have a material adverse effect on the Company's financial condition, results of operations or cash flows. The Company accrues contingent liabilities when it is probable that future expenditures will be made and such expenditures can be reasonably estimated.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnifications of varying scope and terms to customers, vendors, lessors, business partners, and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from services to be provided to the Company, or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and its executive officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. In addition, the Company maintains officers and directors insurance coverage. The Company does not believe that the outcome of any claims under indemnification arrangements will have a material effect on its financial position, results of operations or cash flows, and has not accrued any liabilities related to such obligations in its financial statements as of March 31, 2018.

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, 2017 included in our Annual Report on Form 10-K for that fiscal year which is referred to as our 2017 Form 10-K. Please refer to our note regarding forward-looking statements on page 2 of this Form 10-Q, which is incorporated herein by this reference.

The Enanta name and logo are our trademarks. This Quarterly Report also includes trademarks, trade names and service marks of other persons. All other trademarks, trade names and service marks appearing in this Quarterly Report are the property of their respective owners.

Overview

We are a biotechnology company that uses our robust, chemistry-driven approach and drug discovery capabilities to create small molecule drugs primarily for the treatment of viral infections and liver diseases. We discovered glecaprevir, the second of two protease inhibitors discovered and developed through our collaboration with AbbVie and marketed as part of AbbVie's new direct-acting antiviral (DAA) regimen under the tradenames MAVYRET™ (U.S.) or MAVIRET™ (ex-U.S.) (glecaprevir/pibrentasvir) for the treatment of chronic hepatitis C virus, or HCV. The other protease inhibitor under our HCV collaboration is part of AbbVie's initial DAA regimens for the treatment of chronic HCV marketed under the tradenames VIEKIRA PAK® (paritaprevir/ritonavir/

ombitasvir/dasabuvir) (U.S.) or VIEKIRAX® (paritaprevir/ritonavir/ombitasvir) (ex-U.S.). Our royalties from our AbbVie collaboration and our existing financial resources provide us funding to support our wholly-owned research and development programs, which are currently focused on the following disease targets:

- non-alcoholic steatohepatitis, or NASH, a liver disease estimated to affect approximately 1.5% to 6.5% of the population (which is the equivalent of approximately 5 to 20 million individuals in the U.S. alone);
- primary biliary cholangitis, or PBC, a chronic liver disease that slowly destroys bile ducts in the liver, which affects an estimated 17,000 individuals in the U.S.;
- respiratory syncytial virus, or RSV, the most common cause of bronchiolitis and pneumonia in children under one year of age in the U.S., resulting in an estimated 57,000 to 125,000 hospitalizations each year in the U.S.; and
- hepatitis B virus, or HBV, the most prevalent chronic hepatitis, which is estimated to affect approximately 250 million individuals worldwide.

We had $288.9 million in cash and marketable securities at March 31, 2018. In the first half of our fiscal year 2018, we earned $67.2 million in royalties on the portion of AbbVie's net sales of its HCV regimens allocated to glecaprevir or paritaprevir and earned the remaining $15.0 million milestone under our collaboration with AbbVie as a result of commercialization regulatory approval of MAVIRET™ in Japan. We expect our existing financial resources and cash flows will allow us to continue to fund our wholly-owned research and development programs for the foreseeable future.

Our Wholly-Owned Programs

Our wholly-owned research and development programs are in liver disease (non-virology), namely NASH and PBC, and in virology, namely RSV and HBV:

- NASH and PBC: We are working on multiple compounds that selectively bind to and activate the farnesoid X receptor, or FXR. We plan to develop these compounds, referred to as FXR agonists, for use in the treatment of NASH and PBC, both of which are liver diseases with very few therapeutic options. Our lead FXR agonist, EDP-305, represents a new class of FXR agonist designed to take advantage of increased binding interactions with the receptor. We believe this class is significantly different from other FXR agonists in clinical development.

- In October 2017, we announced results of a Phase 1a/b clinical study of EDP-305, which was generally safe and well tolerated over a broad range of single and multiple doses with pharmacokinetic data supporting once daily oral dosing. Additional data from this study were also presented at the 2018 NASH-TAG conference and the 2018 International Liver Conference (ILC). The study included 98 healthy volunteer subjects, or HV subjects, and 48 subjects who were obese and with or without pre-diabetes or type 2 diabetes, whom we refer to as subjects with presumptive non-alcoholic fatty liver disease, or PN subjects.

EDP-305 exhibited strong engagement of the FXR receptor as evidenced by increased levels of FGF19 and reduced levels of C4, both of which are monitored as downstream markers indicating FXR receptor activity.

Results support the ability to administer EDP-305 in future trials at doses that neither elicit clinically significant changes in lipids nor result in pruritus (itching).

- Since November 2016, we have presented data at the 2016 and 2017 annual meetings of the American Association for the Study of Liver Diseases (AASLD), the 2017 and 2018 NASH-TAG conferences and the 2017 and 2018 ILC conferences that demonstrated that EDP-305 is a highly selective FXR agonist and shows more potent activity in a variety of in vitro and in vivo NASH models compared to the most advanced NASH candidate in development today, obeticholic acid, or OCA.
- We initiated a Phase 2 clinical study, known as INTREPID, of EDP-305 in PBC patients in December 2017.
- We initiated a Phase 2 clinical study, known as ARGON-1, of EDP-305 in NASH patients in February 2018.
    - EDP-305 has been granted Fast Track designation by the U.S. Food and Drug Administration (FDA) for the treatment of NASH patients with liver fibrosis and separately for the treatment of PBC.
- In addition, we are pursuing research in other classes of FXR agonists as well as other mechanisms that may provide therapeutic benefit in NASH, any of which could be used as combination therapies for NASH.

• RSV: We have selected EDP-938, a potent N-protein inhibitor of activity of both major subgroups of RSV, referred to as RSV-A and RSV-B, as our first development candidate for RSV. We believe EDP-938 is differentiated from fusion inhibitors currently in development for RSV because N-protein inhibitors directly target the viral replication process of RSV and have demonstrated high barriers to resistance against RSV in vitro.

- In June 2017, we presented preclinical data demonstrating that EDP-938 is a potent inhibitor of both RSV-A and RSV-B activity, maintaining antiviral activity post-infection while presenting a high barrier to resistance in vitro. EDP-938 demonstrated a greater than 4-log reduction in viral load in an animal model challenged with RSV. Further, EDP-938 maintained antiviral potency across all clinical isolates tested in vitro, as well as virus that was resistant to fusion inhibitors. The compound inhibited RSV at a post-entry, replication step and maintained its activity in vitro when given 24 hours post infection. In addition, combination studies of EDP-938 with other types of RSV inhibitors, such as fusion inhibitors, showed synergistic antiviral effects.
    - We initiated a Phase 1 clinical study of EDP-938 in the fourth quarter of calendar 2017.
- Assuming successful completion of the Phase 1 study, we anticipate starting a Phase 2a challenge study of EDP-938 in the fourth quarter of calendar 2018. The challenge study will test the effect of EDP-938 on volunteers who will be infected with RSV in the course of the study.

• HBV: We also have a program to discover and develop new chemical entities for the treatment of HBV. Our initial focus is on core inhibition, a mechanism with early clinical validation. We believe that it may be necessary to utilize more than one compound/mechanism for the treatment of HBV and therefore we are pursuing multiple approaches. We continue to make progress in discovering, characterizing, and seeking patent protection for new HBV core inhibitors, also known as core protein allosteric modulators, or CpAMs, or capsid assembly modulators, with the goal of identifying a development candidate in 2018.

- In April 2018 at the ILC, we presented in vitro and humanized mouse model data on one of our most advanced core inhibitors being evaluated for HBV. The data presented demonstrated that in a chimeric mouse model with human liver cells, EP-027367 reduced HBV DNA levels by up to 3.0 logs from baseline in HBV viral titers with four weeks of treatment and demonstrated a favorable tolerability and safety profile.
- In addition, we are conducting preclinical experiments with compounds we have discovered that use other mechanisms to target HBV.

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

Licensed Products

Through our Collaborative Development and License Agreement with AbbVie, we have developed and licensed to AbbVie two protease inhibitor compounds that have been clinically tested, manufactured, and commercialized by AbbVie. To date, we have earned a total of $330.0 million in milestone payments related to clinical development and commercialization regulatory approvals of these regimens in major markets:

- Glecaprevir: Glecaprevir is the protease inhibitor we discovered that was developed by AbbVie in a fixed-dose combination with its NS5A inhibitor, pibrentasvir, for the treatment of HCV. This combination, currently marketed under the brand name MAVYRET™ in the U.S. and MAVIRET™ (ex-U.S.) and referred to in this report as MAVYRET/MAVIRET, is a new, once daily, all oral, fixed-dose, ribavirin-free treatment for HCV genotypes 1-6, or GT1-6, which is referred to as being pan-genotypic. In the EU, U.S. and Japan it is approved as an 8-week treatment for patients without cirrhosis and new to treatment. Today, these patients are estimated to represent the majority of HCV patients in the developed country markets.

Our economics from AbbVie's MAVYRET/MAVIRET consist of two components:

- We receive annually tiered, double-digit, per-product royalties on 50% of the net sales of the 2-DAA glecaprevir/pibrentasvir combination in MAVYRET/MAVIRET. These royalties are calculated separately from the royalties on paritaprevir-containing regimens.
- We also earned all available milestones, totaling $80.0 million, for commercialization regulatory approvals of the glecaprevir/pibrentasvir combination in the U.S., EU and Japan.

The U.S., EU and Japan authorizations for the MAVYRET/MAVIRET combination of glecaprevir and pibrentasvir, and AbbVie's applications for approval of MAVYRET/MAVIRET in other jurisdictions, are supported by the following studies:

- 8 weeks for treatment-naïve, non-cirrhotics: In November 2016, results from several Phase 3 studies of this combination demonstrated 97.5% of chronic HCV infected patients without cirrhosis and new to treatment across all major genotypes (GT1-6) achieved sustained virologic response at 12 weeks post-treatment, referred to as SVR_{12}, with just 8 weeks of MAVYRET/MAVIRET treatment.
- 8 weeks with chronic kidney disease: Results were also presented from AbbVie's EXPEDITION-4 study in chronic HCV patients with chronic kidney disease (CKD), in which 98% of patients (n=102/104) across all major genotypes (GT1-6) achieved SVR_{12} with 12 weeks of treatment with MAVYRET/MAVIRET.
- 8 weeks for GT-3: Data from AbbVie's ENDURANCE-3 study were presented at the 2017 ILC, demonstrating that 95% of patients with challenging-to-treat, genotype 3 (GT3) chronic HCV infection, without cirrhosis and new to treatment, achieved SVR_{12} after 8 weeks of treatment with MAVYRET/MAVIRET.
- 12 weeks for compensated cirrhosis: Data from AbbVie's EXPEDITION-1 study were also presented at the 2017 ILC, demonstrating that 99% of HCV-infected patients with genotype 1, 2, 4, 5 or 6 and compensated cirrhosis (Child-Pugh A) achieved SVR_{12} following 12 weeks of MAVYRET/MAVIRET treatment without ribavirin.

- Paritaprevir: Paritaprevir is the protease inhibitor contained in AbbVie's initial HCV treatment regimens currently marketed in the U.S., EU, Japan and other countries around the world under the trade names VIEKIRA PAK®, and VIEKIRAX®. First approved and sold in the U.S. in December 2014 for treatment of GT-1 HCV, AbbVie's HCV regimens containing paritaprevir are also approved for GT-4 HCV.

The following table summarizes our product development pipeline in our liver disease and virology programs:

Financial Operations Overview

We are currently funding all research and development for our wholly-owned programs. We expect to incur substantially greater expenses as we continue to advance our FXR agonist program for NASH and PBC. Specifically, we recently initiated two Phase 2 studies of EDP-305 one in PBC patients, known as the INTREPID study, and one in NASH patients, known as the ARGON-1 study. We also initiated a Phase 1 clinical study of our lead RSV candidate, EDP-938, in the fourth quarter of calendar 2017 and plan to initiate a Phase 2a challenge study in RSV in the fourth calendar quarter of 2018. We are increasing our expenses in fiscal 2018 as compared to our fiscal 2017, as we conduct these clinical studies and advance other compounds into substantial preclinical development.

Since our initial public offering in 2013, we have devoted substantially all of our resources to the discovery and development of novel compounds for the treatment of viral infections and liver diseases. For the periods included in this report we have funded our operations primarily through payments received under our collaboration agreement with AbbVie. Our revenue will continue to be dependent on royalty payments we receive from our collaboration with AbbVie.

For its new MAVYRET/MAVIRET regimen, which in the majority of chronic HCV patients only requires 8 weeks of treatment compared to 12 weeks with VIEKIRA PAK®, AbbVie initially set a lower list price compared to its original HCV regimens and other HCV products on the market. Over the past few quarters, AbbVie reported increasing MAVYRET/MAVIRET market share and has

become a leading HCV treatment in several market geographies where it is approved. However, the market for HCV therapies remains very dynamic in several jurisdictions and we cannot predict how it will continue to evolve.

Revenue

In our fiscal 2018 and 2017, our revenue has been derived from our continuing collaboration agreement with AbbVie. In 2017 we generated royalty revenue from AbbVie's net sales allocable to our protease inhibitor, paritaprevir, which is part of AbbVie's initial treatment regimens for HCV approved in the U.S. in December 2014 and in the EU and dozens of other countries since then. Since then, AbbVie received approvals of its new HCV regimen containing glecaprevir in the U.S. and EU in the summer of 2017 and began commercializing the combination under the tradenames MAVYRET™ (U.S.) and MAVIRET™ (ex-U.S.). The large majority of our royalty revenues are now derived from this regimen.

The following table is a summary of revenue recognized from our collaboration agreement for the three and six months ended March 31, 2018 and 2017:

	Three Months Ended March 31,		Six Months Ended March 31,	
	2018	2017	2018	2017
	(in thousands)			
AbbVie agreement:				
Royalties	$44,049	$8,959	$67,158	$19,376
Milestones	—	—	15,000	—
Total revenue	$44,049	$8,959	$82,158	$19,376

AbbVie Agreement

Since all of our research obligations under the AbbVie agreement were concluded by June 30, 2011, all milestone payments received since then have been recognized as revenue upon achievement of each milestone by AbbVie. During the six months ended March 31, 2018, we earned and recognized as revenue the last milestone payment for glecaprevir, which was a $15.0 million milestone payment upon AbbVie's achievement of commercialization regulatory approval of MAVIRET™ in Japan. We did not earn any milestones during the same period in 2017.

We also receive annually tiered, double-digit royalties per protease inhibitor product on AbbVie's net sales allocable to either of our collaboration's protease inhibitors. Under the terms of our AbbVie agreement, as amended in October 2014, 50% of AbbVie's net sales of MAVYRET/MAVIRET are allocated to glecaprevir. In the case of regimens containing paritaprevir, 30% of net sales of 3-DAA regimens containing paritaprevir and 45% of net sales of 2-DAA regimens containing paritaprevir are allocated to paritaprevir for purposes of calculating our annually tiered royalties. Beginning with each January 1, the cumulative net sales of each royalty-bearing product start at zero for purposes of calculating the tiered royalties on a product-by-product basis.

Internal Programs

As our internal product candidates are currently in preclinical or early clinical development, we have not generated any revenue from our own product sales and do not expect to generate any revenue from product sales derived from these product candidates for at least the next several years. We expect that our revenue for 2018 and the next several years will be derived from royalties under our current collaboration agreement with AbbVie, as well as any additional

collaboration that we may enter into in the future.

Operating Expenses

The following table summarizes our operating expenses for the three and six months ended March 31, 2018 and 2017:

	Three Months Ended March 31,		Six Months Ended March 31,	
	2018	2017	2018	2017
	(in thousands)			
Research and development	$21,484	$13,004	$39,446	$25,530
General and administrative	5,706	5,461	11,476	10,398
Total operating expenses	$27,190	$18,465	$50,922	$35,928

Research and Development Expenses

Research and development expenses consist of costs incurred to conduct basic research, such as the discovery and development of novel small molecules as therapeutics, as well as any external expenses of preclinical and clinical development activities. We expense all costs of research and development as incurred. These expenses consist primarily of:

- personnel costs, including salaries, related benefits and stock-based compensation for employees engaged in scientific research and development functions;
- third-party contract costs relating to research, formulation, manufacturing, preclinical study and clinical trial activities;
- 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 report information regarding costs incurred for our early-stage research and drug discovery programs on a project-specific basis. We expect that our research and development expenses will continue to increase in the future as we advance our NASH, PBC, RSV and HBV programs.

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

General and Administrative Expenses

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

We expect that general and administrative expenses will increase in the future primarily due to ongoing expansion of our operating activities in support of our own research and development programs, as well as potential additional costs associated with operating a growing public company.

Other Income (Expense), Net

Other income (expense), net, consists of interest income, interest expense and the change in fair value of our Series 1 nonconvertible preferred stock and the change in fair value of our outstanding warrant liability in 2017. Interest

income consists of interest earned on our cash equivalents and short-term and long-term marketable securities balances as well as interest earned for refunds received from tax authorities. Interest expense consists of interest expense related to our capital lease obligation. The change in fair value of our outstanding warrant liability and Series 1 nonconvertible preferred stock relates to the remeasurement of these financial instruments from period to period as these instruments may require a transfer of assets because of the liquidation preference features of the underlying stock. The change in fair value also includes any forfeiture of unexercised warrants which expired on October 4, 2017.

Income Tax (Expense) Benefit

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

Critical Accounting Policies

Our consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amount of assets, liabilities, revenue, costs and expenses, and related disclosures. We believe that the estimates and assumptions involved in the accounting policies described below may have the greatest potential impact on our consolidated financial statements and, therefore, consider these to be our critical accounting policies. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions and conditions. See also our Annual Report on Form 10-K for the fiscal year ended September 30, 2017 (referred to as our 2017 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; and
- Stock-based compensation

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

There have been no material changes in our critical accounting policies since September 30, 2017 aside from the adoption of ASU 2016-09 in the first quarter of fiscal 2018. For further information, please see the discussion of critical accounting policies included in our 2017 Form 10-K.

Results of Operations

Comparison of the Three Months Ended March 31, 2018 and 2017

	Three Months Ended March 31,	
	2018	2017
	(in thousands)	
Revenue	$44,049	$8,959
Research and development	21,484	13,004
General and administrative	5,706	5,461
Other income (expense), net	1,066	549
Income tax (expense) benefit	(5,370)	3,565

Revenue

Three Months Ended

	March 31,	
	2018	2017
	(in thousands)	
AbbVie agreement:		
Royalties	$44,049	$8,959
Total revenue	$44,049	$8,959

We recognized revenue of $44.0 million during the three months ended March 31, 2018 as compared to $9.0 million during the same period 2017. During the three months ended March 31, 2018, revenue consisted of royalties earned on the portion of AbbVie's net sales of its HCV treatment regimens allocable to glecaprevir or paritaprevir. During the three months ended March 31, 2017, our revenue consisted solely of royalties earned on the portion of AbbVie's net sales of its HCV treatment regimen allocable to paritaprevir.

Our revenue is generated through our collaboration with AbbVie. Our collaboration's new MAVYRET/MAVIRET regimen, a pan-genotypic treatment combining two DAAs, began commercialization in the second half of calendar quarter 2017, following its approval in the EU, and U.S., and most recently, Japan. We receive annually tiered, double-digit, per-product royalties on 50% of all net sales of MAVYRET/MAVIRET. Our royalty revenues eligible to be earned in the future will be dependent on AbbVie's HCV market share, the pricing of the MAVYRET/MAVIRET regimen and the number of patients treated.

Research and development expenses

	Three Months Ended March 31,	
	2018	2017
	(in thousands)	
R&D programs:		
Liver disease	$12,259	$8,200
Virology	9,186	4,722
Other	39	82
Total research and development expenses	$21,484	$13,004

Research and development expenses increased $8.5 million for the three months ended March 31, 2018 as compared to the same period in 2017. The increase was primarily due to progression of preclinical and clinical activities in our liver disease and virology programs. Increases were driven by an increase in headcount to support our preclinical studies and an increase in external costs for clinical and preclinical activities.

General and administrative expenses

General and administrative expenses increased by $0.3 million for the three months ended March 31, 2018 as compared to the same period in 2017. The increase was primarily due to a slight increase in compensation expense due to an increase in headcount.

Other income (expense), net

Other income (expense), net, increased $0.5 million for the three months ended March 31, 2018 as compared to the same period in 2017 due to an increase in interest income due to higher average investment balances and an increase in interest rates year over year.

Income tax (expense) benefit

For the three months ended March 31, 2018, we recorded income tax (expense) of $(5.4) million and for the comparable period in 2017, an income tax benefit of $3.6 million. During the three months ended March 31, 2018, our income tax expense was driven by our pre-tax income during the quarter which increased from the prior comparable quarter due to an increase in royalties earned from the AbbVie Agreement. For the three months ended March 31, 2017, our income tax benefit was driven by our pre-tax loss during the quarter.

Comparison of the Six Months Ended March 31, 2018 and 2017

Six Months Ended
March 31,

	2018	2017
	(in thousands)	
Revenue	$82,158	$19,376
Research and development	39,446	25,530
General and administrative	11,476	10,398
Other income (expense), net	2,026	1,073
Income tax (expense) benefit	(9,014)	5,107

Revenue

	Six Months Ended March 31,	
	2018	2017
	(in thousands)	
AbbVie agreement:		
Royalties	$67,158	$19,376
Milestones	15,000	—
Total revenue	$82,158	$19,376

We recognized revenue of $82.2 million during the six months ended March 31, 2018 as compared to $19.4 million during the same period in 2017. During the six months ended March 31, 2018, revenue consisted of a $15.0 million milestone payment earned upon AbbVie's achievement of commercialization regulatory approval of MAVIRET™ in Japan, as well as royalties earned on the portion of AbbVie's net sales of its HCV treatment regimens allocable to glecaprevir or paritaprevir. During the six months ended March 31, 2017, our revenue consisted solely of royalties earned on the portion of AbbVie's net sales of its HCV treatment regimens allocable to paritaprevir.

Research and development expenses

	Six Months Ended March 31,	
	2018	2017
	(in thousands)	
R&D programs:		
Liver disease	$22,969	$14,112
Virology	16,408	11,246
Other	69	172
Total research and development expenses	$39,446	$25,530

Research and development expenses increased $13.9 million for the six months ended March 31, 2018 as compared to the same period in 2017. The increase was primarily due to progression of preclinical and clinical activities in our liver disease and virology programs. Increases were driven by an increase in headcount to support our preclinical activities and an increase in external costs for clinical and preclinical activities.

General and administrative expenses

General and administrative expenses increased by $1.1 million for the six months ended March 31, 2018 as compared to the same period in 2017. The increase was primarily due to an increase in compensation expense due to increased

headcount.

Other income (expense), net

Other income (expense), net, increased $1.0 million for the six months ended March 31, 2018 as compared to the same period in 2017 due to an increase in interest income due to higher average investment balances and an increase in interest rates year over year.

Income tax (expense) benefit

For the six months ended March 31, 2018, we recorded income tax expense of $(9.0) million and for the comparable period in 2017, recorded an income tax benefit of $5.1 million. Income tax expense for the six months ended March 31, 2018 was driven by our pre-tax income for the year which increased from the prior comparable period due to an increase in royalties earned under the AbbVie Agreement. Our estimated annual effective tax rate of 27.1% for the six months ended March 31, 2018, differs from the federal statutory rate of 21.0% due to the revaluation adjustment against deferred tax assets due to a decrease in the federal corporate income tax rate as enacted under the U.S. Tax Cuts and Jobs Act (the “Tax Act”), offset by federal research and development tax credits and excess tax benefits from stock option exercises and restricted stock units vesting during the first half of 2018. For the six months

ended March 31, 2017, we recorded an income tax benefit due to our pre-tax loss during the first half of fiscal 2017. Our estimated annual effective tax rate of 33.0% for the six months ended March 31, 2017, differs from the prior year U.S. statutory rate of 35.0% due to federal research and development tax credits which reduced our estimated annual effective tax rate slightly below the statutory rate.

Estimates used to prepare our income tax expense are based on our initial analysis of the Tax Act. Given the complexity of the Tax Act, anticipated guidance from the U.S. Treasury regarding implementation of the act, and potential for guidance from the Securities and Exchange Commission or the Financial Accounting Standards Board related to the act, these estimates may be adjusted during our fiscal 2018 to reflect any such guidance provided.

Liquidity and Capital Resources

At March 31, 2018, our principal sources of liquidity were cash, cash equivalents and short-term and long-term marketable securities totaling $288.9 million.

For the periods presented, we have financed our operations primarily through payments under our AbbVie collaboration. The following table shows a summary of our cash flows for the six months ended March 31, 2018 and 2017:

	Six Months Ended March 31,	
	2018	2017
	(in thousands)	
Cash provided by (used in):		
Operating activities	$(3,169)	$143
Investing activities	$4,009	$2,671
Financing activities	$411	$(180)
Net increase in cash and cash equivalents	$1,251	$2,634

Net cash provided by (used in) operating activities

The decrease in cash provided by operating activities of $3.3 million for the six months ended March 31, 2018 as compared to the same period in 2017 is driven primarily by timing of payments received under our collaboration with AbbVie year over year, which were substantially offset by increased expenditures in research and development in order to progress clinical development and preclinical research in our proprietary programs. We received $48.7 million in cash during the six months ended March 31, 2018 from AbbVie, including royalties and a $15.0 million milestone payment, compared to $23.3 million in cash during six months ended March 31, 2017 which consisted exclusively of royalties. The increase in cash received from our collaboration agreement was offset by an increase in cash spending on research and development to progress clinical development and preclinical research in our proprietary programs, an increase in taxes paid of $8.9 million year over year due to timing of estimated tax payments and a decrease in tax refunds received year over year of $4.9 million.

Net cash provided by investing activities

The increase in cash provided by investing activities of $1.3 million for the six months ended March 31, 2018 as compared to the same period in 2017 was driven by the timing of purchases, sales and maturities of marketable securities.

Net cash provided by (used in) financing activities

The increase in net cash provided by financing activities of $0.6 million for the six months ended March 31, 2018 as compared to the same period in 2017 was driven by an increase proceeds from stock option exercises during the first half of 2018 as a result of the increase of the price of our common stock as compared to 2017.

Funding requirements

As of March 31, 2018, we had $288.9 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 March 31, 2018 will be sufficient to meet our anticipated cash requirements for the foreseeable future. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially.

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

- whether our existing collaboration continues to generate substantial royalties to us;
- the number and characteristics of the future product candidates we pursue;
- the scope, progress, results and costs of researching and developing any of our product candidates on our own, including conducting preclinical research and clinical trials;
- opportunities to in-license or otherwise acquire new technologies, therapeutic candidates and therapies;
- the timing and amount of royalties on glecaprevir and paritaprevir and any sales of our product candidates, if any, or royalties thereon;
- the timing of, and the costs involved in, obtaining regulatory approvals for any product candidates we develop independently;
- the cost of commercialization activities, if any, of any product candidates we develop independently that are approved for sale, including marketing, sales and distribution costs;
- the cost of manufacturing our product candidates and any products we successfully commercialize independently, including manufacturing for clinical development;
- our ability to maintain our existing collaboration and to establish new collaborations, licensing or other arrangements and the financial terms of such agreements; and
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patents, including any litigation costs and the outcomes of any such litigation.

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 2017 Form 10-K 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 six months ended March 31, 2018.

Recently Issued Accounting Pronouncements

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Interest Rate Sensitivity

We had cash, cash equivalents and short-term and long-term marketable securities of $288.9 million at March 31, 2018 consisting of cash, money market funds, commercial paper, corporate bonds and government securities. Interest income is sensitive to changes in the general level of interest rates; however, due to the nature of these investments, a 1% change in market interest rates would not be expected to have a material impact on our financial condition or results of operations. Other than our capital lease obligation, we had no debt outstanding as of March 31, 2018.

ITEM 4. CONTROLS AND PROCEDURES

a) Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures.

Our management, with the participation of the principal executive officer and principal financial officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”)) as of the end of the period covered by this quarterly report. Based on this evaluation, the principal executive officer and principal financial officer concluded that these disclosure controls and

procedures are effective and designed to ensure that the information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the requisite time periods.

b) Changes in Internal Control Over Financial Reporting.

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

PART II —OTHER INFORMATION

ITEM 1A.RISK FACTORS

RISK FACTORS

Our business faces significant risks and uncertainties, any of which, alone or in combination with others, may have a material adverse effect on our business prospects, financial condition and results of operations. Accordingly, in evaluating our business, we encourage you to consider the following summary of the risk factors and uncertainties that we believe are most relevant to our business. You should carefully consider the risks described below before making an investment decision, and understand that it is not possible to predict or identify all such factors. 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. In addition, we operate in a competitive and rapidly changing environment. New factors emerge from time to time and it is not possible to predict the impact of all of these factors on our business, financial condition or results of operations. We undertake no obligation to publicly update forward-looking statements, whether as a result of new information, future events, or otherwise.

The statement of risk factors provided in this Item 1A includes any material changes to and supersedes the statement of risk factors associated with our business previously disclosed in Item 1A of our Quarterly Report on Form 10-Q for the quarter ended December 31, 2017 filed on February 9, 2018 with the Securities and Exchange Commission (SEC). In assessing these risks, investors should also refer to the other information contained or incorporated by reference in this Form 10-Q and our other filings made from time to time with the SEC.

Risks Related to Our Business

Our financial prospects for the next several years are dependent upon the commercialization efforts of AbbVie for combination therapies incorporating our protease inhibitor, glecaprevir, 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 commercialization of its regimen containing glecaprevir (our second protease inhibitor, which is one of the two DAAs in AbbVie's MAVYRET/MAVIRET treatment), over which we have granted AbbVie complete control. Our ability to generate revenue will depend primarily on the success of AbbVie's continued efforts to commercialize MAVYRET/MAVIRET. Such success is subject to significant uncertainty, and we have no control over the resources, time and effort that AbbVie may devote to this regimen. Any of several events or factors could have a material adverse effect on our ability to generate revenue from AbbVie's commercialization of glecaprevir in combination therapies. For example, AbbVie:

- may not achieve satisfactory levels of market acceptance and reimbursement by physicians, patients and third-party payers for the MAVYRET/MAVIRET regimen in the various markets of the world where it is being introduced and sold by AbbVie;
- may not compete successfully with its MAVYRET/MAVIRET regimen against other products and therapies for HCV;
- may have to comply with additional requests and recommendations from the FDA, including label restrictions for its regimen containing glecaprevir;
- may not make all regulatory filings and obtain all necessary approvals from foreign regulatory agencies and all commercially necessary reimbursement approvals;
-

may not commit sufficient resources to the marketing and distribution of MAVYRET/MAVIRET, 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; and

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

We do not have access to all information regarding the HCV regimens being commercialized by AbbVie, including certain information about 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 licensed under our collaboration is limited by the degree to which AbbVie keeps us informed. If AbbVie does not perform in the manner we expect or fulfill its responsibilities in a timely manner, or at all, the global commercialization of MAVYRET/MAVIRET could be delayed or terminated in selected jurisdictions or be commercially unsuccessful. In addition, AbbVie has the right to make decisions regarding the commercialization of licensed products without consulting us, and may make decisions with which we do not agree. If AbbVie acts in a manner that is not in our best interest, then it could adversely affect our business and prospects.

Our royalty revenues are derived from AbbVie's net sales of regimens to treat HCV. If AbbVie is unable to increase and maintain sales of these regimens above current levels of sales, our royalty revenues and results of operations would be adversely affected.

Our quarterly royalty revenue from AbbVie's net sales of HCV treatment regimens containing paritaprevir has declined since those sales peaked in the first quarter of our fiscal 2016. AbbVie has priced the MAVYRET/MAVIRET regimen well below the pricing of its first HCV regimens, and below that of its principal competitor, which means AbbVie will need to capture significant increases in market share to maintain or increase its HCV net sales and our royalty revenues. While commercialization of these regimens is exclusively in AbbVie's control without any input from us, we believe it is possible that prices will decline further due to payers obtaining additional discounts or competitive market dynamics and that there may be fluctuation in AbbVie's market share over time due to competitive actions by its principal competitor, Gilead. We also note Gilead has reported a decline year over year across most major geographic markets in the number of new patients starting on DAA treatments for HCV.

In addition, in light of continued fiscal crises experienced by several countries in the European Union and Japan, governments have announced or implemented measures to manage and reduce healthcare expenditures. AbbVie may experience global pricing pressure for its HCV regimens from such measures, which may be reflected in larger discounts or rebates on its regimens or delayed reimbursement. Also, private and public payers may choose to exclude AbbVie's regimens from their formulary coverage lists or limit the types of patients for whom coverage will be provided. Any such change in formulary coverage, discounts or rebates or reimbursement for AbbVie's HCV regimens would negatively affect the demand for such regimens and our royalty revenues from them.

We and AbbVie face substantial competition in the markets for HCV drugs, and there are many companies developing potential therapies for NASH, PBC, RSV and HBV, as well as other liver diseases and viral infections, which may result in others discovering, developing or commercializing products before we do or doing so more successfully than we do.

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, PBC, RSV, HBV and other viral infections 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.

In all the disease areas currently under the focus of our research and development efforts, there are other companies with more product candidates that are more advanced than ours. Our competitors may succeed in developing these product candidates or others and obtaining regulatory approval before we can do so with any of our product candidates. If we are not “first to market” with one of our product candidates in one or more of these 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 follow-on competitor. In addition, any new product that competes with an approved product typically must demonstrate compelling advantages in efficacy, convenience, tolerability or safety, or some combination of these factors, in order to gain regulatory approvals, overcome price competition and be commercially successful.

We expect AbbVie’s MAVYRET/MAVIRET to continue to face intense competition due to existing approved products in the HCV market. AbbVie’s HCV treatment regimens currently face competition in various world markets and subpopulations of HCV from Gilead’s Sovaldi® (sofosbuvir), Harvoni® (a fixed-dose combination of sofosbuvir and ledipasvirm), Epclusa® (a fixed dose combination of sofosbuvir and velpatasvir) and Vosevi™ (a triple combination therapy of sofosbuvir, velpatasvir and voxilaprevir approved by the FDA in July 2017 for specified sofosbuvir -treatment failures and NS5A-inhibitor treatment failures); and to a lesser extent - Merck’s Zepatier® (a fixed-dose combination of grazoprevir and elbasvir). Competitive products in the form of other treatment

methods or a vaccine for HCV may render AbbVie's HCV regimens obsolete or noncompetitive. AbbVie's regimens that contain one of our collaboration's protease inhibitors will face competition based on their safety and effectiveness, reimbursement coverage, price, patent position, AbbVie's marketing and sales capabilities, and other factors. If any of AbbVie's HCV regimens face competition from generic products, the collaboration agreement provides that the royalty rate applicable to our protease product contained in the regimen is reduced significantly by a specified percentage on a product-by-product, country-by-country basis. If AbbVie is not able to compete effectively against its competitors in HCV, our business will not grow and our financial condition, operations and stock price will suffer.

We also expect our other product candidates to face intense and increasing competition in the NASH and antiviral markets and as advanced technologies and products become available. 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 3 in NASH, namely Intercept, Genfit, Gilead, and Tobira (Allergan). In May 2016, the FDA granted conditional approval for Intercept's FXR agonist (brand name Ocaliva®) for the treatment of primary biliary cholangitis (PBC) in combination with first line therapy ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA. In addition, a number of companies are in Phase 2 clinical trials for NASH or related conditions. These companies include Alberio, Astra-Zeneca, BMS, Boehringer Ingelheim, Conatus, Cirius, Cymabay, Galectin, Galmed, Gilead, GlaxoSmithKline, Immuron, Inventiva, Madrigal, Medicinova, Northsea Therapeutics, Novartis, NGM, Novo Nordisk, Pfizer, Shire, and Viking. A significant number of other companies are conducting earlier clinical trials that may be applicable in NASH and other cholestatic diseases. There are also additional companies conducting preclinical studies in these disease areas.

Similarly, HBV and RSV represent competitive therapeutic areas. While there are effective antiviral medications prescribed for HBV, they generally have low true cure rates. Many companies are seeking to develop new HBV drugs that alone or in combination with other mechanisms could lead to a functional cure of HBV. Arbutus, Gilead, HEC, Ionis, Johnson & Johnson, Maxwell, Replicor, Roche and Spring Bank have Phase 2 programs in progress, with many of these companies conducting earlier stage programs as well. In addition, a number of companies have Phase 1 or earlier stage HBV programs, including Aicuris, Alnylam, Altimmune, Assembly, Arrowhead, Enyo and Transgene.

For RSV, there are currently no safe and effective therapies for already established RSV infection. Several companies are seeking new antiviral treatments for RSV infection in adult and pediatric settings. Ark Bioscienes, Johnson & Johnson, Gilead, Pulmocide and ReViral each have compounds in clinical development, as does Ablynx with a potential therapeutic antibody. A prophylactic, monoclonal-antibody-based treatment from MedImmune, which is commercialized by AbbVie outside of the U.S., is approved for infants considered at high risk for RSV infection; however studies have found that most young children with RSV infection were previously healthy, and thus would not normally be prescribed prophylactic treatment. In addition, a number of companies have RSV vaccines in development, primarily directed at prevention of RSV infection, and some companies are also evaluating vaccines in a therapeutic mode for treatment of established RSV infection.

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 product candidates.

AbbVie has been responsible for all of the clinical development of our paritaprevir and glecaprevir protease inhibitor products. We have not yet demonstrated an ability to address successfully 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 NASH, PBC, RSV and HBV programs, we will need to successfully:

- execute clinical development of our product candidates and demonstrate acceptable safety and efficacy for them alone or in combination with other drugs or drug candidates;
- obtain required regulatory approvals for the development and commercialization of our 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 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 product candidates and expand our business or continue our operations.

If we are not successful in discovering further product candidates in addition to EDP-305 and EDP-938, our ability to expand our business and achieve our strategic objectives will be impaired.

Much of our internal research is 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 product candidates less commercially viable or obsolete;
- competitors may obtain intellectual property protection that effectively prevents us from developing a product candidate;
- a product candidate may, on further study, be shown not to be an effective treatment in humans or 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 product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all.

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 the 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.

Expenses associated with development of our product candidates may cause our results of operations to fluctuate from period to period, which may result in operating losses.

Many of the preclinical and clinical development activities required for our product candidates have to be contracted out to contract research organizations (CROs) at significant expense. We expect these expenses to increase substantially in the coming years as we advance compounds and conduct more clinical studies. It is difficult to accurately predict the timing and amounts 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 product 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.

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, Yat Sun Or, Ph.D., our Senior Vice President, Research and Development and Chief Scientific Officer, and Nathalie Adda, M.D., our Senior Vice President, Chief Medical 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 the 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 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 ultimately seek regulatory approvals and prepare for 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.

To date, our principal sources of revenue have been our collaboration agreements, including our current agreement with AbbVie. Future levels of royalties under the AbbVie agreement are uncertain. We have had no other 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 past four fiscal years, our net income resulted primarily from license payments, including milestone payments we earned from AbbVie and royalties we earned since December 2014 on net sales of AbbVie's HCV regimens allocated to our protease inhibitors included in those regimens. There is no assurance, however, that we will report net income in subsequent years. To date, we have not commercialized any products ourselves.

Our principal source of revenue historically has been our collaboration agreements, including our current agreement with AbbVie. The level of future royalties on products containing paritaprevir or glecaprevir is uncertain given the competitive nature of the market for HCV therapies. This is attributed to price competition, the changing nature of payer contracts of AbbVie and others, and the varying rates of reimbursement in different countries. At any time, AbbVie may choose not to continue its commercialization activities for the MAVYRET/MAVIRET regimen or that regimen 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 a collaborator, or if any such product candidate does not achieve market acceptance, we may not generate sufficient product sales or product royalties. In addition, for any of our product candidates 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. 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 could 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 containing regimens is curtailed or if any launch or commercialization of MAVYRET/MAVIRET is not successful. 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 AbbVie in developing MAVYRET/MAVIRET. 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:

- whether our existing collaboration continues to generate substantial royalties to us;
- the number and characteristics of the product candidates we pursue;
- the scope, progress, results and costs of researching and developing any of our product candidates on our own, including conducting preclinical research and clinical trials;

- opportunities to in-license or otherwise acquire new therapeutic candidates and therapies;
- the timing, receipt and amount of royalties on paritaprevir and glecaprevir and any sales of our product candidates, if any, or royalties thereon;
- the timing of, and the costs involved in, obtaining regulatory approvals for any product candidates we develop independently;
- the cost of commercialization activities, if any, of any product candidates we develop independently that are approved for sale, including marketing, sales and distribution costs;
- the cost of manufacturing our product candidates and any products we successfully commercialize independently, including manufacturing for clinical development;
- our ability to maintain our existing collaboration and to establish new collaborations, licensing or other arrangements and the financial terms of such agreements; and
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patents, including any litigation costs and the outcomes of any such litigation.

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.

The U.S. Tax Cuts and Jobs Act enacted in December 2017 includes significant changes from current tax legislation which could result in significant changes to our future tax positions.

The U.S. Tax Cuts and Jobs Act (the “Tax Act”) enacted in December 2017 contains many provisions which differ from current tax law. These changes include, but are not limited to, the reduction in the federal corporate income tax rate from 35% to 21%, the elimination of a corporation’s ability to carryback net operating losses to prior taxable income periods and the elimination of the deductibility of certain performance-based equity awards under Section 162(m). We accounted for the Tax Act during the six months ended March 31, 2018, which resulted in an adjustment that decreased our deferred tax assets by $3.8 million due to the reduction of the federal corporate income tax rate from 35% to 21%. Estimates used to prepare our income tax expense during the quarter are based on our initial analysis of the Tax Act. Given the complexity of the act, anticipated guidance from the U.S. Treasury regarding implementation of the act, and potential for guidance from the Securities and Exchange Commission or the Financial Accounting Standards Board related to the act, these estimates may be adjusted during our fiscal 2018 to reflect any such guidance provided.

Our government funded contract for our antibiotic program, which was 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, was 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 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 and require payments by us to the U.S. government.

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 of any of our proprietary product candidates are prolonged or delayed, we 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 and glecaprevir, which have been clinically developed by AbbVie, has yet to advance beyond completion of Phase 2 clinical trials. Any future clinical trials of our product candidates may fail to demonstrate sufficient safety and efficacy. Moreover, regulatory and administrative delays for any product candidate in our pipeline may adversely affect our or any future collaborator's clinical development plans and jeopardize our or any future collaborator's ability to attain product approval, commence product sales and compete successfully against other therapies.

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

- reaching an 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 treatments for NASH, PBC, RSV or HBV;
- 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.

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 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 any future 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 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.

We may choose to test any of our clinical candidates preclinically and/or clinically in combination with other compounds with different mechanisms of action, and any adverse results from such testing may have adverse consequences for the further development potential of not only the combination but also the clinical candidate itself as a monotherapy or in combination with other mechanisms of action.

We expect that the further development of successful therapies in our principal disease areas of NASH, RSV and HBV may require combining one or more of our compounds with other compounds with different mechanisms of action. To advance our programs and achieve favorable opportunities for any such combinations we may conduct preclinical testing, as well as clinical testing, with one of our other compounds or with a compound of a third party,

with or without a longer-term collaboration with any such party. We may choose to disclose such testing in advance, but we can anticipate that some of the testing would be done without any public disclosure. If any such testing produces adverse results, we may have to disclose it to regulatory authorities as part of the data available with respect to our product candidate and the data may have adverse consequences for the further development and the ultimate conditions attached to any approved use of the product candidate, whether in the combination tested or even as a monotherapy or in combination with other mechanisms.

EDP-305, EDP-938 or any other product candidate emerging from our current NASH, PBC, RSV and HBV programs may have undesirable side effects which may delay or prevent marketing approval, or, if approval is received, require our product candidate to be taken off the market, require us to include safety warnings or otherwise limit sales.

In our NASH/PBC program, we are developing agonists of the farnesoid X receptor, or FXR, that are designed to bind to that receptor and then trigger a response from it. The adverse effects from long-term exposure to the FXR drug class are not well known since within this class only two drugs have been approved by the FDA—Ocaliva®, approved in May 2016 for PBC, and an older drug not commonly used but approved to treat cholesterol gallstones (by dissolving them) and a rare lipid storage disease. 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 could be significant.

In addition, our drug candidates for NASH may 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 populations that may 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 and our stock price may suffer.

Any of these events could prevent us 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 revenue from the sale of any product we develop.

If we are required to suspend or discontinue clinical trials due to side effects or other safety risks associated with our product candidates, or if we are required to conduct studies on the long-term effects associated with the use of any of those product candidates, commercialization any of those 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 may voluntarily suspend or terminate clinical trials if at any time one of our product candidates, or a combination therapy including any of them, presents an unacceptable safety risk to the clinical trial patients. In addition, IRBs or regulatory agencies may order the temporary discontinuation or termination of clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements, including if they present an unacceptable safety risk to patients. Administering any product candidate to humans may produce undesirable side effects. The existence of undesirable side effects resulting from any of our product candidates, or a combination therapy including any of them, could cause us 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 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 may not be predictive of the results of later-stage clinical trials, if any. 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.

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 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 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 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 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. AbbVie obtained all regulatory approvals for its paritaprevir-containing regimens and for MAVYRET/MAVIRET, which contains glecaprevir. We have not obtained regulatory approval by ourselves for any of our wholly owned 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 clinical trials;
- we 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 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 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;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies of any of our product candidates; 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 clinical data insufficient for approval.

We cannot be assured that after spending substantial time and resources, we will obtain regulatory approvals in any desired jurisdiction. Even if we were to obtain approval, regulatory authorities may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Significant clinical trial delays could allow our competitors to obtain marketing approval before we do or could in effect shorten the patent protection period during which we may have the exclusive right to commercialize our product candidates. In addition, it may ultimately not be possible to achieve the prices intended for our products. In many foreign countries, including those in the European Union, a product candidate must be approved for

reimbursement before it can be approved for sale in that country. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates and our business.

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

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

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

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

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

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

Even though the results of preclinical studies and clinical trials that we have conducted or may conduct in the future may support further development of one or more of our product candidates, we may delay, suspend or terminate the future development of a product candidate at any time for strategic, business, financial or other reasons, including the determination or belief that the emerging profile of the product candidate is such that it may not receive regulatory approvals in key markets, gain meaningful market acceptance, otherwise provide any competitive advantages in its intended indication or market or generate a significant return to stockholders. Such a delay, suspension or termination could materially harm our business, results of operations or financial condition. In addition, AbbVie has the right to

make decisions regarding the commercialization of paritaprevir and glecaprevir without consulting us, and may make decisions with which we do not agree.

Risks Related to Commercialization of Our Product Candidates

Even if AbbVie successfully commercializes MAVYRET/MAVIRET, or even if we are able to commercialize any other treatment regimen containing one of our product candidates from any of our proprietary discovery programs, MAVYRET/MAVIRET or the resulting products, as the case may be, may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives in the United States, which would harm our business.

The regulations that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. In the United States, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010, collectively referred to as the ACA, is significantly changing the way healthcare is financed by both governmental and private insurers. While we cannot predict what impact on federal reimbursement policies this law or any amendment to it will continue to have in general or specifically on any product or regimen that we may commercialize, the ACA or any such amendment may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of new products. In addition, although the United States Supreme Court has upheld the constitutionality of most of the ACA, several states have not implemented certain sections of the ACA, including 18 that have rejected the expansion of Medicaid eligibility for low income citizens, and some members of the U.S. Congress are still working to repeal the ACA. More recently, President Trump and the Republican majorities in both houses of the U.S. Congress have been seeking to repeal or replace all or portions of the ACA but to date they have been unable to agree on any such legislation. We cannot predict what legislation, if any, to repeal or replace the ACA will become law, or what impact any such legislation may have on us or on AbbVie's commercialization of its HCV regimens.

Our ability to commercialize any product candidate successfully, as well as AbbVie's commercialization of MAVYRET/MAVIRET, will also depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. In the case of HCV, limitations of coverage have recently been used to limit access to HCV treatments for only those patients with more advanced fibrosis. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and, in many cases involving HCV drugs, seeking discounts in exchange for greater patient access to a particular HCV drug. In addition, there are private and public payors challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product that we may commercialize and, if reimbursement is available, the level of reimbursement. In addition, reimbursement may impact the demand for, or the price of, MAVYRET/MAVIRET or any product candidate for which we may obtain marketing approval. If reimbursement is not available or is available only to limited levels, AbbVie may not be successful in commercializing MAVYRET/MAVIRET and we may not be able to successfully commercialize any product candidate for which we may seek marketing approval.

There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable authorities in other jurisdictions. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also be insufficient to cover our and any collaborator's costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by

government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. AbbVie's inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for MAVYRET/MAVIRET, or our inability to do the same for any product candidate that we develop, could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

In general, the United States and several other jurisdictions are considering a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access to healthcare. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. We expect to experience pricing pressures in connection with the sale of any products that we develop or that are being commercialized under our collaboration with AbbVie. The implementation of cost containment measures or other healthcare reforms may limit our ability to generate revenue, maintain profitability or commercialize our product candidates.

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

We do not have a sales or marketing infrastructure and have no sales, marketing or distribution experience. We will seek to either build our own commercial infrastructure to commercialize any products if and when they are approved, or enter into licensing or collaboration agreements where our collaborator is responsible for commercialization, as in the case of our collaboration with AbbVie, or where we have the right to assist in the future development and commercialization of such products.

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

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

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

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

Our commercial success depends upon significant market acceptance among physicians, patients and healthcare payors of MAVYRET/MAVIRET, as well as similar market acceptance of any product candidates we are developing independently.

MAVYRET/MAVIRET, as well as EDP-305, EDP-938, or any other product candidate that we may develop in the future, whether as part of a combination therapy or as a monotherapy, may not gain market acceptance among physicians, healthcare payors, patients and the medical community. The degree of market acceptance of MAVYRET/MAVIRET or of any product candidate for which we obtain approval for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of treatment regimens containing one of our product candidates, as demonstrated in clinical trials, and the degree to which these regimens represent a clinically meaningful improvement in care as compared with other available therapies;
- the clinical indications for which any treatment regimen containing one of our product candidates become approved;
- acceptance among physicians, major operators of clinics, payors and patients of any treatment regimen containing one of our product candidates;

- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the potential and perceived advantages of treatment regimens containing one of our product candidates over alternative treatments;
- the cost of treatment of regimens containing one of our product candidates in relation to the cost of alternative treatments;
- the availability of adequate reimbursement and pricing by third parties and government authorities and successful negotiation of favorable agreements with payors by us or any collaborator of ours, as well as the impact of any agreements among any of the foregoing and one or more of our competitors limiting access to our product in favor of one or more competitive products;

- the continued longevity of the HCV drug market or growth and longevity of any other market for which we develop a drug;
- the levels of funding provided by government-funded healthcare for HCV treatment or treatment of any other disease for which we develop a drug;
- the relative convenience and ease of administration of any treatment regimen containing one of our product candidates compared to competitive regimens;
- the prevalence and severity of adverse side effects, whether involving the use of treatment regimens containing one of our products candidates or similar, competitive treatment regimens; and
- the effectiveness of our sales and marketing efforts and those of AbbVie in the case of MAVYRET/MAVIRET.

If treatment regimens containing one of our product candidates are approved and then fail to achieve market acceptance, we may not be able to generate significant additional revenue. Further, if new, more favorably received therapies are introduced after any such regimen achieves market acceptance, then we may not be able to maintain that market acceptance over time.

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

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

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

Risks Related to Our Dependence on Third Parties

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

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

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

- the development of certain of our product candidates may be terminated or delayed;
- our cash expenditures related to development of certain of our product candidates would increase significantly and we may need to seek additional financing;
- we may be required to hire additional employees or otherwise develop expertise, such as clinical, regulatory, sales and marketing expertise, which we do not currently have;

- we will bear all of the risk related to the development of any such product candidates; and
- the competitiveness of any product candidate that is commercialized could be reduced.

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

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

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

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

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

A portion of our research and a portion of our manufacturing of certain key intermediates used in the manufacture of the active pharmaceutical ingredients for our product candidates takes place in China through third-party researchers and manufacturers. A significant disruption in the operation of those researchers or manufacturers, a trade war, or political unrest in China could materially adversely affect our business, financial condition and results of operations.

Although manufacturing for MAVYRET/MAVIRET is being conducted by AbbVie, we have relied on third parties located in China to manufacture and supply certain key intermediates used in the manufacture of our active pharmaceutical ingredients, or API, for our current product candidates, and we expect to continue to use such third party manufacturers for such intermediates for any product candidates we develop independently. Any disruption in production or inability of our manufacturers in China to produce adequate quantities to meet our needs, whether as a result of a natural disaster or other causes, could impair our ability to operate our business on a day-to-day basis and to continue our research and development of our product candidates. We also use contract researchers in China to conduct a portion of our research for our early stage programs. Any disruption in the team conducting that research could cause delays in one or more of our research programs and could require us to curtail one or more programs, at least until we could

contract for that research to be done elsewhere. Furthermore, since these researchers and manufacturers are located in China, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the United States or Chinese governments, political unrest or unstable economic conditions in China. For example, a trade war could lead to tarrifs on the chemical intermediates we use that are manufactured in China. Any of these matters could materially and adversely affect our business and results of operations. Any recall of the manufacturing lots or similar action regarding our API used in clinical trials could delay the trials or detract from the integrity of the trial data and its potential use in future regulatory filings. In addition, manufacturing interruptions or failure to comply with regulatory requirements by any of these manufacturers could significantly delay clinical development of potential products and reduce third-party or clinical researcher interest and support of proposed trials. These interruptions or failures could also impede commercialization of our product candidates and impair our competitive position. Further, we may be exposed to fluctuations in the value of the local currency in China. Future appreciation of the local currency could increase our costs. In addition, our labor costs could continue to rise as wage rates increase due to increased demand for skilled laborers and the availability of skilled labor declines in China.

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

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

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

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

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

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

Risks Related to Our Intellectual Property Rights

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

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

In addition, certain of our activities have been funded, and may in the future be funded, by the United States federal government. For example, the preclinical and early clinical development of the lead antibiotic product candidate in our former antibiotic program, which we are no longer developing, was funded under a contract with NIAID, an entity of the United States federal government. When new technologies are developed with United States federal government funding, the government obtains certain rights in any resulting patents, including a nonexclusive license authorizing the government to use the invention for non-commercial purposes. These rights may permit the government to disclose our confidential information to third parties and to exercise “march-in” rights to use or allow third parties to use our patented technology. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the United States government-funded technology, or because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations or to give preference to United States industry. In addition, United States government-funded inventions must be reported to the government and United States government funding must be disclosed in any resulting patent applications. In addition, our rights in such inventions are subject to certain requirements to manufacture products in the United States.

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

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

prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on a product candidate. Even if a defendant does not prevail on a legal assertion of invalidity and/or unenforceability, our patent claims may be construed in a manner that would limit our ability to enforce such claims against the defendant and others. Any loss of patent protection could have a material adverse impact on one or more of our product candidates and our business.

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

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

Our commercial success depends upon our ability to develop, manufacture, market and sell our product candidates and use our proprietary technology without infringing the intellectual property rights of others. We cannot guarantee that our product candidates or any uses of our product candidates do not and will not in the future infringe third-party patents or other intellectual property rights.

Third parties might allege that we or our collaborators are infringing their patent rights or that we have misappropriated their trade secrets, or that we are otherwise violating their intellectual property rights, whether with respect to the manner in which we have conducted our research or to the composition, use or manufacture of the compounds we have developed or are developing with our collaborators. Such third parties might resort to litigation against us or other parties we have agreed to indemnify, which litigation could be based on either existing intellectual property or intellectual property that arises in the future.

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

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

In addition, if AbbVie licenses or otherwise acquires rights to intellectual property controlled by a third party in various circumstances, for example, where a product could not be legally developed or commercialized in a country without the third-party intellectual property right, it is entitled under our collaboration agreement to decrease payments payable to us on a product-by-product basis and, in certain cases, on a country-by-country basis. Any of the foregoing events could harm our business significantly.

Defending against claims of patent infringement, misappropriation of trade secrets or other violations of intellectual property rights could be costly and time consuming, regardless of the outcome. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs. In addition, litigation or threatened litigation could result in significant demands on the time and attention of our management team, distracting them from the pursuit of other company business. Claims that our product candidates or the sale or use of our future products infringe, misappropriate or otherwise violate third-party intellectual property rights could therefore have a material adverse impact on our business.

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

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

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

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

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

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

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

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

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

Our collaborators may have rights to publish data and other information to which we have rights. In addition, we sometimes engage individuals or entities to conduct research relevant to our business. The ability of these

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

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

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

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

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

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

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

and patents that we might obtain in the future.

Risks Related to Our Industry

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

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

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

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

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We currently carry product liability insurance covering our clinical studies in the amount of $10.0 million in the aggregate. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

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

Despite the implementation of security measures, our internal computer systems and those of our collaborators, CROs, and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Information security risks have significantly increased in recent years in part due to the proliferation of new technologies and the increased sophistication and activities of organized crime, hackers, terrorists and other external parties, including foreign state actors. As cyber threats continue to evolve, we may be required to expend significant additional resources to continue to modify or enhance our protective measures or to investigate and remediate any information security breaches.

While we have not experienced any such system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our independent drug development programs. For example, the loss of clinical trial data from ongoing or future clinical trials for any of our product candidates could result in delays in regulatory approval efforts and significantly increase costs to recover or reproduce the data. Our information security systems are also subject to laws and regulations requiring that we take measures to protect the privacy and security of certain information we gather and use in our business. For example, HIPAA and its implementing regulations impose, among other requirements, certain regulatory and contractual requirements regarding the privacy and security of personal health information. In addition to HIPAA, numerous other

federal and state laws, including, without limitation, state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use, disclosure and storage of personal information. To the extent that any disruption or security breach were to result in a loss of or damage to data or applications, or inappropriate disclosure of confidential or proprietary information or personal health information, we could incur substantial liability, our reputation would be damaged, and the further development of our product candidates could be delayed.

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

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

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

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

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

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

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

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

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

Our insurance policies are expensive and only protect us from specified business risks, which will leave us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include general liability, employment practices liability, property, auto, workers' compensation, products liability and directors' and officers' insurance. We do not know, however, if we have adequate levels of coverage for any liability we may incur, or whether we will always be able to continue to maintain such insurance. Any significant uninsured liability may require us to make substantial payments, which would adversely affect our financial position and results of operations. Furthermore, any increase in the volatility of our stock price may result in us being required to pay substantially higher premiums for our directors' and officers' liability insurance than those to which we are currently subject, and may even cause one or more of our underwriters to be unwilling to insure us.

Risks Related to Our Common Stock

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

Our stock price has been volatile and could be subject to wide fluctuations in response to various factors, many of which are beyond our control. Since our initial public offering in March 2013 and through May 8, 2018, the price of our common stock on the NASDAQ Global Select Market has ranged from $16.18 to $107.29. The stock market in general and the market for biopharmaceutical companies, and for those developing potential therapies for viral infections and liver diseases in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above your purchase price, if at all. The market price for our common stock may be influenced by many factors, including:

- actions by AbbVie regarding HCV treatment regimens containing paritaprevir or the MAVYRET/MAVIRET regimen containing glecaprevir as approved in the U.S., EU and Japan, including announcements regarding clinical, regulatory or commercial developments or our collaboration;
- market expectations about and response to the levels of sales or scripts achieved by, or the announced prices or discounts for, AbbVie's MAVYRET/MAVIRET regimen or competitive HCV drugs;
- failure of AbbVie's paritaprevir-containing HCV treatment regimens to maintain their sales levels or AbbVie's MAVYRET/MAVIRET regimen to achieve commercial success;
- results from or delays of clinical trials of our other product candidates, as well as results of regulatory reviews relating to the approval of our product candidates;
- new products, product candidates or new uses for existing products or technologies introduced or announced by our competitors and the timing of these introductions or announcements;
- the results of our efforts to discover or develop additional product candidates;

- our dependence on third parties, including our collaborators, CROs, manufacturers, clinical trial sponsors and clinical investigators;
- regulatory, political or legal developments in the United States or other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key scientific or management personnel;
- our ability to commercialize our product candidates we develop independently, if approved;
- the level of expenses related to any of our product candidates or clinical development programs;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- period-to-period variations in our financial results or those of companies that are perceived to be similar to us;
- sales of common stock by us or our stockholders in the future, as well as the overall trading volume of our common stock;
- changes in the structure of healthcare payment systems or other actions that affect the effective reimbursement rates for treatment regimens containing our products or for competitive regimens;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies; and
- the other factors described in this “Risk Factors” section.

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

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

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

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

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

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

Our executive officers are parties to employment agreements that provide for aggregate cash payments of up to approximately $4.5 million for severance and other non-equity-based benefits in the event of a termination of employment in connection with a change of control of our company. In addition, based on the closing price of our common stock as of March 31, 2018 of $80.91 per common share, the aggregate intrinsic value of unvested stock options and other equity awards subject to accelerated vesting upon these events was $40.5 million. The accelerated vesting of awards options could result in dilution to our stockholders and harm the market price of our common stock. The payment of these severance benefits could harm our company's financial condition and results. In addition, these potential severance payments may discourage or prevent third parties from seeking a business combination with us.

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

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

We are required to disclose changes made in our internal controls and procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. However, for as long as we are an "emerging growth company" under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. We will cease to be an "emerging growth company" as of our fiscal year ending September 30, 2018. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

Because we do not anticipate paying cash dividends on our common stock for the foreseeable future, investors in our common stock may never receive a return on their investment.

You should not rely on an investment in our common stock to provide dividend income. We do not anticipate that we will pay any cash dividends to holders of our common stock for the foreseeable future. Instead, we plan to retain any earnings to maintain and expand our existing operations.

Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any return on their investment. As a result, investors seeking cash dividends should not invest in our common stock.

A sale of a substantial number of shares of our common stock in the public market could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. As of March 31, 2018, we had 19.3 million shares of common stock outstanding. In addition, as of March 31, 2018, 2.7 million and 0.2 million shares of common stock that are subject to outstanding options or restricted stock unit awards, respectively, under our outstanding equity plans are eligible for sale in the public market to the extent permitted by the provisions of various vesting

schedules, and Rules 144 and 701 under the Securities Act. If these additional shares of common stock are sold, or it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If those analysts are unable to predict accurately the demand and net sales of AbbVie's HCV regimens, that could result in our reported revenues and earnings being lower than the so-called "market consensus" of our projected revenues, which could negatively affect our stock price. In addition, if too few securities or industry analysts cover our company, the trading price for our stock would likely be negatively impacted. In the event that one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

ITEM 6. EXHIBITS

Exhibit Number	Exhibit Description	Incorporated by Reference Form	Date	Exhibit Number	File Number	Filed Herewith
3.1	Restated Certificate of Incorporation of Enanta Pharmaceuticals, Inc.	8-K	08/18/2015	3.1	001-35839	
3.2	Amended and Restated Bylaws of Enanta Pharmaceuticals, Inc. (as amended and restated in August 2015)	8-K	08/18/2015	3.2	001-35839	
31.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.	—	—	—	—	X
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.	—	—	—	—	X
32.1	Certification of the Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	—	—	—	—	X
101	The following materials from the Quarterly Report of Enanta Pharmaceuticals, Inc. on Form 10-Q for the quarter ended of March 31, 2018, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets as of March 31, 2018 and September 30, 2017 of Enanta Pharmaceuticals, Inc., (ii) Consolidated Statements of Operations for the three and six months ended March 31, 2018 and 2017 of Enanta Pharmaceuticals, Inc., (iii) Consolidated Statements of Comprehensive Income (Loss) for the three and six months ended March 31, 2018 and 2017 of Enanta Pharmaceuticals, Inc., (iv) Consolidated Statements of Cash Flows for the six months ended March 31, 2018 and 2017 of Enanta Pharmaceuticals, Inc., and (v) Notes to Consolidated Financial Statements of Enanta Pharmaceuticals, Inc.					X

ENANTA PHARMACEUTICALS, INC.

SIGNATURE

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

ENANTA PHARMACEUTICALS, INC.

Date: May 10, 2018

/s/ Paul J. Mellett
Paul J. Mellett

Chief Financial Officer

(Principal Financial and Accounting Officer)