ENANTA PHARMACEUTICALS INC
Form 10-Q
August 09, 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 June 30, 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 August 1, 2018, the registrant had 19,377,527 shares of common stock, $0.01 par value per share, outstanding.

ENANTA PHARMACEUTICALS, INC.

FORM 10-Q — Quarterly Report

For the Quarterly Period Ended June 30, 2018

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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)

	June 30, 2018	September 30, 2017
Assets		
Current assets:		
Cash and cash equivalents	$42,477	$65,675
Short-term marketable securities	230,750	157,994
Accounts receivable	57,262	10,614
Prepaid expenses and other current assets	9,404	3,536
Total current assets	339,893	237,819
Long-term marketable securities	22,272	70,038
Property and equipment, net	8,383	8,049
Deferred tax assets	7,929	10,123
Restricted cash	608	608
Total assets	$379,085	$326,637
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$4,902	$3,714
Accrued expenses and other current liabilities	9,127	7,970
Income taxes payable	—	9,298
Total current liabilities	14,029	20,982
Warrant liability	—	807
Series 1 nonconvertible preferred stock	1,528	762
Other long-term liabilities	2,627	2,410
Total liabilities	18,184	24,961
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Common stock; $0.01 par value per share, 100,000 shares authorized; 19,360 and 19,120 shares issued and outstanding at June 30, 2018 and September 30, 2017, respectively	194	191
Additional paid-in capital	271,365	256,241
Accumulated other comprehensive loss	(595)	(112)
Retained earnings	89,937	45,356
Total stockholders' equity	360,901	301,676
Total liabilities and stockholders' equity	$379,085	$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 June 30,		Nine Months Ended June 30,	
	2018	2017	2018	2017
Revenue				
Royalties	$57,262	$7,511	$124,420	$26,887
Milestones	—	—	15,000	—
Total revenue	57,262	7,511	139,420	26,887
Operating expenses:				
Research and development	28,487	15,407	67,933	40,937
General and administrative	6,135	5,233	17,611	15,631
Total operating expenses	34,622	20,640	85,544	56,568
Income (loss) from operations	22,640	(13,129)	53,876	(29,681)
Other income (expense):				
Interest income (expense), net	1,328	617	3,324	1,718
Other income (expense), net	10	—	(1)	—
Change in fair value of warrant liability and Series 1 nonconvertible preferred stock	—	(17)	41	(45)
Income (loss) before income taxes	23,978	(12,529)	57,240	(28,008)
Income tax (expense) benefit	(3,690)	4,103	(12,704)	9,210
Net income (loss)	$20,288	$(8,426)	$44,536	$(18,798)
Net income (loss) per share:				
Basic	$1.05	$(0.44)	$2.32	$(0.99)
Diluted	$0.97	$(0.44)	$2.17	$(0.99)
Weighted average shares outstanding:				
Basic	19,303	19,081	19,212	19,055
Diluted	21,017	19,081	20,509	19,055

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 June 30,		Nine Months Ended June 30,	
	2018	2017	2018	2017
Net income (loss)	$20,288	$(8,426)	$44,536	$(18,798)
Other comprehensive income (loss):				
Net unrealized income (loss) on marketable securities, net of tax of $76, ($17), ($159), ($93)	199	(29)	(483)	(156)
Total other comprehensive income (loss)	199	(29)	(483)	(156)
Comprehensive income (loss)	$20,487	$(8,455)	$44,053	$(18,954)

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

ENANTA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

(in thousands)

	Nine Months Ended June 30,	
	2018	2017
Cash flows from operating activities		
Net income (loss)	$44,536	$(18,798)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Stock-based compensation expense	11,735	9,861
Depreciation and amortization expense	1,857	1,573
Deferred income taxes	2,353	(9,240)
Income tax benefit from stock awards	3,520	—
Premium on marketable securities	(297)	(840)
Amortization of (discount) premium on marketable securities	(238)	564
Change in fair value of warrant liability and Series 1 nonconvertible preferred stock	(41)	45
Other non-cash items	(84)	—
Change in operating assets and liabilities:		
Accounts receivable	(46,648)	5,330
Prepaid expenses and other current assets	(5,868)	2,584
Accounts payable	1,446	2,717
Accrued expenses	1,150	1,145
Income taxes payable	(12,818)	—
Other long-term liabilities	276	406
Net cash provided by (used in) operating activities	879	(4,653)
Cash flows from investing activities		
Purchase of property and equipment	(2,358)	(2,272)
Purchase of marketable securities	(179,076)	(186,222)
Proceeds from maturities and sales of marketable securities	153,981	198,823
Net cash provided by (used in) investing activities	(27,453)	10,329
Cash flows from financing activities		
Proceeds from exercise of stock options	5,192	266
Payments of capital lease obligations	(59)	(54)
Payments for settlement of share-based awards	(1,757)	(202)
Net cash provided by financing activities	3,376	10
Net increase (decrease) in cash and cash equivalents	(23,198)	5,686
Cash and cash equivalents at beginning of period	65,675	16,577
Cash and cash equivalents at end of period	$42,477	$22,263
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	$21,404	$1,027

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, which is part of AbbVie's initial DAA regimens for the treatment of chronic HCV, is currently marketed outside the U.S. under the tradename VIEKIRAX® (paritaprevir/ritonavir/ombitasvir). 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 June 30, 2018 and for the three and nine months ended June 30, 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 June 30, 2018 and results of operations for the three and nine months ended June 30, 2018 and 2017 and cash flows for the nine months ended June 30, 2018 and 2017, have been made. The results of operations for the nine months ended June 30, 2018 are not necessarily indicative of the results of operations that may be expected for subsequent quarters or for 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 conform 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 accounting policy change on retained earnings and deferred tax assets in the consolidated balance sheet was not material. In addition, the consolidated statements of cash flows now presents excess tax benefits 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 will adopt the standard under the modified retrospective method, the impact of which is not expected to have a material impact on the Company's consolidated financial statements as the AbbVie Agreement is the only revenue-generating arrangement outstanding and all performance obligations under the agreement have been achieved. The Company is currently 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 June 30, 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 June 30, 2018 Using:			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets:				
Cash equivalents:				
Money market funds	$16,837	$—	$—	$16,837
U.S. Treasury notes	5,997	—	—	5,997
Commercial paper	—	15,459	—	15,459
Marketable securities:				
U.S. Treasury notes	39,674	—	—	39,674
Corporate bonds	—	129,665	—	129,665
Commercial paper	—	83,683	—	83,683
	$62,508	$228,807	$—	$291,315
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 nine months ended June 30, 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)	
		June 30,	September 30,
	Unobservable Input	2018	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, June 30, 2018	$ —	$ 1,528

4. Marketable Securities

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

	June 30, 2018	
	Amortized	Gross
	Cost	Gross

	Cost	Unrealized Gains	Unrealized Losses	Fair Value
	(in thousands)			
Corporate bonds	$130,355	$ —	$ (690)	$129,665
Commercial paper	83,683	—	—	83,683
U.S. Treasury notes	39,805	1	(132)	39,674
	$253,843	$ 1	$ (822)	$253,022

	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 June 30, 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 $22,272, 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 June 30, 2018 and September 30, 2017:

	June 30, 2018	September 30, 2017
	(in thousands)	
Accrued expenses:		
Accrued preclinical and clinical expenses	$3,205	$ 3,156
Accrued vendor manufacturing	2,444	1,130
Accrued payroll and related expenses	2,340	2,829
Accrued professional fees	773	456
Accrued other	365	399
	$9,127	$ 7,970
Other long-term liabilities:		
Uncertain tax positions	$1,493	$ 1,175
Accrued rent expense	611	676
Capital lease obligation	315	379
Asset retirement obligation	208	180
	$2,627	$ 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 $592,000 through June 30, 2018. Since the Company completed all of 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 ten percent 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. The following table details the royalty tiers associated with cumulative calendar year net sales allocated to each royalty-bearing product as provided in the AbbVie Agreement:

Calendar Year Net Sales (in thousands)	Royalty Tier (%)
up to $500,000	10%
from $500,000 up to $750,000	12%
from $750,000 up to $1,000,000	14%
from $1,000,000 up to $2,500,000	17%
greater than or equal to $2,500,000	20%

ENANTA PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

(Amounts in thousands, except per share data)

During the nine months ended June 30, 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 were classified as liabilities. The following table summarizes the activity of the warrants to purchase Series 1 nonconvertible preferred stock:

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

As of June 30, 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, performance share units, and relative total stockholder return units, under its 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 June 30, 2018:

	Shares Issuable Under Options (in thousands)	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of September 30, 2017	2,298	$ 30.36	7.4	$ 37,821
Granted	585	$ 56.36		
Exercised	(194)	$ 26.75		
Forfeited	(26)	$ 38.86		
Outstanding as of June 30, 2018	2,663	$ 36.26	7.3	$ 212,103
Options exercisable as of June 30, 2018	1,551	$ 31.01	6.4	$ 131,696

ENANTA PHARMACEUTICALS, INC.

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(Amounts in thousands, except per share data)

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 June 30, 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 June 30, 2018	70	$ 50.97	70	$ 59.96

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 June 30, 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	(1)	$ 30.00
Unvested at June 30, 2018	109	$ 30.00

Stock-Based Compensation Expense

During the three and nine months ended June 30, 2018 and 2017, the Company recognized the following stock-based compensation expense:

	Three Months ended June 30,		Nine Months Ended June 30,	
	2018	2017	2018	2017
	(in thousands)			
Research and development	$1,590	$990	$4,490	$2,998
General and administrative	2,435	2,112	7,245	6,863
	$4,025	$3,102	$11,735	$9,861

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	Three Months ended June 30,		Nine Months Ended June 30,	
	2018	2017	2018	2017
	(in thousands)			
Stock options	$3,317	$2,544	$9,295	$7,797
Performance stock units	—	—	641	667
rTSRUs	509	358	1,203	905
Restricted stock units	199	200	596	492
	$4,025	$3,102	$11,735	$9,861

During the nine months ended June 30, 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. The expense for time-based stock options and restricted stock units reflects time-based vesting during the periods presented.

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, 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 June 30, 2018, the Company had an aggregate of $33,853 of unrecognized stock-based compensation cost, which is expected to be recognized over a weighted average period of 2.3 years.

ENANTA PHARMACEUTICALS, INC.

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(Amounts in thousands, except per share data)

9. Net Income (Loss) Per Share

Basic and diluted net income (loss) per share attributable to common stockholders for the three and nine months ended June 30, 2018 and 2017 was calculated as follows:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2018	2017	2018	2017
	(in thousands, except per share data)			
Basic net income (loss) per share:				
Numerator:				
Net income (loss)	$20,288	$(8,426)	$44,536	$(18,798)
Denominator:				
Weighted average common shares outstanding—basic	19,303	19,081	19,212	19,055
Net income (loss) per share common share—basic	$1.05	$(0.44)	$2.32	$(0.99)
Diluted net income (loss) per share:				
Numerator:				
Net income (loss)	$20,288	$(8,426)	$44,536	$(18,798)
Denominator:				
Weighted average common shares outstanding—basic	19,303	19,081	19,212	19,055
Dilutive effect of common stock equivalents	1,714	—	1,297	—
Weighted average common shares outstanding—diluted	21,017	19,081	20,509	19,055
Net income (loss) per share common share—diluted	$0.97	$(0.44)	$2.17	$(0.99)
Anti-dilutive common stock equivalents excluded from above	117	2,244	338	1,832

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 June 30, 2018, the Company recorded income tax expense of $(3,690) and for the comparable period in 2017, recorded an income tax benefit of $4,103, both of which were attributable to the Company's domestic operations. Income tax expense for the three months ended June 30, 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 June 30, 2017, the Company's income tax benefit was driven by the Company's pre-tax loss during the quarter.

For the nine months ended June 30, 2018, the Company recorded income tax expense of $(12,704) and for the comparable period in 2017, recorded an income tax benefit of $9,210, representing effective tax rates of 22.2% and 32.9%, respectively. Income tax expense for the nine months ended June 30, 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 and milestones earned under the AbbVie Agreement. The effective tax rate of 22.2% 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 nine months of 2018. During the nine months ended June 30, 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 32.9% 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.

ENANTA PHARMACEUTICALS, INC.

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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. During 2018, the Company received notice of examination by the Internal Revenue Service ("IRS") for the year ending September 30, 2016. During the three months ended June 30, 2018, the Company received and agreed to a notice of proposed adjustment from the IRS, the amount of which was immaterial to the financial statements. The Company is in process of finalizing the completion of the IRS audit. 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 $1,493 and $1,175 as of June 30, 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 $1,519 for both the nine months ended June 30, 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 June 30, 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 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 June 30, 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, paritaprevir, which is part of AbbVie's initial DAA regimens for the treatment of chronic HCV, is currently marketed outside the U.S. under the tradename

VIEKIRAX® (paritaprevir/ritonavir/ombitasvir). 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 $295.5 million in cash and marketable securities at June 30, 2018. In the first nine months of our fiscal year 2018, we earned $124.4 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.

- Preclinical data has demonstrated 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 and completed dosing in July 2018.
- 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 was 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 (see Note 6 in Notes to Consolidated Financial Statements) on 50% of the calendar year 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 EU, Japan and other countries around the world under the tradename VIEKIRAX®. In the U.S. the HCV regimen containing paritaprevir, which is sold under the tradename VIEKIRA PAK® (paritaprevir/ritonavir/ombitasvir/dasabuvir), is no longer being actively marketed. 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.

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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 as well as our RSV program. Specifically, in fiscal 2018, we 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, which has finished dosing, and we plan to initiate a Phase 2a challenge study in RSV in the fourth calendar quarter of 2018. We have been increasing our expenses in fiscal year 2018, as compared to our fiscal year 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® and other HCV regimens, 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 has reported increasing MAVYRET/MAVIRET sales and market share and has become a leading HCV treatment in the U.S. and several market geographies in developed countries where it is approved. However, the market for HCV therapies remains very dynamic in several jurisdictions where MAVYRET/MAVIRET is already approved or AbbVie is seeking approval, and we cannot predict how that market 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 subsequently. 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 nine months ended June 30, 2018 and 2017:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2018	2017	2018	2017
	(in thousands)			
AbbVie agreement:				
Royalties	$57,262	$7,511	$124,420	$26,887
Milestones	—	—	15,000	—
Total revenue	$57,262	$7,511	$139,420	$26,887

AbbVie Agreement

Since all of our research obligations under the AbbVie agreement were concluded by June 30, 2011, all milestone payments received since then have been recognized as revenue upon achievement of each milestone by AbbVie. During the nine months ended June 30, 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 (see Note 6 in Notes to Consolidated Financial Statements at page 12 of this report which is incorporated herein by reference).

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 nine months ended June 30, 2018 and 2017:

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2018	2017	2018	2017
	(in thousands)			
Research and development	$28,487	$15,407	$67,933	$40,937
General and administrative	6,135	5,233	17,611	15,631
Total operating expenses	$34,622	$20,640	$85,544	$56,568

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 publicly traded company.

Other Income (Expense

Other income (expense) 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 any 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 June 30, 2018 and 2017

	Three Months Ended

	June 30, 2018	2017
	(in thousands)	
Revenue	$57,262	$7,511
Research and development	28,487	15,407
General and administrative	6,135	5,233
Other income (expense), net	1,338	600
Income tax (expense) benefit	(3,690)	4,103
Net income (loss)	20,288	(8,426)

Revenue

	Three Months Ended June 30,	
	2018	2017
	(in thousands)	
AbbVie agreement:		
Royalties	$57,262	$7,511
Total revenue	$57,262	$7,511

We recognized revenue of $57.3 million during the three months ended June 30, 2018 as compared to $7.5 million during the same period 2017. During the three months ended June 30, 2018, revenue consisted of royalties earned on the portion of AbbVie's net sales of its respective HCV treatment regimens allocable to glecaprevir or paritaprevir, and substantially all of our royalties are now earned on MAVYRET/MAVIRET. During the three months ended June 30, 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 MAVYRET/MAVIRET regimen, a pan-genotypic treatment combining two DAAs, began commercialization in the second half of 2017, following its approval in the EU, U.S., and Japan. We receive annually tiered, double-digit, per-product royalties on 50% of all net sales of MAVYRET/MAVIRET. During the three months ended June 30, 2018, the net sales of MAVYRET/MAVIRET moved our cumulative annual royalties for glecaprevir for the calendar year through the 12% and into the 14% tier of our royalty rate schedule under our agreement with AbbVie. 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. In addition, at the beginning of each calendar year our royalty rates reset to the lowest tier for each of our royalty-bearing products licensed to AbbVie.

Research and development expenses

	Three Months Ended June 30,	
	2018	2017
	(in thousands)	
R&D programs:		
Liver disease	$16,578	$10,281
Virology	11,884	5,069
Other	25	57
Total research and development expenses	$28,487	$15,407

Research and development expenses increased $13.1 million for the three months ended June 30, 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 studies and an increase in external costs for clinical and preclinical activities.

General and administrative expenses

General and administrative expenses increased by $0.9 million for the three months ended June 30, 2018 as compared to the same period in 2017. The increase was primarily due to an increase in compensation expense due to an increase in headcount.

Other income (expense)

Other income (expense) increased $0.7 million for the three months ended June 30, 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 June 30, 2018, we recorded income tax (expense) of $(3.7) million and for the comparable period in 2017, an income tax benefit of $4.1 million. During the three months ended June 30, 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 as a result of the launch of MAVRYET/MAVIRET in late 2017 and was offset by excess tax benefits from

employee stock option exercises during the quarter. For the three months ended June 30, 2017, our income tax benefit was driven by our pre-tax loss during the quarter.

Comparison of the Nine Months Ended June 30, 2018 and 2017

	Nine Months Ended June 30,	
	2018	2017
	(in thousands)	
Revenue	$139,420	$26,887
Research and development	67,933	40,937
General and administrative	17,611	15,631
Other income (expense), net	3,364	1,673
Income tax (expense) benefit	(12,704)	9,210
Net income (loss)	44,536	(18,798)

Revenue

	Nine Months Ended June 30,	
	2018	2017
	(in thousands)	
AbbVie agreement:		
Royalties	$124,420	$26,887
Milestones	15,000	—
Total revenue	$139,420	$26,887

We recognized revenue of $139.4 million during the nine months ended June 30, 2018 as compared to $26.9 million during the same period in 2017. During the nine months ended June 30, 2018, revenue consisted primarily of royalties earned on the portion of AbbVie’s net sales of its respective HCV treatment regimens allocable to glecaprevir or paritaprevir, as well as a $15.0 million milestone payment earned upon AbbVie’s achievement of commercialization regulatory approval of MAVIRET™ in Japan. Substantially all of our royalties are now earned on MAVYRET/MAVIRET. During the nine months ended June 30, 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

	Nine Months Ended June 30,	
	2018	2017
	(in thousands)	
R&D programs:		
Liver disease	$39,547	$24,393
Virology	28,292	16,315
Other	94	229
Total research and development expenses	$67,933	$40,937

Research and development expenses increased $27.0 million for the nine months ended June 30, 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 studies and an increase in external costs for clinical and preclinical activities.

General and administrative expenses

General and administrative expenses increased by $2.0 million for the nine months ended June 30, 2018 as compared to the same period in 2017. The increase was primarily due to an increase in compensation expense due to increased headcount and to a lesser extent an increase in external accounting and consulting fees.

Other income (expense)

Other income (expense) increased $1.7 million for the nine months ended June 30, 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 nine months ended June 30, 2018, we recorded income tax expense of $(12.7) million and for the comparable period in 2017, recorded an income tax benefit of $9.2 million. Income tax expense for the nine months ended June 30, 2018 was driven by our pre-tax income for the year which increased from the prior comparable period due to an increase in royalties and milestones earned under the AbbVie Agreement. Our estimated annual effective tax rate of 22.2% for the nine months ended June 30, 2018, differs from the U.S. 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 nine months of 2018. For the nine months ended June 30, 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 32.9% for the nine months ended June 30, 2017, differs from the prior year U.S. federal 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 June 30, 2018, our principal sources of liquidity were cash, cash equivalents and short-term and long-term marketable securities totaling $295.5 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 nine months ended June 30, 2018 and 2017:

	Nine Months Ended June 30,	
	2018	2017
	(in thousands)	
Cash provided by (used in):		

Operating activities	$879	$(4,653)
Investing activities	$(27,453)	$10,329
Financing activities	$3,376	$10
Net increase (decrease) in cash and cash equivalents	$(23,198)	$5,686

Net cash provided by (used in) operating activities

The increase in cash provided by operating activities of $5.5 million for the nine months ended June 30, 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 $92.8 million in cash during the nine months ended June 30, 2018 from AbbVie, including royalties and a $15.0 million milestone payment, compared to $32.2 million in cash during nine months ended June 30, 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, and an increase in taxes paid of $20.4 million year over year due to timing of estimated tax payments.

Net cash provided by (used in) investing activities

The decrease in cash provided by investing activities of $37.8 million for the nine months ended June 30, 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 financing activities

The increase in net cash provided by financing activities of $3.4 million for the nine months ended June 30, 2018 as compared to the same period in 2017 was driven by an increase in proceeds from stock option exercises during the 2018 period as a result of the increase in the price of our common stock.

Funding requirements

As of June 30, 2018, we had $295.5 million in cash, cash equivalents and short-term and long-term marketable securities. We believe that our existing cash, cash equivalents and marketable securities as of June 30, 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 nine months ended June 30, 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 $295.5 million at June 30, 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 June 30, 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 March 31, 2018 filed on May 10, 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 primarily derived from AbbVie's net sales of its MAVYRET/MAVIRET regimen for HCV. If AbbVie is unable to maintain sales of this regimen at or above current levels of sales, our royalty revenues would be adversely affected.

Our quarterly royalty revenue from AbbVie's net sales of its MAVYRET/MAVIRET regimen have grown substantially even as it is priced well below the pricing of AbbVie's first HCV regimens, and below that of its principal competitor, Gilead. While commercialization of this regimen 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 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 MAVYRET/MAVIRET regimen 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 MAVYRET/MAVIRET would negatively affect the demand for such regimen and our royalty revenue derived from its sale.

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 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 Epclusa® (a fixed dose combination of sofosbuvir and velpatasvir), 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 Harvoni® (a fixed-dose combination of sofosbuvir and ledipasvir); 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 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 NASH programs that are significantly more advanced than ours, including companies with compounds in Phase 3 clinical trials 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 have NASH or related programs with compounds in Phase 2 clinical trials. These companies include Alberio, Astra-Zeneca, BMS, Boehringer Ingelheim, Can-Fite BioPharma, Conatus, Cirius, Cymabay, Galectin, Galmed, Gemphire Therapeutics, Gilead, GlaxoSmithKline, Immuron, Inventiva, Madrigal, Medicinova, Northsea Therapeutics, Novartis, NGM, Novo Nordisk, Pfizer and Viking. A significant number of other companies are conducting earlier stage 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 developing EDP-305 and/or EDP-938 or in discovering further product candidates in addition to those product candidates, 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. 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 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 nine months ended June 30, 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;