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 December 31, 2019

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)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.01 per share	ENTA	NASDAQ

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 every Interactive Data File required to be submitted 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 such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a 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	☐	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 January 31, 2020, the registrant had 19,924,426 shares of common stock, $0.01 par value per share, outstanding.

ENANTA PHARMACEUTICALS, INC.
FORM 10-Q — Quarterly Report
For the Quarterly Period Ended December 31, 2019

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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. 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," "may," "objective," "plan," "predict," "potential," "positioned," "seek," "should," "target," "will," "would," and other similar expressions that are predictions 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 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)

	December 31, 2019	September 30, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 27,558	$ 51,230
Short-term marketable securities	346,227	284,006
Accounts receivable	52,570	51,313
Prepaid expenses and other current assets	14,153	15,299
Total current assets	440,508	401,848
Long-term marketable securities	40,941	65,013
Property and equipment, net	10,407	10,927
Deferred tax assets	10,656	11,341
Operating lease, right-of-use assets	7,762	—
Restricted cash	608	608
Other long-term assets	92	92
Total assets	$ 510,974	$ 489,829
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 6,596	$ 6,689
Accrued expenses and other current liabilities	9,411	15,920
Operating lease liabilities	3,132	—
Total current liabilities	19,139	22,609
Operating lease liabilities, net of current portion	5,987	—
Series 1 nonconvertible preferred stock	1,628	1,628
Other long-term liabilities	1,933	3,100
Total liabilities	28,687	27,337
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Common stock; $0.01 par value per share, 100,000 shares authorized; 19,810 and 19,703 shares issued and outstanding at December 31, 2019 and September 30, 2019, respectively	198	197
Additional paid-in capital	304,672	298,409
Accumulated other comprehensive income	234	146
Retained earnings	177,183	163,740
Total stockholders' equity	482,287	462,492
Total liabilities and stockholders' equity	$ 510,974	$ 489,829

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 December 31,	
	2019	2018
Royalty revenue	$ 52,570	$ 69,886
Operating expenses:		
Research and development	32,778	34,878
General and administrative	6,921	7,152
Total operating expenses	39,699	42,030
Income from operations	12,871	27,856
Other income (expense):		
Interest income (expense), net	2,076	1,885
Total other income (expense), net	2,076	1,885
Income before income taxes	14,947	29,741
Income tax expense	(1,504)	(3,730)
Net income	$ 13,443	$ 26,011
Net income per share:		
Basic	$ 0.68	$ 1.34
Diluted	$ 0.65	$ 1.25
Weighted average shares outstanding:		
Basic	19,751	19,426
Diluted	20,773	20,810

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

ENANTA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(unaudited)
(in thousands)

	Three Months Ended December 31,	
	2019	2018
Net income	$ 13,443	$ 26,011
Other comprehensive income:		
Net unrealized gains on marketable securities, net of tax of ($28) and ($45)	88	141
Total other comprehensive income, net of tax	88	141
Comprehensive income	$ 13,531	$ 26,152

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

ENANTA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(unaudited)
(in thousands)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Retained Earnings	Total Stockholders' Equity
	Shares	Amount				
Balances at September 30, 2018	**19,395**	**$ 194**	**$ 276,526**	**$ (398)**	**$ 117,357**	**$ 393,679**
Exercise of stock options	40	—	1,161	—	—	1,161
Stock-based compensation expense	—	—	5,843	—	—	5,843
Other comprehensive income, net of tax	—	—	—	141	—	141
Net income	—	—	—	—	26,011	26,011
Balances at December 31, 2018	**19,435**	**$ 194**	**$ 283,530**	**$ (257)**	**$ 143,368**	**$ 426,835**

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Retained Earnings	Total Stockholders' Equity
	Shares	Amount				
Balances at September 30, 2019	**19,703**	**$ 197**	**$ 298,409**	**$ 146**	**$ 163,740**	**$ 462,492**
Exercise of stock options	76	1	2,305	—	—	2,306
Vesting of restricted stock units, net of withholding	31	—	(1,140)	—	—	(1,140)
Stock-based compensation expense	—	—	5,098	—	—	5,098
Other comprehensive income, net of tax	—	—	—	88	—	88
Net income	—	—	—	—	13,443	13,443
Balances at December 31, 2019	**19,810**	**$ 198**	**$ 304,672**	**$ 234**	**$ 177,183**	**$ 482,287**

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

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

	Three Months Ended December 31,	
	2019	**2018**
Cash flows from operating activities		
Net income	$ 13,443	$ 26,011
Adjustments to reconcile net income to net cash provided by operating activities:		
Stock-based compensation expense	5,098	5,843
Depreciation and amortization expense	904	680
Deferred income taxes	657	(918)
Premium paid on marketable securities	(988)	—
Accretion of discount on marketable securities	(330)	(977)
Other non-cash items	(2)	39
Change in operating assets and liabilities:		
Accounts receivable	(1,257)	(2,681)
Prepaid expenses and other current assets	1,146	(3,182)
Operating lease, right-of-use assets	520	—
Accounts payable	(179)	124
Accrued expenses	(5,989)	598
Income taxes payable	—	4,470
Operating lease liabilities	(593)	—
Other long-term liabilities	(67)	247
Net cash provided by operating activities	12,363	30,254
Cash flows from investing activities		
Purchase of marketable securities	(117,461)	(119,546)
Proceeds from maturities and sale of marketable securities	80,748	98,999
Purchase of property and equipment	(488)	(384)
Net cash used in investing activities	(37,201)	(20,931)
Cash flows from financing activities		
Proceeds from exercise of stock options	2,306	1,161
Payments for settlement of share-based awards	(1,140)	—
Payments of capital lease obligations	—	(21)
Net cash provided by financing activities	1,166	1,140
Net increase (decrease) in cash, cash equivalents and restricted cash	(23,672)	10,463
Cash, cash equivalents and restricted cash at beginning of period	51,838	64,510
Cash, cash equivalents and restricted cash at end of period	$ 28,166	$ 74,973
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	$ —	$ 5
Supplemental disclosure of non-cash investing information:		
Purchases of fixed assets included in accounts payable and accrued expenses	$ 216	$ 1,304
Operating lease liabilities arising from obtaining right-of-use assets	$ 1,131	$ —

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

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 protease inhibitor discovered and developed through its collaboration with AbbVie for the treatment of chronic hepatitis C virus, or HCV. Glecaprevir is co-formulated as part of AbbVie's leading direct-acting antiviral (DAA) combination treatment for HCV, which is marketed under the tradenames MAVYRET® (U.S.) and MAVIRET™ (ex-U.S.) (glecaprevir/pibrentasvir). Royalties from the Company's AbbVie collaboration and its existing financial resources provide funding to support the Company's wholly-owned research and development programs, which are primarily focused on the following disease targets: respiratory syncytial virus ("RSV"), non-alcoholic steatohepatitis ("NASH"), and hepatitis B virus ("HBV").

The Company is subject to many of the 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 regulation. 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, 2019 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 December 31, 2019 and for the three months ended December 31, 2019 and 2018 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, 2019.

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 December 31, 2019 and results of operations for the three months ended December 31, 2019 and 2018 and cash flows for the three months ended December 31, 2019 and 2018, have been made. The results of operations for the three months ended December 31, 2019 are not necessarily indicative of the results of operations that may be expected for subsequent quarters or the year ending September 30, 2020.

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

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, 2019. Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB"). Other than the adoption of ASC 842 as of October 1, 2019, there were no other significant changes to the Company's Significant Accounting Policies during the quarter.

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 with respect to its revenue arrangements; valuation of Series 1 nonconvertible preferred stock and stock-based awards; the accrual of research and development expenses, 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 Adopted Accounting Pronouncements

The Company adopted ASU No. 2016-02, Leases (Topic 842), as of October 1, 2019, using the modified retrospective method under ASU No. 2018-11, Leases (Topic 842): Targeted Improvements. The transition method allows entities to apply the transition requirements at the effective date rather than at the beginning of the earliest comparative period presented. The Company's reporting for comparative periods is presented in accordance with ASC 840, Leases. Adoption of the new standard resulted in the recording of right of use ("ROU") assets and lease liabilities of $7,151 and $8,622, respectively. The adoption of the standard did not have a material impact on the Company's results of operations or cash flows. The Company elected to use the transition package of three practical expedients, which among other things, allowed the Company to carry forward the historical lease classification. The Company has elected, under Topic 842, the further practical expedient not to separate non-lease components from the lease components to which they relate and instead to combine them and account for them as a single lease component. The Company also elected the accounting policy election to keep leases with a term of twelve months or less off the balance sheet and to recognize payments for those leases on a straight-line basis over the lease term.

ROU assets represent the Company's right to use an underlying asset for the lease term, and lease liabilities represent the Company's obligation to make lease payments arising from the lease. At the inception of the arrangement, the Company determines if an arrangement is a lease based on assessment of the terms and conditions of the contract. Operating lease ROU assets and lease liabilities are recognized at commencement date, and thereafter if modified, based on the present value of lease payments over the lease term. The lease term includes any renewal or early-termination options that the Company is reasonably assured to exercise. The present value of lease payments is determined by using the interest rate implicit in the lease, if that rate is readily determinable; otherwise, the Company uses its estimated secured incremental borrowing rate for that lease term. The underlying assets of the Company's leases as of the adoption date consisted of office and laboratory space.

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 period through 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. The Company adopted the new standard on the effective date of October 1, 2019. The adoption of the standard did not have a material impact on the Company's financial position and results of operations.

Recently Issued Accounting Pronouncements

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses (Topic 326)* ("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 December 31, 2019 and September 30, 2019, and indicate the fair value hierarchy of the valuation inputs utilized to determine such fair value:

	Fair Value Measurements at December 31, 2019 Using:			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets:				
Cash equivalents:				
Money market funds	$ 6,065	$ —	$ —	$ 6,065
Commercial paper	—	17,423	—	17,423
Marketable securities:				
U.S. Treasury notes	176,856	—	—	176,856
Commercial paper	—	77,269	—	77,269
Corporate bonds	—	133,043	—	133,043
	$ 182,921	$ 227,735	$ —	$ 410,656
Liabilities:				
Series 1 nonconvertible preferred stock	$ —	$ —	$ 1,628	$ 1,628
	$ —	$ —	$ 1,628	$ 1,628

	Fair Value Measurements at September 30, 2019 Using:			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets:				
Cash equivalents:				
Money market funds	$ 44,569	$ —	$ —	$ 44,569
Marketable securities:				
U.S. Treasury notes	170,515	—	—	170,515
Corporate bonds	—	111,837	—	111,837
Commercial paper	—	66,667	—	66,667
	$ 215,084	$ 178,504	$ —	$ 393,588
Liabilities:				
Series 1 nonconvertible preferred stock	$ —	$ —	$ 1,628	$ 1,628
	$ —	$ —	$ 1,628	$ 1,628

During the three months ended December 31, 2019 and 2018, there were no transfers between Level 1, Level 2 and Level 3.

The outstanding shares of Series 1 nonconvertible preferred stock are measured at fair value. The fair value of these instruments was based on significant inputs not observable in the market, which represented a Level 3 measurement within the fair value hierarchy. The Company utilized a probability-weighted valuation model which takes into consideration various outcomes that may require the Company to transfer assets upon exercise. Changes in the fair value of the Series 1 nonconvertible preferred stock are recognized in other income (expense), net in the consolidated statements of operations.

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

	Range (Weighted Average)	
Unobservable Input	December 31, 2019	September 30, 2019
Probabilities of payout	0%-60%	0%-60%
Discount rate	5.75%	6.00%

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

	Series 1 Nonconvertible Preferred Stock
Balance, September 30, 2019	$ 1,628
Change in fair value of nonconvertible preferred stock	—
Balance, December 31, 2019	$ 1,628

4. Marketable Securities

As of December 31, 2019 and September 30, 2019, the fair value of available-for-sale marketable securities, by type of security, was as follows:

	December 31, 2019			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(in thousands)			
U.S. Treasury notes	$ 176,712	$ 144	$ —	176,856
Corporate bonds	132,928	127	(12)	133,043
Commercial Paper	77,269	—	—	77,269
	$ 386,909	$ 271	$ (12)	$ 387,168

	September 30, 2019			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(in thousands)			
U.S. Treasury notes	$ 170,519	$ 60	$ (64)	$ 170,515
Corporate bonds	111,690	170	(23)	111,837
Commercial Paper	66,667	—	—	66,667
	$ 348,876	$ 230	$ (87)	$ 349,019

As of December 31, 2019 and September 30, 2019 marketable securities consisted of investments that mature within one year, with the exception of certain corporate bonds and U.S. Treasury notes, which have maturities between one and three years and an aggregate fair value of $40,941 and $65,013, respectively.

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 December 31, 2019 and September 30, 2019:

	December 31, 2019	September 30, 2019
	(in thousands)	
Accrued expenses:		
Accrued research and development expenses	$ 3,877	$ 6,936
Accrued payroll and related expenses	1,628	3,894
Accrued clinical manufacturing	2,580	3,447
Accrued professional fees	921	759
Accrued other	405	884
	$ 9,411	$ 15,920
Other long-term liabilities:		
Uncertain tax positions	$ 1,679	$ 1,746
Accrued rent expense	—	900
Capital lease obligation	—	200
Asset retirement obligation	254	254
	$ 1,933	$ 3,100

6. 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 $922,000 through December 31, 2019. Since the Company satisfied 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 receiving annually tiered royalties per Company protease product ranging from ten percent up to twenty percent, or on a blended basis from ten percent 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 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.

7. Series 1 Nonconvertible Preferred Stock

As of December 31, 2019, 1,931 shares of Series 1 nonconvertible preferred stock were issued and outstanding. Since these shares qualify as a derivative, the outstanding shares are carried at fair value as a liability on the Company’s consolidated balance sheet.

8. Stock-Based Awards

The Company grants stock-based awards, including stock options and unit awards under its 2019 Equity Incentive Plan (the “2019 Plan”), which was approved by its stockholders on February 28, 2019. The Company also has outstanding unit awards, stock options and restricted stock unit awards under its 2012 Equity Incentive Plan (the “2012 Plan”) and its amended and restated 1995 Equity Incentive Plan (the “1995 Plan”), but is no longer granting awards under these plans.

The following table summarizes stock option activity, including performance-based options, for the year-to-date period ending December 31, 2019:

	Shares Issuable Under Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
	(in thousands)		(in years)	(in thousands)
Outstanding as of September 30, 2019	2,967	$ 46.54	6.7	$ 57,336
Granted	577	63.32		
Exercised	(76)	30.16		
Forfeited	(23)	75.36		
Outstanding as of December 31, 2019	3,445	$ 49.53	6.8	$ 58,637
Options vested and expected to vest as of December 31, 2019	3,445	$ 49.53	6.8	$ 58,637
Options exercisable as of December 31, 2019	2,002	$ 38.28	5.4	$ 51,630

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 150% of the target number. The following table summarizes PSU and rTSRU activity for the year-to-date period ending December 31, 2019:

	PSUs		rTSRUs	
	Shares	Weighted Average Grant Date Fair Value	Shares	Weighted Average Grant Date Fair Value
	(in thousands, except per share data)			
Unvested at September 30, 2019	41	$ 73.02	41	$ 67.76
Granted	27	63.94	27	45.81
Vested	—	—	—	—
Cancelled	—	—	—	—
Unvested at December 31, 2019	68	$ 69.37	68	$ 58.94

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 per share of these awards was determined based on the intrinsic value of the stock on the date of grant and is being 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 December 31, 2019:

	Restricted Stock Units	Weighted Average Grant Date Fair Value
	(in thousands, except per share data)	
Unvested at September 30, 2019	95	$ 30.00
Granted	—	—
Vested	(48)	30.00
Cancelled	(1)	30.00
Unvested at December 31, 2019	46	$ 30.00

Stock-Based Compensation Expense

During the three months ended December 31, 2019 and 2018, the Company recognized the following stock-based compensation expense:

	Three Months ended December 31,	
	2019	2018
	(in thousands)	
Research and development	$ 2,492	$ 2,274
General and administrative	2,606	3,569
	$ 5,098	$ 5,843

	Three Months ended December 31,	
	2019	2018
	(in thousands)	
Stock options	$ 4,335	$ 3,904
Performance stock units	243	1,206
rTSRUs	362	531
Restricted stock units	158	202
	$ 5,098	$ 5,843

During the three months ended December 31, 2019 and 2018, the Company recognized stock-based compensation expense for PSUs and performance-based options for which vesting became probable upon achievement of performance-based targets that occurred during their respective periods.

As of December 31, 2019, the Company had an aggregate of $52,006 of unrecognized stock-based compensation cost, which is expected to be recognized over a weighted average period of 2.8 years.

9. Net Income Per Share

Basic and diluted net income per share attributable to common stockholders was calculated as follows for the three months ended December 31, 2019 and 2018:

	Three Months Ended December 31,	
	2019	2018
	(in thousands, except per share data)	
Basic net income per share:		
Numerator:		
Net income	$ 13,443	$ 26,011
Denominator:		
Weighted average common shares outstanding—basic	19,751	19,426
Net income per share common share—basic	$ 0.68	$ 1.34
Diluted net income per share:		
Numerator:		
Net income	$ 13,443	$ 26,011
Denominator:		
Weighted average common shares outstanding—basic	19,751	19,426
Dilutive effect of common stock equivalents	1,022	1,384
Weighted average common shares outstanding—diluted	20,773	20,810
Net income per share common share—diluted	$ 0.65	$ 1.25
Anti-dilutive common stock equivalents excluded from above	1,896	606

10. Income Taxes

The Company's provision for income taxes consists of federal and state taxes necessary to align the Company's year-to-date tax provision with the annual effective rate that it expects to achieve for the full year. At each interim period, the Company updates its estimate of the annual effective tax rate and records cumulative adjustments as necessary. The authoritative guidance for accounting for income taxes allows use of the year-to-date effective tax rate (the "discrete method") when a reliable estimate of the estimated annual effective tax rate cannot be made. During the three months ended December 31, 2019, the Company determined the use of the discrete method is more appropriate than the annual effective tax rate method due to the sensitivity of the Company's tax rate to small changes in projected pre-tax earnings, which resulted in significant variations in the customary relationship between income tax expense and pretax income. As such, the Company has discretely calculated the tax provision based on pre-tax results through the three months ended December 31, 2019. For the three months ended December 31, 2019 and 2018, the Company recorded income tax expense of $1,504 and $3,730, respectively, both of which were attributable to the Company's domestic operations. The Company has no foreign operations and therefore, has not provided for any foreign taxes.

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 2015 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. The Company received and agreed to a notice of proposed adjustment from the IRS, which was paid in September 2018, the amount of which was immaterial to the financial statements. The Company is in the process of finalizing the completion of the IRS audit. During October 2018, the Company received notice of examination by the Massachusetts Department of Revenue ("DOR") for the years ending September 30, 2015 and September 30, 2016. The Company received a notice of proposed adjustment from the DOR, the amount of which was immaterial to the financial statements. The Company is in the process of finalizing the completion of the DOR 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 $1,679 and $1,650 as of December 31, 2019 and September 30, 2019, 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. Leases

The Company has two real estate leases for properties located in Watertown, Massachusetts. The first lease, for office and laboratory space at 500 Arsenal Street, was effective in fiscal 2011 and expires in September 2022 with an option to extend the lease term for an additional five years. The second lease, for office space located at 400 Talcott Avenue, was effective September 2018 and expires in August 2024 with two options to extend the lease term for an additional three years each. The options to extend the lease terms were not included in the right-of-use assets and lease liabilities as they were not reasonably certain of being exercised. The lease payments for the office and laboratory space include fixed lease payments that escalate over the terms of the leases. Additionally, the Company's office and laboratory space leases require the Company to pay for certain operating expenses based on actual costs incurred and therefore as the amounts are variable in nature are expensed in the period incurred and included in variable lease costs.

In October 2019, the Company entered into an agreement to lease units of equipment over eighteen-month lease periods commencing upon shipment of each unit. The lease agreement contains an option to terminate the lease early, however this early-termination option was not included in the right-of-use asset and lease liability as it was not reasonably certain of being exercised. The equipment lease requires the Company to pay for certain consumable and peripheral equipment supplies based on actual costs incurred and therefore as these costs are variable in nature, they are expensed in the period incurred and included in variable lease costs.

The components of lease expense for the Company's real estate and equipment leases were as follows:

	Three Months Ended December 31, 2019
	(in thousands)
Operating lease cost	$ 663
Short-term lease cost	—
Variable lease cost	479
	$ 1,142

Other information:

	Three months ended December 31, 2019 (in thousands)
Cash paid for amounts included in the measurement of operating lease liabilities	$ 736
Operating lease liabilities arising from obtaining right-of-use assets	$ 1,131

	December 31, 2019 (in thousands)
Weighted-average remaining lease term - operating leases (in years)	2.99
Weighted-average discount rate - operating leases	6.50%

Incremental borrowing rates were used to calculate the present value of the Company's real estate and equipment leases.

Future annual minimum lease payments under the Company's real estate and equipment operating leases as of December 31, 2019 were as follows:

Years ended September 30,	(in thousands)
2020	$ 2,713
2021	3,457
2022	2,786
2023	608
2024	519
Total future minimum lease payments	10,083
Less: imputed interest	(964)
Total operating lease liabilities	$ 9,119

Included in the balance sheet:	December 31, 2019 (in thousands)
Current operating lease liabilities	$ 3,132
Operating lease liabilities, net of current portion	5,987
Total operating lease liabilities	$ 9,119

As previously disclosed in the Company's 2019 Annual Report on Form 10-K and under the previous lease accounting standard, *ASC 840, Leases*, the following table summarizes the future minimum lease payments due under the operating leases as of September 30, 2019:

Years Ended September 30,	Operating Leases	Capital Leases
	(in thousands)	
2020	$ 2,728	$ 93
2021	2,803	101
2022	2,684	99
2023	608	—
2024	519	—
Thereafter	—	—
Total	$ 9,342	$ 293

In connection with one of the real estate leases, the Company has a total outstanding letter of credit in the amount of $608 as of December 31, 2019 and September 30, 2019, collateralized by a money market account. As of December 31, 2019 and September 30, 2019, the Company classified the $608 related to the money market account as long-term restricted cash.

12. Commitments and Contingencies

Litigation and Contingencies Related to Use of Intellectual Property

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

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnifications of varying scope and terms to customers, vendors, lessors, business partners, and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements 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 it has not accrued any liabilities related to such obligations in its financial statements as of December 31, 2019.

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, 2019 included in our Annual Report on Form 10-K for that fiscal year which is referred to as our 2019 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 for the treatment of chronic hepatitis C virus, or HCV. Glecaprevir is co-formulated as part of AbbVie's leading direct-acting antiviral (DAA) combination treatment for HCV and marketed under the tradenames MAVYRET® (U.S.) and MAVIRET™ (ex-U.S.) (glecaprevir/pibrentasvir). Our royalties from our AbbVie collaboration and, to the extent necessary, our existing financial resources, provide us funding to support our wholly-owned research and development programs, which are primarily focused on the following disease targets with the following compounds in clinical development, all of which have been granted Fast Track designation by the U.S. Food and Drug Administration (FDA):

- EDP-938, for respiratory syncytial virus, or RSV, infection, the most common cause of bronchiolitis and pneumonia in young children and a significant cause of respiratory illness in older adults, with estimates suggesting that approximately 200,000 hospitalizations in the U.S. and EU occur each year in children under the age of two and approximately 170,000 hospitalizations in these regions occur each year in adults over the age of 65;
- EDP-305, for non-alcoholic steatohepatitis, or NASH, a liver disease estimated to affect approximately 1.5% to 6.5% of the population in the developed world (which translates to approximately 5 to 20 million individuals in the U.S. alone); and
- EDP-514, for hepatitis B virus, or HBV, the most prevalent chronic hepatitis, which is estimated to affect approximately 250 million individuals worldwide.

We had $414.7 million in cash and marketable securities at December 31, 2019. We expect cash flows from continuing royalties on our HCV products and, to the extent necessary, our existing financial resources, 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 virology, namely RSV, HBV and human metapneumovirus, or hMPV, and in liver disease (non-viral), namely NASH and PBC:

- RSV and hMPV: We have a clinical stage program for RSV, for which the lead asset is EDP-938, and we have recently launched discovery efforts in hMPV, a virus that causes respiratory infection with symptoms similar to RSV.

  We discovered EDP-938, a potent N-protein inhibitor of activity of both major subgroups of RSV, referred to as RSV-A and RSV-B, and have been investigating it as our first clinical candidate for RSV. EDP-938 is the only N-protein inhibitor in clinical development.

  - In June 2019, we announced positive topline results from our Phase 2a human challenge study of EDP-938 in healthy adults infected with a specific strain of RSV.
  - In November 2019, we initiated our first Phase 2b study of EDP-938, which is in adult outpatients with community-acquired RSV infection. This study, named RSVP, is designed to help us better understand the feasibility of this direct-acting antiviral (DAA) therapy. Due to the apparent peak of the RSV season being early in North America this winter, we are now planning to continue the study in the southern hemisphere later in the year and enrollment in all sites through 2020, with the goal of having data in the first half of 2021.
  - Concurrent with the RSVP study, we are also planning to initiate two additional studies by the end of calendar 2020, one in pediatric patients and one in an immune-compromised population.

Since announcing our new drug discovery program for hMPV in January 2020, we are currently optimizing nanomolar inhibitor leads against this virus.

- NASH and PBC: We are working on compounds, referred to as FXR agonists, that selectively bind to and activate the farnesoid X receptor, or FXR. FXR agonists have shown efficacy in NASH and we believe that this mechanism has promise as an important component in potential combination therapies for NASH. We have EDP-305 ready for a Phase 2b study and we have identified a follow-on compound, EDP-297, to initiate clinical development in mid-calendar 2020. We plan to develop at least one of these compounds primarily for use in combination treatments of NASH, a liver disease with very few therapeutic options. Our lead FXR agonist, EDP-305, represents a class of FXR agonists designed to take advantage of increased binding interactions with this receptor.
    - By early in the second quarter of calendar 2020, we plan to initiate dosing in a 72-week Phase 2b study, named ARGON-2, with histological endpoints, including fibrosis in biopsy-confirmed NASH patients treated with EDP-305 or placebo. The study will include an interim analysis to enhance our ability to seek opportunities more quickly for development of EDP-305 in combinations with other mechanisms for NASH.
    - Next, we expect to initiate Phase 1 development in mid-calendar 2020 of EDP-297 as our follow-on FXR development candidate.
    - In addition, we have been pursuing research in other mechanisms that may provide therapeutic benefit in NASH, any of which could be used in combination with an FXR agonist or other therapies for NASH.
    - We also have an ongoing Phase 2a study, named INTREPID, to assess the safety, tolerability, pharmacokinetics and efficacy of EDP-305 in subjects with primary biliary cholangitis, or PBC. We expect to have data from this study in the second quarter of calendar 2020.
- HBV: In July 2019, we announced initiation of a Phase 1a/1b clinical study of EDP-514, our lead core inhibitor for the treatment of hepatitis B virus (HBV).
    - The randomized, double-blind, placebo-controlled Phase 1a/1b study is designed to evaluate first the safety, tolerability and pharmacokinetics (PK) of single ascending doses (SAD) and multiple ascending doses (MAD) of EDP-514 in healthy subjects, and then the antiviral activity of EDP-514 in patients with chronic HBV infection that is being suppressed with nucleos(t)ide-reverse-transcriptase treatment, whom we refer to as nuc-suppressed patients.
    - The SAD and MAD part of the study (Part 1) has been completed successfully. Overall, EDP-514 demonstrated a favorable safety profile in healthy subjects for up to 14 days and was well tolerated with all treatment emergent adverse events being mild in intensity and with no discontinuations due to adverse events. Further, there were no significant individual laboratory data findings or pattern of abnormalities and EDP-514's pharmacokinetic profile demonstrated good blood levels that support once-daily dosing.
    - Based on these results, we have initiated Part 2 of the study to evaluate EDP-514 in nuc-suppressed patients.
    - We are also planning to initiate in the second quarter of calendar 2020 a separate Phase 1b study in patients with chronic HBV infection who are not on HBV therapy and have high levels of virus in their blood, whom we refer to as viremic patients.

We have utilized our internal chemistry and drug discovery capabilities to generate all of our development-stage programs. We continue to invest substantial resources in research programs to discover back-up compounds as well as new compounds targeting different mechanisms of action, both in our disease areas of focus as well as potentially in other disease areas.

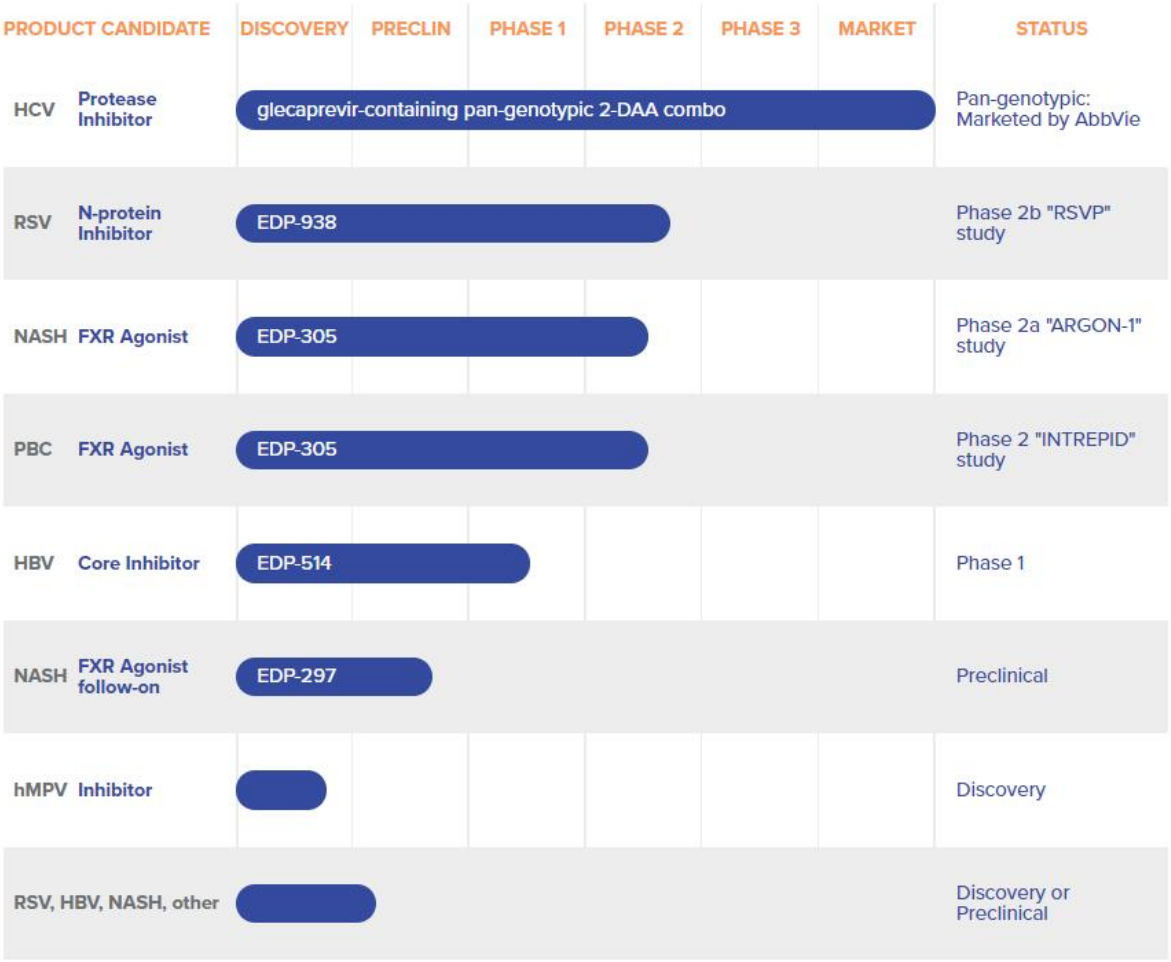
Our Out-Licensed Products

Through our Collaborative Development and License Agreement with AbbVie, we have discovered and out-licensed to AbbVie two protease inhibitor compounds that have been clinically tested, manufactured, and commercialized by AbbVie as part of its combination regimens for HCV. We have earned all $330.0 million milestone payments under the agreement related to clinical development and commercialization regulatory approvals of these regimens in major markets.

- 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 names MAVYRET® (U.S.) and MAVIRET™ (ex-U.S.) is referred to in this report as MAVYRET/MAVIRET. This regimen is a novel, 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 U.S., EU and Japan it is approved as an 8-week treatment for patients with and without compensated cirrhosis and new to treatment. Today, these patients are estimated to represent the majority of HCV patients in developed country markets, and MAVYRET/MAVIRET remains the only 8-week pangenotypic HCV treatment.

- Since August 2017, substantially all of our royalty revenue has been derived from AbbVie's net sales of MAVYRET/MAVIRET. Our ongoing royalty revenues from this regimen consist of annually tiered, double-digit, per-product royalties 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 AbbVie's paritaprevir-containing regimens, and the annual royalty tiers return to the lowest tier for sales on and after each January 1.

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



*Fixed-dose combination contains glecaprevir and AbbVie's NS5A inhibitor, pibrentasvir. Marketed as MAVYRET (U.S.) and MAVIRET (ex-U.S.), it replaces VIEKIRA PAK (no longer sold in the U.S.) and VIEKIRAX (sold primarily in select jurisdictions where MAVIRET is not yet approved).

Financial Operations Overview

We are currently funding all research and development for our wholly-owned programs, which are targeted towards the discovery and development of novel compounds for the treatment of viral infections and liver diseases. In calendar 2020 we are continuing enrollment in our Phase 2b study of EDP-938 in adult out-patients with RSV and plan to initiate additional Phase 2 RSV studies in the fourth quarter, one in a pediatric patient population and a second in transplant patients. In the first quarter we announced data from our Phase 1 study of EDP-514 in healthy volunteers, we initiated a Phase 1b study in patients with chronic HBV infection that is suppressed by nucleos(t)ide-reverse-transcriptase treatment (nuc-suppressed), and we plan to initiate a separate Phase 1b study of EDP-514 in chronic HBV patients who are not on HBV therapy. We also plan to initiate our ARGON-2 study of EDP-305 in NASH patients by early in the second quarter of calendar 2020, as well as a Phase 1 study of EDP-297, our FXR follow-on development candidate**,** in mid-calendar 2020. As a result of our clinical development program as well as efforts to advance other compounds into

preclinical development, we expect to incur greater expenses in fiscal 2020 than in 2019 as we continue to advance our RSV, NASH and HBV programs.

We are funding our operations primarily through payments received under our collaboration agreement with AbbVie and, to the extent necessary, our existing cash, cash equivalents, and short-term and long-term marketable securities. Our revenue is currently dependent on royalty payments we receive from AbbVie on its sales of MAVYRET/MAVIRET. AbbVie has guided that it expects its calendar 2020 HCV sales will be approximately $2.5 billion.

Given the uncertainty regarding the level of AbbVie's future MAVYRET/MAVIRET sales that will generate our royalty revenue, as well as the development risks affecting the extent and timing of our future expenditures for the advancement of our internally developed compounds, it is uncertain whether we will continue to report net income in future periods.

Royalty Revenue

Our revenue consists of royalties received under our collaboration agreement with AbbVie, substantially all of which are now derived from sales of MAVYRET/MAVIRET. Under the terms of our AbbVie agreement, as amended in October 2014, we earn annually tiered, double-digit royalties on the 50% of AbbVie's net sales of MAVYRET/MAVIRET allocated to glecaprevir. 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.

We expect all of our revenue in fiscal 2020 to be generated from royalties received under our collaboration agreement with AbbVie. There are no further milestones expected to be earned under the agreement.

Internal Programs

As our internal product candidates are currently in Phase 1 or Phase 2 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.

Operating Expenses

The following table summarizes our operating expenses for the three months ended December 31, 2019 and 2018:

	Three Months Ended December 31,	
	2019	2018
	(in thousands)	
Research and development	$ 32,778	$ 34,878
General and administrative	6,921	7,152
Total operating expenses	$ 39,699	$ 42,030

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

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 research and development 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 the 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), Net

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

Income Tax Expense

Income tax (expense) benefit is based on our best estimate of applicable income tax rates, net research and development tax credits and deferred income taxes, for the entire fiscal year applied to pre-tax profit or loss reported for the year-to-date period, except when a reliable estimate of the annual effective tax rate cannot be made and we instead use the year-to-date effective tax rate.

Results of Operations

Comparison of Three Months Ended December 31, 2019 and 2018

	Three Months Ended December 31,	
	2019	2018
	(in thousands)	
Royalty revenue	$ 52,570	$ 69,886
Research and development	32,778	34,878
General and administrative	6,921	7,152
Other income (expense), net	2,076	1,885
Income tax expense	(1,504)	(3,730)

Royalty Revenue

Our revenue consists of royalties received under our collaboration agreement with AbbVie, substantially all of which are now derived from sales of MAVYRET/MAVIRET. Our collaboration's MAVYRET/MAVIRET regimen, a pan-genotypic treatment combining two DAAs, began commercialization in the third calendar quarter of 2017, following its approval in the EU and the U.S. We are entitled to annually tiered, double-digit, per-product royalties on 50% of all net sales of MAVYRET/MAVIRET. Our royalty revenues eligible to be earned in the future will potentially fluctuate depending on AbbVie's HCV market share, the pricing of the MAVYRET/MAVIRET regimen and the number of patients treated with that regimen. 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.

We recognized royalty revenue of $52.6 million during the three months ended December 31, 2019 as compared to $69.9 million during the three months ended December 31, 2018.

Research and development expenses

	Three Months Ended December 31,	
	2019	2018
	(in thousands)	
R&D programs:		
Liver disease (non-viral)	$ 13,433	$ 18,655
Virology	19,236	16,132
Other	109	91
Total research and development expenses	$ 32,778	$ 34,878

Research and development expense decreased by $2.1 million for the three months ended December 31, 2019 as compared to the same period in 2018. The decrease in expenses in our liver disease program was due to timing of clinical studies. We completed a Phase 2a study of EDP-305 in a NASH population in fiscal 2019 and plan to initiate a Phase 2b study by early in in the second calendar quarter of 2020. The increase in expenses in our virology program was primarily due to the progression of clinical activities in our HBV program, including initiation of the ongoing Phase 1a/1b clinical study of EDP-514. We expect our research and development expenses to increase as our wholly owned programs advance.

General and administrative expenses

General and administrative expenses remained relatively flat quarter over quarter.

Other income (expense), net

Other income (expense), net, remained relatively flat quarter over quarter.

Income tax expense

For the three months ended December 31, 2019 and 2018, we recorded an income tax expense of $1.5 million and $3.7 million, respectively. Income tax expense for the three months ended December 31, 2019 was driven primarily by our pre-tax income, research and development tax credits and the federal income tax benefit from foreign-derived royalty income. Income tax expense for the three months ended December 31, 2018 was driven primarily by our pre-tax income and research and development tax credits.

Liquidity and Capital Resources

At December 31, 2019, our principal sources of liquidity were cash, cash equivalents and short-term and long-term marketable securities totaling $414.7 million.

The following table shows a summary of our cash flows for the three months ended December 31, 2019 and 2018:

	December 31,	
	2019	2018
	(in thousands)	
Cash provided by (used in):		
Operating activities	$ 12,363	$ 30,254
Investing activities	(37,201)	(20,931)
Financing activities	1,166	1,140
Net increase (decrease) in cash, cash equivalents and restricted cash	$ (23,672)	$ 10,463

Net cash provided by operating activities

The decrease in cash provided by operating activities of $17.9 million for the three months ended December 31, 2019 as compared to the same period in 2018 was primarily driven by decreased net income year-over-year and net cash used by changes in our operating assets and liabilities of $6.4 million in the three months ended December 31, 2019 as compared to net cash used by changes in our operating assets and liabilities of $0.4 million for the same period in 2018. Changes in our operating assets and liabilities in both periods were generally due to payments received under our collaboration with AbbVie, the advancement of our research programs and the timing of vendor invoicing and payments.

Net cash used in investing activities

The increase in cash used in investing activities of $16.3 million for the three months ended December 31, 2019 as compared to the same period in 2018 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 for the three months ended December 31, 2019 as compared to the same period in 2018 was driven by a $1.1 million increase in proceeds from exercises of stock options, partially offset by a $1.1 million increase in withholding tax payments for the settlement of share-based awards.

Funding requirements

As of December 31, 2019, we had $414.7 million in cash, cash equivalents and short-term and long-term marketable securities. We believe that our existing cash, cash equivalents and marketable securities as of December 31, 2019 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:

- the amount of royalties generated from our existing collaboration with AbbVie;
- the number and characteristics of our research and development programs;
- the scope, progress, results and costs of researching and developing any of our product candidates on our own, including conducting advanced clinical trials;
- the cost of manufacturing our product candidates for clinical development and any products we successfully commercialize independently;
- opportunities to in-license or otherwise acquire new technologies, therapeutic candidates and therapies;
- 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 timing and amount of any sales of our product candidates, if any, or royalties thereon;
- our ability to establish new collaborations, licensing or other arrangements, if any, and the financial terms of such arrangements;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patents, including any litigation costs and the outcomes of any such litigation; and
- potential fluctuations in foreign currency exchange rates.

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 2019 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 to our total contractual commitments and obligations during the three months ended December 31, 2019.

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 evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions and conditions. See our Annual Report on Form 10-K for the fiscal year ended September 30, 2019 (referred to as our 2019 Form 10-K) for information about critical accounting policies as well as a description of our other significant accounting policies.

Other than the impact of the adoption of ASC 842 in the first quarter of fiscal 2020, as disclosed in Note 2 to our unaudited financial statements included in this Quarterly Report on Form 10-Q, there have been no material changes to our significant accounting policies since September 30, 2019. For further information, please see the discussion of critical accounting policies included in our 2019 Form 10-K.

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 $414.7 million at December 31, 2019 consisting of cash, money market funds, agency securities, commercial paper, treasury notes and corporate bonds. Interest income is sensitive to changes in the general level of interest rates; however, due to the nature of these investments, a change in market interest rates of 100 basis points would not be expected to have a material impact on our financial condition or results of operations.

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 Annual Report on Form 10-K for the fiscal year ended September 30, 2019 filed on November 27, 2019 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 continue to generate revenue will depend primarily on the success of AbbVie's efforts to maintain sales of MAVYRET/MAVIRET. Such success is subject to uncertainty, and we have no control over the resources, time and effort that AbbVie may devote to sales of this regimen. Any of several events or factors could have a material adverse effect on our ability to continue to generate revenue from AbbVie's sales of MAVYRET/MAVIRET. For example, AbbVie:

- may not maintain satisfactory levels of prescriptions by physicians and reimbursement by third-party payers for the MAVYRET/MAVIRET regimen in the various markets of the world where it is being sold;
- may not compete successfully with its MAVYRET/MAVIRET regimen against other products and therapies for HCV, including competition for exclusive arrangements with third-party payers and governmental entities as well as price competition;
- 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 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. AbbVie may also 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.

AbbVie's MAVYRET/MAVIRET regimen continues to be the leading HCV treatment in the U.S. and several market geographies in developed countries where it is approved even though in the U.S. 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 required input from us, we believe it is possible that prices will decline further due to payers obtaining additional discounts or competitive market dynamics. For example, the states of Louisiana and Washington have each announced efforts to negotiate a blanket price for one of the HCV drug companies to treat all patients in one or more state programs (e.g. Medicaid). Gilead was awarded the contract in Louisiana and AbbVie was awarded the contract in Washington. It is unknown whether these programs or other programs that states may adopt could have an impact on MAVYRET/MAVIRET sales. There may also be fluctuations in AbbVie's market share over time due to these and other competitive actions by Gilead.

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 this regimen and our royalty revenue derived from its sales.

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). Gilead launched authorized generic versions of Epclusa and Harvoni in January 2019 through a newly created subsidiary, Asegua Therapeutics, LLC, which has had an impact on the competitive landscape. For example, in March 2019, the state of Louisiana announced the selection of Asegua Therapeutics as their HCV subscription model pharmaceutical partner to provide the state with unrestricted access to its direct-acting antiviral medication. Other 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 other than authorized generic versions by the manufacturer of the branded product (i.e. Gilead and Asegua Therapeutics), 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. In February 2019, Intercept Pharmaceuticals announced positive Phase 3 trial results for OCA (brand name Ocaliva®) in NASH and has also signaled its intent to submit U.S. and European regulatory filings in the second half of calendar 2019 for approvals in this indication. We are aware of several other companies with NASH programs that are significantly more advanced than ours, including companies with compounds in Phase 3 clinical trials in NASH, namely Genfit, Madrigal and Tobira (Allergan). In addition, a number of companies have NASH or related programs with compounds in Phase 2 clinical trials. These companies include Akero, Alberio, Astra-Zeneca, BMS, Boehringer Ingelheim, Can-Fite BioPharma, Cirius, Cymabay, Galectin, Galmed, Gilead, GlaxoSmithKline, Immuron, Inventiva, Ionis, Lipocine, Medicinova, Metacrine, Northsea Therapeutics, Novartis, NGM, Novo Nordisk, Pfizer, Second Genome, Viking and Zydus. For PBC, in May 2016, the FDA granted conditional approval for Intercept's FXR agonist, OCA for the treatment of 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, several other companies are conducting advanced trials in PBC, including Cymabay (Phase 3) and Genfit (Phase 2 completed). A significant number of other companies are conducting earlier stage clinical trials that may be applicable in NASH, PBC 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, Assembly, 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, Aligos, Altimmune, Arrowhead, Contravir, Dicerna, ENYO, Transgene and Vir.

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 patients. Ark Biosciences, Johnson & Johnson, Pulmocide and ReViral each have compounds in clinical development. 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 RSV, NASH, PBC 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, EDP-938 and/or EDP-514 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.

Changes in royalty revenue earned under our AbbVie agreement or changes in the level of 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.

As discussed above, our principal source of revenue continues to be our royalty revenue earned under the AbbVie collaboration agreement. There is uncertainty regarding this future revenue stream given the competitive nature of the market for HCV therapies, which reflects price competition, the changing nature of payer contracts of AbbVie and others, and the varying rates of reimbursement in different countries. Changes in royalty revenue earned under the AbbVie collaboration agreement, including those that occur from period to period due to the annually tiered structure of our royalties, may cause our revenues and operating results to fluctuate significantly from quarter to quarter and could have an adverse effect on our stock price.

Additionally, many of the preclinical and clinical development activities required for our product candidates must 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. We also conduct clinical development activities outside the U.S. and are therefore exposed to foreign currency fluctuations for payments made to CROs in currencies other than the U.S. dollar. 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 and 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.

Our net income results primarily from the revenue we earn from AbbVie on net sales of its 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 in one or more countries. 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 sales of MAVYRET/MAVIRET decline substantially. 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. In addition, we may seek opportunities to in-license or otherwise acquire new therapeutic candidates and therapies.

Our future capital requirements depend on many factors, including:

- the amount of royalties generated from our existing collaboration with AbbVie;
- the number and characteristics of our research and development programs;
- the scope, progress, results and costs of researching and developing any of our product candidates on our own, including conducting advanced clinical trials;
- the cost of manufacturing our product candidates for clinical development and any products we successfully commercialize independently;
- opportunities to in-license or otherwise acquire new technologies, therapeutic candidates and therapies;
- 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 timing and amount of any sales of our product candidates, if any, or royalties thereon;
- our ability to establish new collaborations, licensing or other arrangements, if any, and the financial terms of such arrangements;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patents, including any litigation costs and the outcomes of any such litigation; and
- potential fluctuations in foreign currency exchange rates.

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.

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;
- failure to obtain on a timely basis, or at all, 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,
- seasonality and variations in incidents of infection year to year (e.g. RSV) affecting enrollment in clinical trials;
- 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;
- changes in governmental or regulatory administration, including, for example, administrative delays due to the planned relocation of the EMA to the Netherlands;
- changes in regulatory requirements, policy and guidelines, including guidelines specifically addressing requirements for the development of treatments for RSV, NASH, PBC or HBV;
- difficulty in obtaining and maintaining adequate insurance coverage;
- 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 RSV, NASH 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, EDP-514 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.

In our RSV program, we are developing inhibitors of the N protein. No inhibitor of the RSV N protein has progressed beyond a Phase 2 clinical trial, so we are not yet able to assess the potential liabilities of an N inhibitor in large scale studies or in the general population. In addition, in RSV the principal target populations, namely infants, the elderly, and the immunocompromised, represent sensitive patient populations that could be more prone to adverse effects of therapy.

In our HBV program, we are developing modulators of capsid assembly. This is a new mechanistic approach to HBV, and no capsid assembly modulators have advanced beyond Phase 2 clinical studies. Thus, we are not able to predict what adverse effects may arise in longer term studies conducted in larger populations. In addition, long term consequences of an HBV infection can include hepatocellular carcinoma, liver failure, or liver transplant. It may be difficult to determine whether our drug candidates are playing a direct role in contributing to (or protecting from) these downstream effects of HBV infection.

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

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

- regulatory authorities may require us to take our approved product off the market;
- we may be subject to litigation or product liability claims; and
- our reputation and our stock price may suffer.

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

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

Clinical trials involving our product candidates may be suspended or terminated at any time for a number of safety-related reasons. For example, we may voluntarily suspend or terminate clinical trials if at any time one of our product candidates, or a combination therapy including any of them, presents an unacceptable safety risk to the clinical trial patients. In addition, IRBs or regulatory agencies may order the temporary discontinuation or termination of clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements, including if they present an unacceptable safety risk to patients. Administering any product candidate to humans may produce undesirable side effects. The existence of undesirable side effects resulting from any of our product candidates, or a combination therapy including any of them, could cause us or regulatory authorities, such as the FDA or EMA, to interrupt, delay or halt clinical trials of our product candidates and could result in the FDA or EMA or other regulatory agencies denying further development or approval of our product candidates for any or all targeted indications. This, in turn, could prevent us from commercializing our product candidates.

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

The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials, if any. In addition, results of Phase 3 clinical trials in one or more ethnic groups are not necessarily indicative of results in other ethnic groups. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy results despite having progressed through preclinical studies and initial clinical trials. Many companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to adverse safety profiles or lack of efficacy, notwithstanding promising results in earlier studies. Similarly, future clinical trial results may not be successful for these or other reasons.

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

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

The regulatory approval process is expensive and, while the time required to gain FDA and foreign regulatory approval is uncertain, it may take years. Regulatory approvals are unpredictable and depend upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of preclinical and clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We may be required to undertake and complete certain additional preclinical studies to generate toxicity and other data required to support the submission of a New Drug Application, or NDA, to the FDA or comparable application to other regulatory authorities. AbbVie obtained all regulatory approvals for its paritaprevir-containing regimens and for MAVYRET/MAVIRET, which contains glecaprevir. We have not obtained regulatory approval by ourselves for any of our wholly-owned product candidates and it is possible that none of our existing product candidates or any of our future product candidates will ever obtain regulatory approval. Furthermore, approval in the United States by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA.

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

- the FDA, the EMA or other comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA, the EMA or other comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;

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

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

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

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

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

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

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

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

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

Risks Related to Commercialization of Our Product Candidates

Unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives in the United States could harm our business.

The regulations that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. In the United States, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010, collectively referred to as the ACA, has significantly changed the way healthcare is financed by both governmental and private insurers. While we cannot predict what impact on federal reimbursement policies this law or any amendment to it will continue to have in general or specifically on MAVYRET/MAVIRET or any product or regimen that we may commercialize, the ACA or any such amendment may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of new products. In addition, although the United States Supreme Court has upheld the constitutionality of most of the ACA, several states have not implemented certain sections of the ACA, including 14 that have rejected the expansion of Medicaid eligibility for low income citizens, and some members of the U.S. Congress are still working to repeal the ACA. More recently, President Trump and the Republicans in both houses of the U.S. Congress have been seeking to repeal or replace all or portions of the ACA but to date they have been unable to agree on any such legislation. On December 14, 2018, a United States District Court judge in Texas ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. While this U.S. District Court judge, as well as the Trump administration and Centers for Medicare and Medicaid Services, have stated that the ruling will have no immediate effect pending appeal of the decision, on December 18, 2019, the Fifth Circuit U.S. Court of Appeals held that the individual mandate is unconstitutional and remanded the case to the District Court to reconsider its earlier invalidation of the entire Affordable Care Act. It is unclear how this decision, subsequent proceedings and appeals in this case, and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act. We cannot predict what legislation, if any, to repeal or replace the ACA will become law, or what impact any such legislation, or the Texas court challenge, may have on us or on AbbVie's sales of MAVYRET/MAVIRET.

In addition, other legislative changes have been proposed since the Affordable Care Act was enacted. There has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there have been several recent U.S. congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. We expect any healthcare reform measures that may be adopted in the future could result in more rigorous coverage criteria and an additional downward pressure on the price that AbbVie receives for MAVYRET/MAVIRET, which could seriously harm our future revenues, and the price of our common stock could be materially adversely affected.

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

There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable authorities in other jurisdictions. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also be insufficient to cover our and any collaborator's costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. AbbVie's inability to continue to obtain coverage and profitable payment rates from both government-funded and private payors for MAVYRET/MAVIRET, or our inability to obtain the same for any product candidate that we develop, could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

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

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

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

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

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

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

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

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

Where and when appropriate, we may elect to utilize contract sales forces or distribution partners to assist in the commercialization of our product candidates. If we enter into arrangements with third parties to perform sales, marketing and distribution services for our

products, the resulting revenues or the profitability from these revenues to us are likely to be lower than if we had sold, marketed and distributed our products ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of these third parties may fail to devote the necessary resources and attention to sell, market and distribute our products effectively.

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

Commercial success of our product candidates depends upon significant market acceptance among physicians, patients and healthcare payors of any resulting approved drug.

MAVYRET/MAVIRET, as well as EDP-305, EDP-938, EDP-514 and any other product candidate that we may develop in the future, whether as part of a combination therapy or as a monotherapy, are subject to market acceptance among physicians, healthcare payors, patients and the medical community. The degree of market acceptance of MAVYRET/MAVIRET or of any product candidate for which we obtain approval for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of treatment regimens containing one of our product candidates, as demonstrated in clinical trials, and the degree to which these regimens represent a clinically meaningful improvement in care as compared with other available therapies;
- the clinical indications for which any treatment regimen containing one of our product candidates become approved;
- acceptance among physicians, major operators of clinics, payors and patients of any treatment regimen containing one of our product candidates;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the potential and perceived advantages of treatment regimens containing one of our product candidates over alternative treatments;
- the cost of treatment of regimens containing one of our product candidates in relation to the cost of alternative treatments;
- the availability of adequate reimbursement and pricing by third parties and government authorities and successful negotiation of favorable agreements with payors by us or any collaborator of ours, as well as the impact of any agreements among any of the foregoing and one or more of our competitors limiting access to our product in favor of one or more competitive products;
- the continued longevity of the HCV drug market or growth and longevity of any other market for which we develop a drug;
- the levels of funding provided by government-funded healthcare for HCV treatment or treatment of any other disease for which we develop a drug;
- the relative convenience and ease of administration of any treatment regimen containing one of our product candidates compared to competitive regimens;
- the prevalence and severity of adverse side effects, whether involving the use of treatment regimens containing one of our products candidates or similar, competitive treatment regimens; and
- the effectiveness of our sales and marketing efforts and those of AbbVie in the case of MAVYRET/MAVIRET.

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

Risks Related to Our Dependence on Third Parties

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

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

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

- the development of certain of our product candidates may be terminated or delayed;
- our cash expenditures related to development of certain of our product candidates would increase significantly and we may need to seek additional financing;
- we may be required to hire additional employees or otherwise develop expertise, such as clinical, regulatory, sales and marketing expertise, which we do not currently have;
- we will bear all of the risk related to the development of any such product candidates; and
- the competitiveness of any product candidate that is commercialized could be reduced.

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

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

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

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

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

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

Although manufacturing for MAVYRET/MAVIRET is being conducted by AbbVie, we have relied on third parties located in China to manufacture and supply certain key intermediates used in the manufacture of our active pharmaceutical ingredients, or API, for our current product candidates, and we expect to continue to use such third party manufacturers for such intermediates for any product candidates we develop independently. Any disruption in production or inability of our manufacturers in China to produce adequate quantities to meet our needs, whether as a result of a natural disaster or other causes, could impair our ability to operate our business on a day-to-day basis and to continue our research and development of our product candidates. We also use contract researchers in China to conduct a portion of our research for our early stage programs. Any disruption in the team conducting that research could cause delays in one or more of our research programs and could require us to curtail one or more programs, at least until we could contract for that research to be done elsewhere. For example, either of these risks could be triggered by an epidemic such as the recent outbreak of the 2019 nCoV coronavirus in the Wuhan region of China. To date our contract manufacturer in China, which is not located in the Wuhan region, has advised that the Chinese government has required it to remain closed for a three-day extension of the Chinese New Year holiday week. Furthermore, since these researchers and manufacturers are located in China, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the United States or Chinese governments, political unrest or unstable economic conditions in China. For example, a trade war could lead to tariffs on the chemical intermediates we use that are manufactured in China. Any of these matters could materially and adversely affect our business and results of operations. Any recall of the manufacturing lots or similar action regarding our API used in clinical trials could delay the trials or detract from the integrity of the trial data and its potential use in future regulatory filings. In addition, manufacturing interruptions or failure to comply with regulatory requirements by any of these manufacturers could significantly delay clinical development of potential products and reduce third-party or clinical researcher interest and support of proposed trials. These interruptions or failures could also impede commercialization of our product candidates and impair our competitive position. Further, we may be exposed to fluctuations in the value of the local currency in China. Future appreciation of the local currency could increase our costs. In addition, our labor costs could continue to rise as wage rates increase due to increased demand for skilled laborers and the availability of skilled labor declines in China.

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

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

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

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

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

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

Risks Related to Our Intellectual Property Rights

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Industry

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

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

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

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

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

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

Despite the implementation of security measures, our internal computer systems and those of our collaborators, CROs, and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Information security risks have significantly increased in recent years in part due to the

proliferation of new technologies and the increased sophistication and activities of organized crime, hackers, terrorists and other external parties, including foreign state actors. As cyber threats continue to evolve, we may be required to expend significant additional resources to continue to modify or enhance our protective measures or to investigate and remediate any information security breaches.

While we have not experienced any such system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our independent drug development programs. For example, the loss of clinical trial data from ongoing or future clinical trials for any of our product candidates could result in delays in regulatory approval efforts and significantly increase costs to recover or reproduce the data. Our information security systems are also subject to laws and regulations requiring that we take measures to protect the privacy and security of certain information we gather and use in our business. For example, HIPAA and its implementing regulations impose, among other requirements, certain regulatory and contractual requirements regarding the privacy and security of personal health information. In addition to HIPAA, numerous other federal and state laws, including, without limitation, state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use, disclosure and storage of personal information. To the extent that any disruption or security breach were to result in a loss of or damage to data or applications, or inappropriate disclosure of confidential or proprietary information or personal health information, we could incur substantial liability, our reputation would be damaged, and the further development of our product candidates could be delayed.

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

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

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

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our

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

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

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

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

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

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

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

Risks Related to Our Common Stock

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

Our stock price has been volatile and could be subject to wide fluctuations in response to various factors, many of which are beyond our control. From September 30, 2014 through December 31, 2019, the daily closing price of our common stock on the NASDAQ Global Select Market has ranged from $21.00 to $126.37. The stock market in general and the market for biopharmaceutical companies, and for those developing potential therapies for viral infections and liver diseases in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above your purchase price, if at all. The market price for our common stock may be influenced by many factors, including:

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

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

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

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

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

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

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibit a person who owns 15% or more of our outstanding voting stock from merging or combining with us

for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. Any provision in our corporate charter or our bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

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

Our executive officers are parties to employment agreements that provide for aggregate cash payments of up to approximately $4.3 million for severance and other non-equity-based benefits in the event of a termination of employment in connection with a change of control of our company. In addition, based on the closing price of our common stock as of December 31, 2019 of $61.78 per common share, the aggregate intrinsic value of unvested stock options and other equity awards subject to accelerated vesting upon these events was $12.9 million. The accelerated vesting of awards options could result in dilution to our stockholders and harm the market price of our common stock. The payment of these severance benefits could harm our company's financial condition and results. In addition, these potential severance payments may discourage or prevent third parties from seeking a business combination with us.

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

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

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

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

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

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. As of December 31, 2019, we had 19.8 million shares of common stock outstanding. In addition, as of December 31, 2019, 3.4 million and 0.2 million shares of common stock that are subject to outstanding options or restricted stock unit awards, respectively, under our outstanding equity plans are eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, and Rules 144 and 701 under the Securities Act. If these additional shares of common stock are sold, or it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

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

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

ITEM 6. EXHIBITS

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	Date	Exhibit Number	File Number	
3.1	Restated Certificate of Incorporation of Enanta Pharmaceuticals, Inc.	8-K	08/18/2015	3.1	001-35839	
3.2	Amended and Restated Bylaws of Enanta Pharmaceuticals, Inc. (as amended and restated in August 2015)	8-K	08/18/2015	3.2	001-35839	
31.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.	—	—	—	—	X
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.	—	—	—	—	X
32.1	Certification of the Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	—	—	—	—	X
101	The following financial statements from the Quarterly Report of Enanta Pharmaceuticals, Inc. on Form 10-Q for the quarter ended December 31, 2019, formatted in Inline XBRL: (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Comprehensive Income, (iv) Consolidated Statements of Stockholders' Equity, (v) Consolidated Statements of Cash Flows, (vi) and Notes to Consolidated Financial Statements, tagged as blocks of text and including detailed tags					X
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).					X

SIGNATURE

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

ENANTA PHARMACEUTICALS, INC.

Date: February 10, 2020

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

Exhibit 31.1

CERTIFICATION

I, Jay R. Luly, Ph.D., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Enanta Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 10, 2020

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

Exhibit 31.2

CERTIFICATION

I, Paul J. Mellett, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Enanta Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 10, 2020

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

Exhibit 32.1

ENANTA PHARMACEUTICALS, INC.

Certification of Periodic Financial Report
Pursuant to 18 U.S.C. Section 1350
as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Each of the undersigned officers of Enanta Pharmaceuticals, Inc. ("Enanta") certifies, to his knowledge and solely for the purposes of 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report on Form 10-Q of Enanta for the quarter ended December 31, 2019 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of Enanta.

Dated: February 10, 2020

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

Dated: February 10, 2020

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