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 SEPTEMBER 30, 2020
or
☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE TRANSITION PERIOD FROM _ TO _

Commission file number 000-19319

Vertex Pharmaceuticals Incorporated
(Exact name of registrant as specified in its charter)

Massachusetts	**04-3039129**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
50 Northern Avenue, Boston, Massachusetts	**02210**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code **(617) 341-6100**

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, $0.01 Par Value Per Share	VRTX	The Nasdaq Global Select Market

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 ☒

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Common Stock, par value $0.01 per share	260,037,894	Outstanding at October 23, 2020

VERTEX PHARMACEUTICALS INCORPORATED
FORM 10-Q
FOR THE QUARTER ENDED SEPTEMBER 30, 2020

TABLE OF CONTENTS

"We," "us," "Vertex" and the "Company" as used in this Quarterly Report on Form 10-Q refer to Vertex Pharmaceuticals Incorporated, a Massachusetts corporation, and its subsidiaries.

We use the brand name for our products when we refer to the product that has been approved and with respect to the indications on the approved label. Otherwise, including in discussions of our cystic fibrosis development programs, we refer to our compounds by their scientific (or generic) name or VX developmental designation.

Part I. Financial Information

Item 1. Financial Statements

VERTEX PHARMACEUTICALS INCORPORATED
Condensed Consolidated Statements of Operations
(unaudited)
(in thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenues:				
Product revenues, net	$ 1,536,271	$ 949,828	$ 4,575,863	$ 2,747,461
Collaborative and royalty revenues	2,000	—	2,000	2,095
Total revenues	1,538,271	949,828	4,577,863	2,749,556
Costs and expenses:				
Cost of sales	186,182	131,914	533,199	362,746
Research and development expenses	493,497	555,948	1,362,953	1,274,529
Sales, general and administrative expenses	184,551	159,674	558,613	463,221
Change in fair value of contingent consideration	1,800	2,959	12,600	2,959
Total costs and expenses	866,030	850,495	2,467,365	2,103,455
Income from operations	672,241	99,333	2,110,498	646,101
Interest income	3,100	17,628	19,919	51,319
Interest expense	(13,856)	(14,548)	(41,863)	(44,253)
Other income (expense), net	84,386	(31,747)	139,621	64,802
Income before provision for income taxes	745,871	70,666	2,228,175	717,969
Provision for income taxes	78,437	13,148	120,718	124,393
Net income	$ 667,434	$ 57,518	$ 2,107,457	$ 593,576
Net income per common share:				
Basic	$ 2.56	$ 0.22	$ 8.10	$ 2.32
Diluted	$ 2.53	$ 0.22	$ 7.98	$ 2.28
Shares used in per share calculations:				
Basic	260,392	256,946	260,313	256,289
Diluted	264,079	260,473	264,031	260,182

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

VERTEX PHARMACEUTICALS INCORPORATED
Condensed Consolidated Statements of Comprehensive Income
(unaudited)
(in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Net income	$ 667,434	$ 57,518	$ 2,107,457	$ 593,576
Other comprehensive (loss) income:				
Unrealized holding (losses) gains on marketable securities, net	(1,132)	64	818	1,111
Unrealized (losses) gains on foreign currency forward contracts, net of tax of $7.6 million, $2.2 million, $7.3 million and $5.5 million, respectively	(26,313)	12,812	(27,211)	6,814
Foreign currency translation adjustment	584	9,172	(12,616)	10,263
Total other comprehensive (loss) income	(26,861)	22,048	(39,009)	18,188
Comprehensive income	$ 640,573	$ 79,566	$ 2,068,448	$ 611,764

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

VERTEX PHARMACEUTICALS INCORPORATED
Condensed Consolidated Balance Sheets
(unaudited)
(in thousands, except per share amounts)

	September 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 5,358,087	$ 3,109,322
Marketable securities	792,971	698,972
Accounts receivable, net	791,917	633,518
Inventories	245,460	167,502
Prepaid expenses and other current assets	270,021	213,515
Total current assets	7,458,456	4,822,829
Property and equipment, net	920,913	745,080
Goodwill	1,002,158	1,002,158
Intangible assets	400,000	400,000
Deferred tax assets	1,147,816	1,190,815
Other assets	372,290	157,583
Total assets	$ 11,301,633	$ 8,318,465
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 107,786	$ 87,610
Accrued expenses	1,703,699	1,116,912
Other current liabilities	192,541	130,305
Total current liabilities	2,004,026	1,334,827
Long-term finance lease liabilities	546,514	538,576
Long-term contingent consideration	189,100	176,500
Other long-term liabilities	428,520	183,318
Total liabilities	3,168,160	2,233,221
Commitments and contingencies	—	—
Shareholders' equity:		
Preferred stock, $0.01 par value; 1,000 shares authorized; none issued and outstanding	—	—
Common stock, $0.01 par value; 500,000 shares authorized, 260,174 and 258,993 shares issued and outstanding, respectively	2,601	2,589
Additional paid-in capital	7,917,375	7,937,606
Accumulated other comprehensive loss	(40,982)	(1,973)
Retained earnings (accumulated deficit)	254,479	(1,852,978)
Total shareholders' equity	8,133,473	6,085,244
Total liabilities and shareholders' equity	$ 11,301,633	$ 8,318,465

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

VERTEX PHARMACEUTICALS INCORPORATED
Condensed Consolidated Statements of Shareholders' Equity
(unaudited)
(in thousands)

	Three Months Ended					
	Common Stock					
	Shares	Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Retained Earnings (Accumulated Deficit)	Total Shareholders' Equity
Balance at June 30, 2019	256,671	$ 2,565	$ 7,564,331	$ (3,201)	$ (2,493,730)	$ 5,069,965
Other comprehensive income, net of tax	—	—	—	22,048	—	22,048
Net income	—	—	—	—	57,518	57,518
Repurchase of common stock	(71)	—	(12,001)	—	—	(12,001)
Common stock withheld for employee tax obligations	—	—	(104)	—	—	(104)
Issuance of common stock under benefit plans	665	6	30,006	—	—	30,012
Stock-based compensation expense	—	—	85,956	—	—	85,956
Balance at September 30, 2019	257,265	$ 2,571	$ 7,668,188	$ 18,847	$ (2,436,212)	$ 5,253,394
Balance at June 30, 2020	260,124	$ 2,601	$ 7,943,717	$ (14,121)	$ (412,955)	$ 7,519,242
Other comprehensive loss, net of tax	—	—	—	(26,861)	—	(26,861)
Net income	—	—	—	—	667,434	667,434
Repurchase of common stock	(403)	(4)	(108,003)	—	—	(108,007)
Common stock withheld for employee tax obligations	(141)	(1)	(40,527)	—	—	(40,528)
Issuance of common stock under benefit plans	594	5	21,699	—	—	21,704
Stock-based compensation expense	—	—	100,489	—	—	100,489
Balance at September 30, 2020	260,174	$ 2,601	$ 7,917,375	$ (40,982)	$ 254,479	$ 8,133,473

	Nine Months Ended					
	Common Stock					
	Shares	Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Retained Earnings (Accumulated Deficit)	Total Shareholders' Equity
Balance at December 31, 2018	255,172	$ 2,546	$ 7,421,476	$ 659	$ (2,989,478)	$ 4,435,203
Cumulative effect adjustment for adoption of new accounting guidance	—	—	—	—	(40,310)	(40,310)
Other comprehensive income, net of tax	—	—	—	18,188	—	18,188
Net income	—	—	—	—	593,576	593,576
Repurchase of common stock	(904)	(9)	(162,009)	—	—	(162,018)
Common stock withheld for employee tax obligations	(27)	—	(5,936)	—	—	(5,936)
Issuance of common stock under benefit plans	3,024	34	144,523	—	—	144,557
Stock-based compensation expense	—	—	270,134	—	—	270,134
Balance at September 30, 2019	257,265	$ 2,571	$ 7,668,188	$ 18,847	$ (2,436,212)	$ 5,253,394
Balance at December 31, 2019	258,993	$ 2,589	$ 7,937,606	$ (1,973)	$ (1,852,978)	$ 6,085,244
Other comprehensive loss, net of tax	—	—	—	(39,009)	—	(39,009)
Net income	—	—	—	—	2,107,457	2,107,457
Repurchase of common stock	(1,807)	(18)	(408,015)	—	—	(408,033)
Common stock withheld for employee tax obligations	(727)	(7)	(179,768)			(179,775)
Issuance of common stock under benefit plans	3,715	37	232,042	—	—	232,079
Stock-based compensation expense	—	—	335,510	—	—	335,510
Balance at September 30, 2020	260,174	$ 2,601	$ 7,917,375	$ (40,982)	$ 254,479	$ 8,133,473

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

VERTEX PHARMACEUTICALS INCORPORATED
Condensed Consolidated Statements of Cash Flows
(unaudited)
(in thousands)

	Nine Months Ended September 30,	
	2020	**2019**
Cash flows from operating activities:		
Net income	$ 2,107,457	$ 593,576
Adjustments to reconcile net income to net cash provided by operating activities:		
Stock-based compensation expense	332,434	268,898
Depreciation expense	80,160	80,685
Increase in fair value of contingent consideration	12,600	2,959
Deferred income taxes	65,110	94,175
Gains on equity securities	(140,866)	(68,862)
Other non-cash items, net	52,371	(4,024)
Changes in operating assets and liabilities:		
Accounts receivable, net	(151,191)	(41,444)
Inventories	(94,907)	(45,280)
Prepaid expenses and other assets	(264,909)	(23,709)
Accounts payable	16,153	(12,210)
Accrued expenses	451,084	255,699
Other liabilities	296,477	22,859
Net cash provided by operating activities	2,761,973	1,123,322
Cash flows from investing activities:		
Purchases of available-for-sale debt securities	(246,937)	(381,739)
Maturities of available-for-sale debt securities	184,419	375,145
Sale of equity securities	149,595	—
Payment to acquire business, net of cash acquired	—	(245,824)
Expenditures for property and equipment	(212,109)	(58,690)
Investment in equity securities	(19,327)	(27,219)
Net cash used in investing activities	(144,359)	(338,327)
Cash flows from financing activities:		
Issuances of common stock under benefit plans	234,854	144,630
Repurchases of common stock	(408,033)	(150,017)
Payments in connection with common stock withheld for employee tax obligations	(179,775)	(5,936)
Payments on finance leases	(31,378)	(28,879)
Proceeds related to finance leases	8,642	1,002
Advance from collaborator	5,000	10,000
Repayments of advanced funding	(2,741)	(4,316)
Other financing activities	(6,658)	(1,132)
Net cash used in financing activities	(380,089)	(34,648)
Effect of changes in exchange rates on cash	2,779	(4,009)
Net increase in cash and cash equivalents	2,240,304	746,338
Cash, cash equivalents and restricted cash—beginning of period	3,120,681	2,658,253
Cash, cash equivalents and restricted cash—end of period	$ 5,360,985	$ 3,404,591
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 40,769	$ 41,704
Cash paid for income taxes	$ 81,684	$ 22,838
Issuances of common stock from employee benefit plans receivable	$ 45	$ 13
Accrued share repurchase liability	$ —	$ 12,001

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

VERTEX PHARMACEUTICALS INCORPORATED
Notes to Condensed Consolidated Financial Statements
(unaudited)

A. Basis of Presentation and Accounting Policies

Basis of Presentation

The accompanying condensed consolidated financial statements are unaudited and have been prepared by Vertex Pharmaceuticals Incorporated ("Vertex" or the "Company") in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP").

The condensed consolidated financial statements reflect the operations of the Company and its wholly-owned subsidiaries. All material intercompany balances and transactions have been eliminated. The Company operates in one segment, pharmaceuticals. The Company has reclassified certain items from the prior year's condensed consolidated financial statements to conform to the current year's presentation.

Certain information and footnote disclosures normally included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2019 (the "2019 Annual Report on Form 10-K") have been condensed or omitted. These interim financial statements, in the opinion of management, reflect all normal recurring adjustments necessary for a fair presentation of the financial position and results of operations for the interim periods ended September 30, 2020 and 2019.

The results of operations for the interim periods are not necessarily indicative of the results of operations to be expected for the full fiscal year. These interim financial statements should be read in conjunction with the audited financial statements for the year ended December 31, 2019, which are contained in the Company's 2019 Annual Report on Form 10-K.

Use of Estimates

The preparation of condensed consolidated financial statements in accordance with U.S. GAAP requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements, and the amounts of revenues and expenses during the reported periods. Significant estimates in these condensed consolidated financial statements have been made in connection with (i) determining the transaction price of revenues and (ii) accounting for intangible assets and contingent consideration. The Company bases its estimates on historical experience and various other assumptions, including in certain circumstances future projections that management believes to be reasonable under the circumstances. Actual results could differ from those estimates. Changes in estimates are reflected in reported results in the period in which they become known.

Recently Adopted Accounting Standards

Leases

On January 1, 2019, the Company adopted Accounting Standards Codification ("ASC") 842, *Leases* ("ASC 842") using the modified-retrospective method, which amended a number of aspects of lease accounting and required the Company to recognize right-of-use assets and liabilities on the balance sheet. As of January 1, 2019, the Company recorded a cumulative effect adjustment to increase its "Accumulated deficit" by $40.3 million, which related to its leases that were accounted for as build-to-suit leases under the previous accounting guidance.

Internal-Use Software

In 2018, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2018-15, *Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract* ("ASU 2018-15"), which clarifies the accounting for implementation costs in cloud computing arrangements. ASU 2018-15 became effective on January 1, 2020. The adoption of ASU 2018-15 resulted in an insignificant amount of additional assets recorded on the Company's condensed consolidated balance sheet.

Fair Value Measurement

In 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement* ("ASU 2018-13"), which modifies the disclosure requirements for fair value measurements. ASU 2018-13 became effective on January 1, 2020. The adoption of ASU 2018-13 resulted in additional disclosures related to the Company's Level 3 inputs. Please refer to Note E, "Fair Value Measurements," for further information.

Credit Losses

In 2016, the FASB issued ASU 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"), which requires entities to record expected credit losses for certain financial instruments, including trade receivables, as an allowance that reflects the entity's current estimate of credit losses expected to be incurred. For available-for-sale debt securities in unrealized loss positions, ASU 2016-13 requires allowances to be recorded instead of reducing the amortized cost of the investment. ASU 2016-13 became effective on January 1, 2020. The adoption of ASU 2016-13 did not have a significant impact on the Company's condensed consolidated financial statements.

Recently Issued Accounting Standards

Income Taxes

In 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740)* ("ASU 2019-12"), which simplifies the accounting for income taxes. ASU 2019-12 is effective on January 1, 2021. The Company is evaluating the impact the adoption of ASU 2019-12 may have on its condensed consolidated financial statements.

For a discussion of other recent accounting pronouncements please refer to Note A, "Nature of Business and Accounting Policies," in the Company's 2019 Annual Report on Form 10-K.

Summary of Significant Accounting Policies

The Company's significant accounting policies are described in Note A, "Nature of Business and Accounting Policies," in its 2019 Annual Report on Form 10-K.

B. Revenue Recognition

Disaggregation of Revenue

Revenues by Product

Product revenues, net consisted of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
	(in thousands)			
TRIKAFTA/KAFTRIO	$ 960,308	$ —	$ 2,773,256	$ —
SYMDEKO/SYMKEVI	156,178	403,714	501,066	1,085,821
ORKAMBI	225,919	296,711	692,038	906,159
KALYDECO	193,866	249,403	609,503	755,481
Total product revenues, net*	$ 1,536,271	$ 949,828	$ 4,575,863	$ 2,747,461

* The preceding table does not include collaborative and royalty revenues.

Revenues by Geographic Location

Net product revenues are attributed to countries based on the location of the customer. Collaborative and royalty revenues outside of the United States are attributed to countries based on the location of the Company's subsidiary associated with the collaborative arrangement related to such revenues. Total revenues from external customers and collaborators by geographic region consisted of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
	(in thousands)			
United States	$ 1,224,565	$ 710,323	$ 3,622,467	$ 2,052,044
Outside of the United States				
Europe	251,366	184,845	766,438	532,809
Other	62,340	54,660	188,958	164,703
Total revenues outside of the United States	313,706	239,505	955,396	697,512
Total revenues	$ 1,538,271	$ 949,828	$ 4,577,863	$ 2,749,556

Contract Liabilities

The Company had contract liabilities of $94.8 million and $62.3 million as of September 30, 2020 and December 31, 2019, respectively, related to annual contracts with government-owned and supported customers in international markets that limit the amount of annual reimbursement the Company can receive. Upon exceeding the annual reimbursement amount, products are provided free of charge, which is a material right. These contracts include upfront payments and fees. The Company defers a portion of the consideration received for shipments made up to the annual reimbursement limit as a portion of "Other current liabilities." The deferred amount is recognized as revenue when the free products are shipped. The Company's product revenue contracts include performance obligations that are one year or less.

The Company's contract liabilities at the end of each fiscal year relate to contracts with annual reimbursement limits in international markets in which the annual period associated with the contract is not the same as the Company's fiscal year. In these markets, the Company recognizes revenues related to performance obligations satisfied in previous years; however, these revenues do not relate to any performance obligations that were satisfied more than 12 months prior to the beginning of the current year.

C. Collaborative Arrangements

The Company has entered into numerous agreements pursuant to which it collaborates with third parties on research, development and commercialization programs, including in-license and out-license agreements.

The Company's in-license and out-license agreements that had a significant impact on its financial statements for the three and nine months ended September 30, 2020 and 2019, or were new or otherwise revised during the three and nine months ended September 30, 2020, are described below. Additional in-license and out-license agreements were described in Note B, "Collaborative Arrangements," of the Company's 2019 Annual Report on Form 10-K.

In-license Agreements

The Company has entered into a number of license agreements in order to advance and obtain access to technologies and services related to its research and early-development activities. The Company is generally required to make an upfront payment upon execution of the license agreement; development, regulatory and commercialization milestones payments upon the achievement of certain product research, development and commercialization objectives; and royalty payments on future sales, if any, of commercial products resulting from the collaboration.

Pursuant to the terms of its in-license agreements, the Company's collaborators typically lead the discovery efforts and the Company leads all preclinical, development and commercialization activities associated with the advancement of any drug candidates and funds all expenses.

The Company typically can terminate its in-license agreements by providing advance notice to its collaborators; the required length of notice is dependent on whether any product developed under the license agreement has received marketing approval. The Company's license agreements may be terminated by either party for a material breach by the other, subject to notice and cure provisions. Unless earlier terminated, these license agreements generally remain in effect until the date on which the royalty term and all payment obligations with respect to all products in all countries have expired.

CRISPR Therapeutics AG

In 2015, the Company entered into a strategic collaboration, option and license agreement (the "CRISPR Agreement") with CRISPR Therapeutics AG and its affiliates ("CRISPR") to collaborate on the discovery and development of potential new treatments aimed at the underlying genetic causes of human diseases using CRISPR-Cas9 gene-editing technology. The Company had the exclusive right to license certain targets. In the fourth quarter of 2019, the Company elected to exclusively license three targets, including cystic fibrosis, pursuant to the CRISPR Agreement. For each of the three targets that the Company elected to license, CRISPR has the potential to receive up to an additional $410.0 million in development, regulatory and commercial milestones as well as royalties on net product sales.

In 2017, the Company entered into a co-development and co-commercialization agreement with CRISPR pursuant to the terms of the CRISPR Agreement, under which the Company and CRISPR are co-developing and will co-commercialize CTX001 (the "CTX001 Co-Co Agreement") for the treatment of hemoglobinopathies, including treatments for sickle cell disease and beta thalassemia. As part of the collaboration, the Company and CRISPR share equally all development costs and potential worldwide revenues related to potential hemoglobinopathy treatments. The Company concluded that the CTX001 Co-Co Agreement is a cost-sharing arrangement, which results in the net impact of the arrangement being recorded in "Research and development expenses" in its condensed consolidated statements of operations. During the three and nine months ended September 30, 2020, the net expense related to the CTX001 Co-Co Agreement was $14.3 million and $33.4 million, respectively. During the three and nine months ended September 30, 2019, the net expense related to the CTX001 Co-Co Agreement was $7.7 million and $22.3 million, respectively.

In July 2019, the Company entered into a separate strategic collaboration and license agreement (the "CRISPR DMD/DM1 Agreement") with CRISPR. Pursuant to this agreement, the Company received an exclusive worldwide license to CRISPR's existing and future intellectual property for Duchenne muscular dystrophy ("DMD") and myotonic dystrophy type 1 ("DM1") and the Company made an upfront payment of $175.0 million to CRISPR. The Company concluded that it did not have any alternative future use for the acquired in-process research and development and recorded the upfront payment to "Research and development expenses" in the third quarter of 2019. In the first quarter of 2020, the Company recorded $25.0 million to "Research and development expenses" related to a pre-clinical milestone earned by CRISPR under the CRISPR DMD/DM1 Agreement. CRISPR has the potential to receive up to an additional $800.0 million in research, development, regulatory and commercial milestones for the DMD and DM1 programs as well as royalties on net product sales. CRISPR has the option to co-develop and co-commercialize all DM1 products globally and forego the milestones and royalties associated with the DM1 program. The Company funds all expenses associated with the collaboration except for research costs for specified guide RNA research conducted by CRISPR, which the Company and CRISPR share equally.

Moderna, Inc.

In 2016, the Company entered into a strategic collaboration and licensing agreement with Moderna, Inc. ("Moderna"), pursuant to which the parties are seeking to identify and develop messenger Ribonucleic Acid ("mRNA") therapeutics for the treatment of cystic fibrosis.

In September 2020, the Company entered into a new strategic collaboration and licensing agreement with Moderna (the "2020 Moderna Agreement") aimed at the discovery and development of lipid nanoparticles and mRNAs that can deliver gene-editing therapies to lung cells for the treatment of cystic fibrosis. Pursuant to the 2020 Moderna Agreement, Moderna received an upfront payment of $75.0 million and is eligible to receive up to $380.0 million in development, regulatory and commercial milestones as well as royalties on net product sales. The Company determined that substantially all of the fair

value of the 2020 Moderna Agreement was attributable to in-process research and development and no substantive processes were acquired that would constitute a business. The Company concluded that it did not have any alternative future use for the acquired in-process research and development and recorded the upfront payment to "Research and development expenses" in the third quarter of 2020.

Out-license Agreements

The Company has entered into licensing agreements pursuant to which it has out-licensed rights to certain drug candidates to third-party collaborators. Pursuant to these out-license agreements, the Company's collaborators become responsible for all costs related to the continued development of such drug candidates and obtain development and commercialization rights to these drug candidates. Depending on the terms of the agreements, the Company's collaborators may be required to make upfront payments, milestone payments upon the achievement of certain product research and development objectives and may also be required to pay royalties on future sales, if any, of commercial products resulting from the collaboration. The termination provisions associated with these collaborations are generally the same as those described above related to the Company's in-license agreements. None of the Company's out-license agreements had a significant impact on the Company's condensed consolidated statement of operations during the three and nine months ended September 30, 2020 and 2019.

Janssen Pharmaceuticals, Inc.

In the third quarter of 2020, Janssen Pharmaceuticals, Inc. ("Janssen") exercised its right to terminate its exclusive worldwide license from the Company to develop and commercialize certain drug candidates for the treatment of influenza, based on Phase 3 clinical trial results for pimodivir. Janssen had been developing pimodivir since 2014.

Cystic Fibrosis Foundation

The Company has a research, development and commercialization agreement that was originally entered into in 2004 with the Cystic Fibrosis Foundation ("CFF"), as successor in interest to the Cystic Fibrosis Foundation Therapeutics, Inc. This agreement was most recently amended in 2016. Pursuant to the agreement, as amended, the Company agreed to pay royalties ranging from low-single digits to mid-single digits on potential sales of certain compounds first synthesized and/or tested between March 1, 2014 and August 31, 2016, including elexacaftor, and tiered royalties ranging from single digits to sub-teens on covered compounds first synthesized and/or tested during a research term on or before February 28, 2014, including KALYDECO (ivacaftor), ORKAMBI (lumacaftor in combination with ivacaftor) and SYMDEKO/SYMKEVI (tezacaftor in combination with ivacaftor). For combination products, such as ORKAMBI, SYMDEKO/SYMKEVI and TRIKAFTA/KAFTRIO (elexacaftor/tezacaftor/ivacaftor and ivacaftor), sales are allocated equally to each of the active pharmaceutical ingredients in the combination product.

D. Earnings Per Share

Basic net income per common share is based upon the weighted-average number of common shares outstanding. Diluted net income per common share utilizing the treasury method is based upon the weighted-average number of common shares outstanding during the period plus additional weighted-average common equivalent shares outstanding during the period when the effect is dilutive.

The following table sets forth the computation of basic and diluted net income per common share for the periods ended:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
	(in thousands, except per share amounts)			
Net income	$ 667,434	$ 57,518	$ 2,107,457	$ 593,576
Basic weighted-average common shares outstanding	260,392	256,946	260,313	256,289
Effect of potentially dilutive securities:				
Stock options	1,887	2,080	1,936	2,297
Restricted stock and restricted stock units (including PSUs)	1,788	1,434	1,765	1,582
Employee stock purchase program	12	13	17	14
Diluted weighted-average common shares outstanding	264,079	260,473	264,031	260,182
Basic net income per common share	$ 2.56	$ 0.22	$ 8.10	$ 2.32
Diluted net income per common share	$ 2.53	$ 0.22	$ 7.98	$ 2.28

The Company did not include the securities in the following table in the computation of the net income per common share because the effect would have been anti-dilutive during each period:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
	(in thousands)			
Stock options	23	3,303	303	3,116
Unvested restricted stock and restricted stock units (including PSUs)	252	13	229	7

E. Fair Value Measurements

The following fair value hierarchy is used to classify assets and liabilities based on observable inputs and unobservable inputs used in order to determine the fair value of the Company's financial assets and liabilities:

Level 1:	Quoted prices in active markets for identical assets or liabilities. An active market for an asset or liability is a market in which transactions for the asset or liability occur with sufficient frequency and volume to provide pricing information on an ongoing basis.
Level 2:	Observable inputs other than Level 1 inputs. Examples of Level 2 inputs include quoted prices in active markets for similar assets or liabilities and quoted prices for identical assets or liabilities in markets that are not active.
Level 3:	Unobservable inputs based on the Company's assessment of the assumptions that market participants would use in pricing the asset or liability.

The Company's investment strategy is focused on capital preservation. The Company invests in instruments that meet the credit quality standards outlined in the Company's investment policy. This policy also limits the amount of credit exposure to any one issue or type of instrument. The Company maintains strategic investments separately from the investment policy that governs its other cash, cash equivalents and marketable securities as described in Note F, "Marketable Securities and Equity Investments." Additionally, the Company utilizes foreign currency forward contracts intended to mitigate the effect of changes in foreign exchange rates on its condensed consolidated statement of operations.

During the three and nine months ended September 30, 2020 and 2019, the Company did not record any other-than-temporary impairment charges related to its financial assets.

VERTEX PHARMACEUTICALS INCORPORATED
Notes to Condensed Consolidated Financial Statements
(unaudited)

The following tables set forth the Company's financial assets and liabilities subject to fair value measurements by level within the fair value hierarchy (and does not include $2.2 billion and $2.3 billion of cash as of September 30, 2020 and December 31, 2019, respectively):

	As of September 30, 2020				As of December 31, 2019			
	Total	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3
	(in thousands)							
Financial instruments carried at fair value (asset positions):								
Cash equivalents:								
Money market funds	$ 3,130,364	$ 3,130,364	$ —	$ —	$ 791,039	$ 791,039	$ —	$ —
Corporate debt securities	—	—	—	—	6,070	—	6,070	—
Commercial paper	5,001	—	5,001	—	29,472	—	29,472	—
Marketable securities:								
Corporate equity securities	312,682	216,142	96,540	—	282,084	261,797	20,287	—
Government-sponsored enterprise securities	91,283	91,283	—	—	12,733	12,733	—	—
Corporate debt securities	276,610	—	276,610	—	301,799	—	301,799	—
Commercial paper	112,396	—	112,396	—	102,356	—	102,356	—
Prepaid expenses and other current assets:								
Foreign currency forward contracts	673	—	673	—	9,725	—	9,725	—
Total financial assets	$ 3,929,009	$ 3,437,789	$ 491,220	$ —	$ 1,535,278	$ 1,065,569	$ 469,709	$ —
Financial instruments carried at fair value (liability positions):								
Other current liabilities:								
Foreign currency forward contracts	$ (29,554)	$ —	$ (29,554)	$ —	$ (5,533)	$ —	$ (5,533)	$ —
Long-term contingent consideration	(189,100)	—	—	(189,100)	(176,500)	—	—	(176,500)
Other long-term liabilities:								
Foreign currency forward contracts	(3,254)	—	(3,254)	—	(1,821)	—	(1,821)	—
Total financial liabilities	$ (221,908)	$ —	$ (32,808)	$ (189,100)	$ (183,854)	$ —	$ (7,354)	$ (176,500)

Please refer to Note F, "Marketable Securities and Equity Investments," for the carrying amount and related unrealized gains (losses) by type of investment.

Fair Value of Corporate Equity Securities

The Company maintains strategic investments in corporate equity securities separately from the investment policy that governs its other cash, cash equivalents and marketable securities. The Company classifies its investments in publicly traded companies as "Marketable securities" on its condensed consolidated balance sheets. Generally, the Company's investments in the common stock of these publicly traded companies are valued based on Level 1 inputs because they have readily determinable fair values. However, certain of the Company's investments in publicly traded companies have been or continue to be valued based on Level 2 inputs due to transfer restrictions associated with these investments. Please refer to Note F, "Marketable Securities and Equity Investments," for further information on these investments.

Fair Value of Contingent Consideration

In 2019, the Company acquired Exonics Therapeutics, Inc. ("Exonics"), a privately-held company focused on creating transformative gene-editing therapies to repair mutations that cause DMD and other severe neuromuscular diseases, including DM1. The Company's Level 3 contingent consideration liabilities are related to $678.3 million of development and regulatory milestones potentially payable to Exonics' former equity holders. The Company bases its estimates of the probability of achieving the milestones relevant to the fair value of contingent payments on industry data attributable to rare diseases. The discount rates used in the valuation model for contingent payments, which were between 0.6% and 1.9% as of September 30, 2020, represent a measure of credit risk and market risk associated with settling the liabilities. Significant judgment is used in determining the appropriateness of these assumptions at each reporting period. Due to the uncertainties

associated with development and commercialization of drug candidates in the pharmaceutical industry and the effects of changes in other assumptions including discount rates, the Company expects its estimates regarding the fair value of contingent consideration to change in the future, resulting in adjustments to the fair value of the Company's contingent consideration liabilities, and the effect of any such adjustments could be material.

The following table represents a rollforward of the fair value of the Company's contingent consideration liabilities:

	Nine Months Ended September 30, 2020
	(in thousands)
Balance at December 31, 2019	$ 176,500
Increase in fair value of contingent payments	12,600
Balance at September 30, 2020	$ 189,100

The "Increase in fair value of contingent payments" in the table above was primarily due to changes in market interest rates.

F. Marketable Securities and Equity Investments

A summary of the Company's cash equivalents and marketable securities, which are recorded at fair value (and do not include $2.2 billion and $2.3 billion of cash as of September 30, 2020 and December 31, 2019, respectively), is shown below:

	As of September 30, 2020				As of December 31, 2019			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(in thousands)							
Cash equivalents:								
Money market funds	$ 3,130,364	$ —	$ —	$ 3,130,364	$ 791,039	$ —	$ —	$ 791,039
Corporate debt securities	—	—	—	—	6,070	—	—	6,070
Commercial paper	5,000	1	—	5,001	29,470	3	(1)	29,472
Total cash equivalents	$ 3,135,364	$ 1	$ —	$ 3,135,365	$ 826,579	$ 3	$ (1)	$ 826,581
Marketable securities:								
Government-sponsored enterprise securities	$ 91,256	$ 33	$ (6)	$ 91,283	$ 12,689	$ 44	$ —	$ 12,733
Corporate debt securities	275,554	1,067	(11)	276,610	301,458	391	(50)	301,799
Commercial paper	112,159	242	(5)	112,396	102,240	121	(5)	102,356
Total marketable debt securities	478,969	1,342	(22)	480,289	416,387	556	(55)	416,888
Corporate equity securities	103,463	209,219	—	312,682	113,829	168,255	—	282,084
Total marketable securities	$ 582,432	$ 210,561	$ (22)	$ 792,971	$ 530,216	$ 168,811	$ (55)	$ 698,972

Available-for-sale debt securities were classified on the Company's condensed consolidated balance sheets at fair value as follows:

	As of September 30, 2020	As of December 31, 2019
	(in thousands)	
Cash and cash equivalents	$ 3,135,365	$ 826,581
Marketable securities	480,289	416,888
Total	$ 3,615,654	$ 1,243,469

Available-for-sale debt securities by contractual maturity were as follows:

	As of September 30, 2020	As of December 31, 2019
	(in thousands)	
Matures within one year	$ 3,514,474	$ 1,137,942
Matures after one year through five years	101,180	105,527
Total	$ 3,615,654	$ 1,243,469

The Company has a limited number of available-for-sale debt securities in insignificant loss positions as of September 30, 2020, which it does not intend to sell and has concluded it will not be required to sell before recovery of the amortized costs for the investments at maturity. The Company did not record any charges for other-than-temporary declines in the fair value of available-for-sale debt securities or gross realized gains or losses in the three and nine months ended September 30, 2020 and 2019.

As of September 30, 2020 and December 31, 2019, the total fair value of the Company's strategic investments in the common stock of publicly traded companies was $312.7 million and $282.1 million, respectively, and was classified as "Marketable securities" on its condensed consolidated balance sheets.

The Company records changes in the fair value of its investments in corporate equity securities to "Other income (expense), net" on its condensed consolidated statements of operations. During the three and nine months ended September 30, 2020, the Company recorded net unrealized gains of $69.8 million and $102.3 million, respectively, on corporate equity securities held as of September 30, 2020. During the three and nine months ended September 30, 2019, the Company recorded a net unrealized loss of $31.2 million and a net unrealized gain of $68.9 million, respectively, on corporate equity securities held as of September 30, 2019. During the nine months ended September 30, 2020, the Company received proceeds of $149.6 million related to the sale of the common stock of publicly traded companies, which had a total original weighted-average cost basis of $51.3 million. There were no sales of the common stock of publicly traded companies during the nine months ended September 30, 2019.

As of September 30, 2020, the carrying value of the Company's equity investments without readily determinable fair values, which are recorded in "Other assets" on its condensed consolidated balance sheets, was $20.8 million.

G. Accumulated Other Comprehensive Income (Loss)

The following table summarizes the changes in accumulated other comprehensive income (loss) by component:

	Foreign Currency Translation Adjustment	Unrealized Holding Gains (Losses), Net of Tax		Total
		On Available-For-Sale Debt Securities	On Foreign Currency Forward Contracts	
	(in thousands)			
Balance at December 31, 2019	$ (895)	$ 503	$ (1,581)	$ (1,973)
Other comprehensive (loss) income before reclassifications	(12,616)	818	(20,913)	(32,711)
Amounts reclassified from accumulated other comprehensive loss	—	—	(6,298)	(6,298)
Net current period other comprehensive (loss) income	(12,616)	818	(27,211)	(39,009)
Balance at September 30, 2020	$ (13,511)	$ 1,321	$ (28,792)	$ (40,982)
Balance at December 31, 2018	$ (11,227)	$ (536)	$ 12,422	$ 659
Other comprehensive income before reclassifications	10,263	1,111	26,663	38,037
Amounts reclassified from accumulated other comprehensive income	—	—	(19,849)	(19,849)
Net current period other comprehensive income	10,263	1,111	6,814	18,188
Balance at September 30, 2019	$ (964)	$ 575	$ 19,236	$ 18,847

H. Hedging

Foreign currency forward contracts - Designated as hedging instruments

The Company maintains a hedging program intended to mitigate the effect of changes in foreign exchange rates for a portion of the Company's forecasted product revenues denominated in certain foreign currencies. The program includes foreign currency forward contracts that are designated as cash flow hedges under U.S. GAAP having contractual durations from one to eighteen months. The Company recognizes realized gains and losses for the effective portion of such contracts in "Product revenues, net" in its condensed consolidated statements of operations in the same period that it recognizes the product revenues that were impacted by the hedged foreign exchange rate changes.

The Company formally documents the relationship between foreign currency forward contracts (hedging instruments) and forecasted product revenues (hedged items), as well as the Company's risk management objective and strategy for undertaking various hedging activities, which includes matching all foreign currency forward contracts that are designated as cash flow hedges to forecasted transactions. The Company also formally assesses, both at the hedge's inception and on an ongoing basis, whether the foreign currency forward contracts are highly effective in offsetting changes in cash flows of hedged items on a prospective and retrospective basis. If the Company were to determine that a (i) foreign currency forward contract is not highly effective as a cash flow hedge, (ii) foreign currency forward contract has ceased to be a highly effective hedge or (iii) forecasted transaction is no longer probable of occurring, the Company would discontinue hedge accounting treatment prospectively. The Company measures effectiveness based on the change in fair value of the forward contracts and the fair value of the hypothetical foreign currency forward contracts with terms that match the critical terms of the risk being hedged. As of September 30, 2020, all hedges were determined to be highly effective.

The Company considers the impact of its counterparties' credit risk on the fair value of the foreign currency forward contracts. As of September 30, 2020 and December 31, 2019, credit risk did not change the fair value of the Company's foreign currency forward contracts.

The following table summarizes the notional amount of the Company's outstanding foreign currency forward contracts designated as cash flow hedges under U.S. GAAP:

Foreign Currency	As of September 30, 2020	As of December 31, 2019
	(in thousands)	
Euro	$ 632,621	$ 501,197
British pound sterling	166,707	87,032
Australian dollar	92,524	89,705
Canadian dollar	74,749	50,452
Total foreign currency forward contracts	$ 966,601	$ 728,386

Foreign currency forward contracts - Not designated as hedging instruments

The Company also enters into foreign currency forward contracts with contractual maturities of less than one month, that are designed to mitigate the effect of changes in foreign exchange rates on monetary assets and liabilities, including intercompany balances. These contracts are not designated as hedging instruments under U.S. GAAP. The Company recognizes realized gains and losses for such contracts in "Other income (expense), net" in its condensed consolidated statements of operations each period. As of September 30, 2020, the notional amount of the Company's outstanding foreign currency forward contracts where hedge accounting under U.S. GAAP is not applied was $609.9 million.

During the three and nine months ended September 30, 2020 and 2019, the Company recognized the following related to foreign currency forward contacts in its condensed consolidated statements of operations:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
	(in thousands)			
Designated as hedging instruments - Reclassified from AOCI				
Product revenues, net	$ (7,249)	$ 10,304	$ 8,039	$ 25,381
Not designated as hedging instruments				
Other income (expense), net	$ 25,897	$ (8,812)	$ 15,724	$ (10,874)
Total reported in the Condensed Consolidated Statement of Operations				
Product revenues, net	$ 1,536,271	$ 949,828	$ 4,575,863	$ 2,747,461
Other income (expense), net	$ 84,386	$ (31,747)	$ 139,621	$ 64,802

The following table summarizes the fair value of the Company's outstanding foreign currency forward contracts designated as cash flow hedges under U.S. GAAP included on its condensed consolidated balance sheets:

As of September 30, 2020

Assets		Liabilities	
Classification	Fair Value	Classification	Fair Value
	(in thousands)		
Prepaid expenses and other current assets	$ 673	Other current liabilities	$ (29,554)
Other assets	—	Other long-term liabilities	(3,254)
Total assets	$ 673	Total liabilities	$ (32,808)

As of December 31, 2019

Assets		Liabilities	
Classification	Fair Value	Classification	Fair Value
	(in thousands)		
Prepaid expenses and other current assets	$ 9,725	Other current liabilities	$ (5,533)
Other assets	—	Other long-term liabilities	(1,821)
Total assets	$ 9,725	Total liabilities	$ (7,354)

As of September 30, 2020, the Company expects the amounts that are related to foreign exchange forward contracts designated as cash flow hedges under U.S. GAAP recorded in "Prepaid expenses and other current assets" and "Other current liabilities" to be reclassified to earnings within twelve months.

The following table summarizes the potential effect of offsetting derivatives by type of financial instrument designated as cash flow hedges under U.S. GAAP on the Company's condensed consolidated balance sheets:

	As of September 30, 2020				
	Gross Amounts Recognized	Gross Amounts Offset	Gross Amounts Presented	Gross Amounts Not Offset	Legal Offset
Foreign currency forward contracts			(in thousands)		
Total assets	$ 673	$ —	$ 673	$ (673)	$ —
Total liabilities	(32,808)	—	(32,808)	673	(32,135)

	As of December 31, 2019				
	Gross Amounts Recognized	Gross Amounts Offset	Gross Amounts Presented	Gross Amounts Not Offset	Legal Offset
Foreign currency forward contracts			(in thousands)		
Total assets	$ 9,725	$ —	$ 9,725	$ (7,354)	$ 2,371
Total liabilities	(7,354)	—	(7,354)	7,354	—

I. Inventories

Inventories consisted of the following:

	As of September 30, 2020	As of December 31, 2019
	(in thousands)	
Raw materials	$ 42,542	$ 26,247
Work-in-process	135,220	107,021
Finished goods	67,698	34,234
Total	$ 245,460	$ 167,502

J. Stock-based Compensation Expense and Share Repurchase Programs

Stock-based compensation expense

During the three and nine months ended September 30, 2020 and 2019, the Company recognized the following stock-based compensation expense:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
	(in thousands)			
Stock-based compensation expense by type of award:				
Restricted stock and restricted stock units (including PSUs)	$ 84,043	$ 61,175	$ 279,611	$ 185,651
Stock options	13,221	21,737	47,334	76,053
ESPP share issuances	3,225	3,044	8,565	8,430
Stock-based compensation expense related to inventories	(950)	(536)	(3,076)	(1,236)
Total stock-based compensation expense included in costs and expenses	$ 99,539	$ 85,420	$ 332,434	$ 268,898
Stock-based compensation expense by line item:				
Cost of sales	$ 1,250	$ 1,337	$ 3,998	$ 4,178
Research and development expenses	60,770	52,504	203,732	167,851
Sales, general and administrative expenses	37,519	31,579	124,704	96,869
Total stock-based compensation expense included in costs and expenses	99,539	85,420	332,434	268,898
Income tax effect	(35,295)	(21,996)	(130,692)	(87,638)
Total stock-based compensation expense, net of tax	$ 64,244	$ 63,424	$ 201,742	$ 181,260

The following table sets forth the Company's unrecognized stock-based compensation expense as of September 30, 2020, by type of award and the weighted-average period over which that expense is expected to be recognized:

	As of September 30, 2020	
	Unrecognized Expense	Weighted-average Recognition Period
	(in thousands)	(in years)
Type of award:		
Restricted stock units (including PSUs)	$ 487,254	2.06
Stock options	$ 76,261	1.95
ESPP share issuances	$ 3,265	0.44

The following table summarizes information about stock options outstanding and exercisable as of September 30, 2020:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding	Weighted-average Remaining Contractual Life	Weighted-average Exercise Price	Number Exercisable	Weighted-average Exercise Price
	(in thousands)	(in years)	(per share)	(in thousands)	(per share)
$36.28–$40.00	62	1.09	$ 38.06	62	$ 38.06
$40.01–$60.00	157	1.98	$ 47.13	157	$ 47.13
$60.01–$80.00	105	3.49	$ 74.82	104	$ 74.82
$80.01–$100.00	1,029	5.66	$ 88.91	919	$ 89.20
$100.01–$120.00	129	4.39	$ 109.27	128	$ 109.21
$120.01–$140.00	282	4.98	$ 129.42	281	$ 129.43
$140.01–$160.00	740	7.36	$ 155.49	369	$ 155.41
$160.01–$180.00	599	7.76	$ 168.34	282	$ 165.74
$180.01–$200.00	1,252	8.14	$ 185.31	422	$ 184.85
$200.01–$286.27	23	9.67	$ 286.27	23	$ 286.27
Total	4,378	6.63	$ 140.26	2,747	$ 123.22

Share repurchase programs

In 2018, the Company's Board of Directors approved a share repurchase program (the "2018 Share Repurchase Program"), pursuant to which the Company repurchased $500.0 million of its common stock in 2018 and 2019. During the nine months ended September 30, 2019, the Company repurchased 832,186 shares of its common stock under the 2018 Share Repurchase Program for an aggregate of $150.0 million including commissions and fees. As of June 30, 2019, the Company had repurchased the entire $500.0 million it was authorized to repurchase of its common stock under the 2018 Share Repurchase Program.

In 2019, the Company's Board of Directors approved a new share repurchase program (the "2019 Share Repurchase Program"), pursuant to which the Company is authorized to repurchase up to $500.0 million of its common stock between August 1, 2019 and December 31, 2020. During the nine months ended September 30, 2020, the Company repurchased 1,806,587 shares of its common stock under the 2019 Share Repurchase Program for an aggregate of $408.0 million including commissions and fees. As of September 30, 2020, there was a total of $56.0 million remaining for repurchases under the 2019 Share Repurchase Program. The Company expects to fund further repurchases of its common stock through a combination of cash on hand and cash generated by operations.

Under the 2019 Share Repurchase Program, the Company is authorized to purchase shares from time to time through open market or privately negotiated transactions. Such purchases are made pursuant to Rule 10b5-1 plans or other means as determined by the Company's management and in accordance with the requirements of the SEC.

K. Income Taxes

The Company is subject to U.S. federal, state, and foreign income taxes. For the three and nine months ended September 30, 2020, the Company recorded provisions for income taxes of $78.4 million and $120.7 million, respectively. For the three and nine months ended September 30, 2019, the Company recorded provisions for income taxes of $13.1 million and $124.4 million, respectively.

The Company's effective tax rate for the third quarter of 2020 was lower than the U.S. statutory rate primarily due to a discrete tax benefit associated with an increase in the United Kingdom's corporate tax rate. The Company's effective tax rate for the nine months ended September 30, 2020 was also lower than the U.S. statutory rate due to discrete tax benefits associated with an intra-entity transfer of intellectual property rights to the United Kingdom and the write-off of a long-term intercompany receivable as well as excess tax benefits related to stock-based compensation. The Company's effective tax rate

for the three and nine months ended September 30, 2019 was lower than the U.S. statutory rate primarily due to excess tax benefits related to stock-based compensation.

In the second quarter of 2020, the Company completed an intra-entity transfer of intellectual property rights to the United Kingdom, resulting in a deferred tax benefit of $209.0 million. The Company expects to be able to utilize the deferred tax asset resulting from the intra-entity transfer.

The Company released its valuation allowance on the majority of its net operating losses and other deferred tax assets as of December 31, 2018. Starting in 2019, the Company began recording a provision for income taxes on its pre-tax income using an effective tax rate approximating statutory rates. The Company expects to utilize its remaining previously benefited U.S. net operating losses in 2020. As a result, a larger portion of the Company's tax provision will represent a cash tax payable in future periods.

The Company maintained a valuation allowance of $205.2 million related primarily to U.S. state and foreign tax attributes as of December 31, 2019. On a periodic basis, the Company reassesses any valuation allowances that it maintains on its deferred tax assets, weighing positive and negative evidence to assess the recoverability of the deferred tax assets.

In March 2020, the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") was signed into law. The CARES Act includes provisions relating to several aspects of corporate income taxes. The Company does not currently expect the CARES Act to have a significant impact on its provision for income taxes; however, it will continue to monitor the provisions of the CARES Act in relation to its operations.

The Company has reviewed the tax positions taken, or to be taken, in its tax returns for all tax years currently open to examination by a taxing authority. Unrecognized tax benefits represent the aggregate tax effect of differences between tax return positions and the benefits recognized in the financial statements. As of September 30, 2020 and December 31, 2019, the Company had $73.8 million and $33.9 million, respectively, of gross unrecognized tax benefits, which would affect the Company's tax rate if recognized. The Company does not expect that its unrecognized tax benefits will materially change within the next twelve months. The Company accrues interest and penalties related to unrecognized tax benefits as a component of its provision for income taxes. The Company did not recognize any material interest or penalties related to uncertain tax positions during the three and nine months ended September 30, 2020 and 2019.

As of September 30, 2020, foreign earnings, which were not significant, have been retained by foreign subsidiaries for indefinite reinvestment. Upon repatriation of those earnings, in the form of dividends or otherwise, the Company could be subject to withholding taxes payable to the various foreign countries.

The Company files U.S. federal income tax returns and income tax returns in various state, local and foreign jurisdictions. The Company is no longer subject to any tax assessment from an income tax examination in the U.S. or any other major taxing jurisdiction for years before 2011, except where the Company has net operating losses or tax credit carryforwards that originate before 2011. The Company has various income tax audits ongoing at any time throughout the world.

L. Commitments and Contingencies

Revolving Credit Facilities

The Company and certain of its subsidiaries have entered into two Credit Agreements (the "Credit Agreements") with Bank of America, N.A., as administrative agent and the lenders referred to therein (the "Lenders"). The Credit Agreements were not drawn upon at closing and the Company has not drawn upon them to date. Amounts drawn pursuant to the Credit Agreements, if any, will be used for general corporate purposes. Any amounts borrowed under the Credit Agreements will bear interest, at the Company's option, at either a base rate or a Eurocurrency rate, in each case plus an applicable margin based on the Company's consolidated leverage ratio (the ratio of the Company's total consolidated funded indebtedness to the Company's consolidated EBITDA for the most recently completed four fiscal quarter period).

In September 2019, the Company and certain of its subsidiaries entered into a $500.0 million unsecured revolving facility (the "2019 Credit Agreement") with the Lenders, which matures on September 17, 2024. The 2019 Credit Agreement

superseded the Company's credit agreement entered into in 2016 with Bank of America, N.A serving in the same capacity. Under the 2019 Credit Agreement, the applicable margins on base rate loans range from 0.125% to 0.500% and the applicable margins on Eurocurrency loans range from 1.125% to 1.500%. The 2019 Credit Agreement provides a sublimit of $50.0 million for letters of credit.

In September 2020, the Company and certain of its subsidiaries entered into a $2.0 billion unsecured revolving facility (the "2020 Credit Agreement") with the Lenders, which matures on September 18, 2022. Under the 2020 Credit Agreement, the applicable margins on base rate loans range from 0.500% to 0.875% and the applicable margins on Eurocurrency loans range from 1.500% to 1.875%. The 2020 Credit Agreement does not include a sublimit for letters of credit.

Subject to satisfaction of certain conditions, the Company may request that the borrowing capacity for each of the Credit Agreements be increased by an additional $500.0 million. Any amounts borrowed pursuant to the Credit Agreements are guaranteed by certain of the Company's existing and future domestic subsidiaries, subject to certain exceptions.

The Credit Agreements contain customary representations and warranties and affirmative and negative covenants, including financial covenants to maintain (x) subject to certain limited exceptions, a consolidated leverage ratio of 3.50 to 1.00, subject to an increase to 4.00 to 1.00 following a material acquisition and (y) a consolidated interest coverage ratio of 2.50 to 1.00, in each case measured on a quarterly basis. As of September 30, 2020, the Company was in compliance with the covenants described above. The Credit Agreements also contain customary events of default. In the case of a continuing event of default, the administrative agent would be entitled to exercise various remedies, including the acceleration of amounts due under outstanding loans.

Direct costs related to the Credit Agreements, which were not material to the Company's financial statements, were deferred and recorded over the term of the Credit Agreements.

Guaranties and Indemnifications

As permitted under Massachusetts law, the Company's Articles of Organization and By-laws provide that the Company will indemnify certain of its officers and directors for certain claims asserted against them in connection with their service as an officer or director. The maximum potential amount of future payments that the Company could be required to make under these indemnification provisions is unlimited. However, the Company has purchased directors' and officers' liability insurance policies that could reduce its monetary exposure and enable it to recover a portion of any future amounts paid. No indemnification claims currently are outstanding, and the Company believes the estimated fair value of these indemnification arrangements is minimal.

The Company customarily agrees in the ordinary course of its business to indemnification provisions in agreements with clinical trial investigators and sites in its drug development programs, sponsored research agreements with academic and not-for-profit institutions, various comparable agreements involving parties performing services for the Company and its real estate leases. The Company also customarily agrees to certain indemnification provisions in its drug discovery, development and commercialization collaboration agreements. With respect to the Company's clinical trials and sponsored research agreements, these indemnification provisions typically apply to any claim asserted against the investigator or the investigator's institution relating to personal injury or property damage, violations of law or certain breaches of the Company's contractual obligations arising out of the research or clinical testing of the Company's compounds or drug candidates. With respect to lease agreements, the indemnification provisions typically apply to claims asserted against the landlord relating to personal injury or property damage caused by the Company, to violations of law by the Company or to certain breaches of the Company's contractual obligations. The indemnification provisions appearing in the Company's collaboration agreements are similar to those for the other agreements discussed above, but in addition provide some limited indemnification for its collaborator in the event of third-party claims alleging infringement of intellectual property rights. In each of the cases above, the indemnification obligation generally survives the termination of the agreement for some extended period, although the Company believes the obligation typically has the most relevance during the contract term and for a short period of time thereafter. The maximum potential amount of future payments that the Company could be required to make under these provisions is generally unlimited. The Company has purchased insurance policies covering personal injury, property damage and general liability that reduce its exposure for indemnification and would enable it in many cases to recover all or a portion of any future amounts paid. The Company has never paid any material amounts to defend lawsuits

or settle claims related to these indemnification provisions. Accordingly, the Company believes the estimated fair value of these indemnification arrangements is minimal.

Other Contingencies

The Company has certain contingent liabilities that arise in the ordinary course of its business activities. The Company accrues a reserve for contingent liabilities when it is probable that future expenditures will be made, and such expenditures can be reasonably estimated. There were no material contingent liabilities accrued as of September 30, 2020 or December 31, 2019.

M. Additional Cash Flow Information

The cash, cash equivalents and restricted cash at the beginning and ending of each period presented in the Company's condensed consolidated statements of cash flows consisted of the following:

	Nine Months Ended September 30,			
	2020		2019	
	Beginning of period	End of period	Beginning of period	End of period
	(in thousands)			
Cash and cash equivalents	$ 3,109,322	$ 5,358,087	$ 2,650,134	$ 3,397,941
Prepaid expenses and other current assets	8,004	2,898	4,910	6,650
Other assets	3,355	—	3,209	—
Cash, cash equivalents and restricted cash per statement of cash flows	$ 3,120,681	$ 5,360,985	$ 2,658,253	$ 3,404,591

N. Facilities

Cell and Genetic Therapies Lease

In 2019, the Company entered into an agreement to lease approximately 269,000 square feet of office and laboratory space near its corporate headquarters in Boston, MA. The lease agreement includes an initial term of 15 years plus a period to install leasehold improvements, with an option to extend the lease term for up to two additional ten-year periods. The Company expects base rent payments to commence in the fourth quarter of 2021. The Company has utilized the initial period, which commenced in the third quarter of 2020 upon occupation of the building, as its lease term. As of September 30, 2020, the Company recorded a right-of-use asset of $256.8 million and an operating lease liability of $268.5 million related to the lease agreement on its condensed consolidated balance sheet.

Boston Continuous Manufacturing Facility

In the third quarter of 2020, the Company purchased its continuous manufacturing facility located near its corporate headquarters in Boston, MA from its former landlord for $155.3 million in cash. As of September 30, 2020, the Company adjusted its condensed consolidated balance sheet to (i) classify the building within "Property and equipment, net" with a 40 years useful life, (ii) derecognize a previously recorded right-of-use asset and operating lease liability for the facility and (iii) record a finance lease for the land on which the facility is constructed. The previously recognized right-of-use asset and operating lease liability and the newly recognized finance lease related to the land were not significant to the Company's condensed consolidated balance sheet for the periods presented.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

OVERVIEW

We invest in scientific innovation to create transformative medicines for people with serious diseases with a focus on specialty markets. We have four approved medicines to treat cystic fibrosis, or CF, a life-threatening genetic disease, and are focused on expanding the number of people with CF eligible for our medicines. We are broadening our pipeline into additional disease areas through internal research efforts and accessing external innovation through business development transactions.

In October 2019, TRIKAFTA (elexacaftor/tezacaftor/ivacaftor and ivacaftor), our triple combination regimen, was approved by the U.S. Food and Drug Administration, or FDA, for the treatment of people with CF 12 years of age and older who have at least one *F508del* mutation in the cystic fibrosis transmembrane conductance regulator, or CFTR, gene. In August 2020, our triple combination regimen was approved by the European Commission for people with CF 12 years of age and older with specific mutations in their CFTR gene. We market our triple combination regimen as KAFTRIO in the European Union, or E.U. Approval of TRIKAFTA and KAFTRIO increased the number of people with CF that are eligible for our medicines by up to 16,000 and provides an additional treatment option for many people who are eligible for one of our previously approved products. Collectively, our medicines currently are approved to treat the majority of the people with CF in North America, Europe and Australia. We are evaluating our triple combination regimen in younger children with the goal of having small molecule treatments for up to 90% of people with CF. We are also pursuing genetic therapies to address the remaining 10% of people with CF.

Beyond CF, our small molecule programs include programs focused on developing treatments for alpha-1 antitrypsin, or AAT, deficiency, APOL1-mediated kidney diseases, and pain. We are evaluating CTX001, a genetic therapy, as a potential treatment for sickle cell disease, or SCD, and transfusion-dependent beta thalassemia, or TDT, in Phase 1/2 clinical trials in collaboration with CRISPR Therapeutics AG, or CRISPR. In 2019, through a series of strategic transactions, we acquired preclinical programs to develop cell-based therapies for type 1 diabetes, or T1D, and preclinical genetic therapy programs for Duchenne muscular dystrophy, or DMD, and myotonic dystrophy type 1, or DM1.

Financial Highlights

Revenues

In the third quarter of 2020, our net product revenues continued to increase due to the approval of TRIKAFTA in late 2019 and uptake of our medicines in ex-U.S. markets following completion of several significant reimbursement agreements.

Expenses

Our combined R&D and SG&A expenses decreased to $678.0 million in the third quarter of 2020 from $715.6 million in the third quarter of 2019. In the third quarter of 2020, cost of sales was 12% of our net product revenues.

Balance Sheet

Business Updates

Cystic Fibrosis

TRIKAFTA/KAFTRIO (elexacaftor/tezacaftor/ivacaftor and ivacaftor)

- In August 2020, the European Commission granted marketing authorization for KAFTRIO to treat people with CF 12 years of age and older with one *F508del* mutation and one minimal function mutation, or two *F508del* mutations.
- The European Medicines Agency, or EMA, validated a Type II Variation Marketing Authorization Application, or MAA, for KAFTRIO that we believe supports an expansion of the E.U. label to people with CF who have one copy of the *F508del* mutation.
- We reported positive data from our Phase 3 clinical trial evaluating the use of our triple combination regimen in children 6 to 11 years of age with CF who have two copies of the *F508del* mutation or who have one *F508del* mutation and one minimal function mutation. We plan to submit a supplemental New Drug Application, or sNDA, to the FDA for children 6 to 11 years of age with at least one *F508del* mutation in the fourth quarter of 2020.
- The FDA accepted three sNDAs for TRIKAFTA, SYMDEKO and KALYDECO. These regulatory submissions are intended to expand the labels of TRIKAFTA, SYMDEKO and KALYDECO to include people with CF who have rare CFTR mutations.
- We are initiating a Phase 3 clinical trial evaluating the use of our triple combination regimen in children two to five years of age with CF who have either two copies of the *F508del* mutation or one copy of the *F508del* mutation and one minimal function mutation.

SYMDEKO/SYMKEVI (tezacaftor and ivacaftor)

- The EMA's Committee for Medicinal Products for Human Use, or CHMP, adopted a positive opinion for the label extension of SYMKEVI for the treatment of children 6 to 11 years of age with CF with two *F508del* mutations or one *F508del* mutation and certain residual function mutations.

KALYDECO (ivacaftor)

- In September 2020, the FDA approved KALYDECO to treat infants with CF four months of age to less than six months of age who have at least one mutation in their CFTR gene that is responsive to KALYDECO.
- The EMA's CHMP adopted a positive opinion for the label extension of KALYDECO for the treatment of infants with CF four months of age to less than six months of age who have at least one mutation in their CFTR gene that is responsive to KALYDECO.

Genetic Therapies

- We entered into a new collaboration with Moderna, Inc., or Moderna, aimed at the discovery and development of lipid nanoparticles and mRNAs that can deliver gene-editing therapies to lung cells for the treatment of CF.

Pipeline

Beta Thalassemia and Sickle Cell Disease

- We and our collaborator, CRISPR, are evaluating the use of an ex-vivo CRISPR gene-editing therapy for the treatment of TDT and SCD. This approach aims to edit a patient's hematopoietic stem cells to produce fetal hemoglobin in red blood cells, which has the potential to reduce or eliminate symptoms associated with disease.
- We and our collaborator, CRISPR, previously announced that, as of June 2020, seven patients had been dosed across the two Phase 1/2 clinical trials of the investigational CRISPR/Cas9 gene-editing therapy CTX001 and presented data at the European Hematology Association Congress from two patients with TDT and one patient with severe SCD. Additional patients have been enrolled and dosed in both TDT and SCD Phase 1/2 clinical trials. In the fourth quarter of 2020, we expect to report clinical data from additional patients treated with CTX001 and data from patients with longer follow-up.

- The EMA granted Priority Medicines designation to CTX001 for the treatment of severe SCD. CTX001 has been granted Regenerative Medicine Advanced Therapy, Fast Track, Orphan Drug and Rare Pediatric Disease designations from the FDA and Orphan Drug Designation from the European Commission for both TDT and SCD.

Alpha-1 Antitrypsin Deficiency

- We are focused on identifying and developing multiple drug candidates with the potential to correct the misfolding of Z-AAT protein in the liver in order to increase the levels of functional AAT in the blood. Misfolded Z-AAT protein is the root cause of AAT deficiency.
- Enrollment is ongoing in a Phase 2 proof-of-concept clinical trial for the Z-AAT corrector, VX-864. We expect data from this clinical trial in the first half of 2021.
- In October 2020, we discontinued development of VX-814 based on the safety and pharmacokinetic profile of VX-814 observed in a Phase 2 clinical trial.

APOL1-Mediated Kidney Diseases

- We are evaluating inhibitors of APOL1 function to reduce proteinuria in people with serious kidney disease, including focal segmental glomerulosclerosis, or FSGS.
- Enrollment is ongoing in a Phase 2 proof-of-concept clinical trial designed to evaluate the reduction of proteinuria in people with APOL1-mediated FSGS after treatment with VX-147. We expect data from this clinical trial in 2021.

Type 1 Diabetes

- We are developing a cell therapy designed to replace insulin-producing islet cells in patients with T1D. We are pursuing two programs for the transplant of these functional islets into patients: transplantation of islet cells alone, using immunosuppression to protect the implanted cells, and implantation of the islet cells inside a novel immunoprotective device.
- We have completed the required enabling nonclinical studies and manufacturing work to support the submission of an Investigational New Drug, or IND, application to the FDA for the first program (transplantation of islet cells alone) in the fourth quarter of 2020.

COVID-19

We continue to monitor the impacts of the COVID-19 global pandemic on our business. COVID-19 has not affected our supply chain or the demand for our medicines, and we believe that we will be able to continue to supply all of our approved medicines to patients globally. We have adjusted our business operations in response to COVID-19, with a majority of our employees continuing to work remotely. We continue to monitor local COVID-19 trends and government guidance for each of our site locations, and we have begun to re-open certain of our sites utilizing a phased, site-specific approach. To provide a safe working environment for our on-site employees, we have, among other things, limited employee numbers at our sites and increased safety measures, including enhanced cleaning and sanitation protocols, required use of personal protective equipment for all on-site employees, hand sanitation stations throughout our sites and implementation of various social distancing measures while on-site.

Research

We continue to invest in our research programs and foster scientific innovation in order to identify and develop transformative medicines. Our strategy is to combine transformative advances in the understanding of human disease and the science of therapeutics in order to identify and develop new medicines. We believe that pursuing research in diverse areas allows us to balance the risks inherent in drug development and may provide drug candidates that will form our pipeline in future years. To supplement our internal research programs, we acquire technologies and programs and collaborate with biopharmaceutical and technology companies, leading academic research institutions, government laboratories, foundations and other organizations, as needed, to advance research in our areas of therapeutic interest and to access technologies needed to execute on our strategy.

Drug Discovery and Development

Discovery and development of a new pharmaceutical product is a difficult and lengthy process that requires significant financial resources along with extensive technical and regulatory expertise. Potential drug candidates are subjected to rigorous evaluations, driven in part by stringent regulatory considerations, designed to generate information concerning efficacy, side effects, proper dosage levels and a variety of other physical and chemical characteristics that are important in determining whether a drug candidate should be approved for marketing as a pharmaceutical product. Most chemical compounds that are investigated as potential drug candidates never progress into development, and most drug candidates that do advance into development never receive marketing approval. Because our investments in drug candidates are subject to considerable risks, we closely monitor the results of our discovery, research, clinical trials and nonclinical studies and frequently evaluate our drug development programs in light of new data and scientific, business and commercial insights, with the objective of balancing risk and potential. This process can result in abrupt changes in focus and priorities as new information becomes available and as we gain additional understanding of our ongoing programs and potential new programs, as well as those of our competitors. For example, in October 2020, we discontinued development of VX-814 based on the safety and pharmacokinetic profile of VX-814 observed in a Phase 2 clinical trial.

If we believe that data from a completed registration program support approval of a drug candidate, we submit an NDA to the FDA requesting approval to market the drug candidate in the United States and seek analogous approvals from comparable regulatory authorities in jurisdictions outside the United States. To obtain approval, we must, among other things, demonstrate with evidence gathered in nonclinical studies and well-controlled clinical trials that the drug candidate is safe and effective for the disease it is intended to treat and that the manufacturing facilities, processes and controls for the manufacture of the drug candidate are adequate. The FDA and ex-U.S. regulatory authorities have substantial discretion in deciding whether or not a drug candidate should be granted approval based on the benefits and risks of the drug candidate in the treatment of a particular disease, and could delay, limit or deny regulatory approval. If regulatory delays are significant or regulatory approval is limited or denied altogether, our financial results and the commercial prospects for the drug candidate involved will be harmed.

Regulatory Compliance

Our marketing of pharmaceutical products is subject to extensive and complex laws and regulations. We have a corporate compliance program designed to actively identify, prevent and mitigate risk through the implementation of compliance policies and systems and through the promotion of a culture of compliance. Among other laws, regulations and standards, we are subject to various U.S. federal and state laws, and comparable laws in other jurisdictions, pertaining to health care fraud and abuse, including anti-kickback and false claims laws, and laws prohibiting the promotion of drugs for unapproved or off-label uses. Anti-kickback laws generally make it illegal for a prescription drug manufacturer to knowingly and willfully solicit, offer, receive or pay any remuneration in return for or to induce the referral of business, including the purchase or prescription of a particular drug that is reimbursed by a state or federal health care program. False claims laws prohibit anyone from knowingly or willfully presenting for payment to third-party payors, including Medicare and Medicaid, claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. We are subject to laws and regulations that regulate the sales and marketing practices of pharmaceutical manufacturers, as well as laws such as the U.S. Foreign Corrupt Practices Act, which govern our international business practices with respect to payments to government officials. In addition, we are subject to various data protection and privacy laws and regulations in the U.S., E.U., U.K., Canada, Australia and other jurisdictions. We expect to continue to devote substantial resources to maintain, administer and expand these compliance programs globally.

Reimbursement

Sales of our products depend, to a large degree, on the extent to which our products are reimbursed by third-party payors, such as government health programs, commercial insurance and managed health care organizations. We dedicate substantial management and other resources in order to obtain and maintain appropriate levels of reimbursement for our products from third-party payors, including governmental organizations in the U.S. and ex-U.S. markets.

In the U.S., we have worked successfully with third party payors in order to promptly obtain appropriate levels of reimbursement for our CF medicines. We plan to continue to engage in discussions with numerous commercial insurers and managed health care organizations, along with government health programs that are typically managed by authorities in the

individual states, to ensure that payors recognize the significant benefits that our medicines provide by treating the underlying cause of CF and continue to provide access to our medicines.

In Europe and other ex-U.S. markets, we seek government reimbursement for our medicines on a country-by-country basis. This is necessary for each new medicine, as well as label expansions for our current medicines in most countries. We successfully obtained reimbursement for KALYDECO in each significant ex-U.S. market within two years of approval, but experienced significant challenges in obtaining reimbursement for ORKAMBI in certain ex-U.S. markets. With the completion of reimbursement discussions in England and France in 2019, we have reimbursement for ORKAMBI or SYMKEVI in most of our significant ex-U.S. markets. In addition, in several ex-U.S. markets, including England, Ireland, Denmark and Australia, our reimbursement agreements include innovative arrangements that provide a pathway to access and rapid reimbursement for certain future CF medicines. For example, our existing reimbursement agreements in England, Ireland, and Denmark have been expanded to include KAFTRIO. We expect to continue to focus significant resources to obtain appropriate reimbursement for our products in ex-U.S. markets.

Strategic Transactions

Acquisitions

As part of our business strategy, we seek to acquire drugs, drug candidates and other technologies and businesses that have the potential to complement our ongoing research and development efforts. In 2019, we invested significantly in business development transactions designed to augment our pipeline, including the acquisition of Semma Therapeutics, Inc., or Semma, a privately-held company focused on the use of stem cell-derived human islets as a potentially curative treatment for T1D, and Exonics Therapeutics, Inc., or Exonics, a privately-held company focused on creating transformative gene-editing therapies to repair mutations that cause DMD and other severe neuromuscular diseases, including DM1. In the Semma acquisition, we paid approximately $950.0 million in cash to Semma equity holders. In the Exonics acquisition, we paid approximately $245.0 million upfront to Exonics equity holders and agreed to additional payments based upon successful achievement of specified development and regulatory milestones. We expect to continue to identify and evaluate potential acquisitions that may be similar to or different from the transactions that we have engaged in previously.

Both of our 2019 acquisitions were accounted for as business combinations. As of the acquisition date for each transaction, the cash payments, as well as the fair value of contingent consideration for Exonics, were allocated primarily to goodwill and the fair value of several in-process research and development assets that we acquired. The fair value of contingent consideration related to Exonics was recorded as a liability and will be adjusted on a quarterly basis in the future. As a result, these acquisitions are primarily reflected in additional assets and liabilities on our condensed consolidated balance sheet. Please refer to Note C, “Acquisitions,” and our critical accounting policies, “Acquisitions,” in our 2019 Annual Report on Form 10-K for further information regarding the significant judgments and estimates related to our 2019 acquisitions.

Collaboration and Licensing Arrangements

We enter into arrangements with third parties, including collaboration and licensing arrangements, for the development, manufacture and commercialization of drugs, drug candidates and other technologies that have the potential to complement our ongoing research and development efforts. We expect to continue to identify and evaluate collaboration and licensing opportunities that may be similar to or different from the collaborations and licenses that we have engaged in previously.

In-License Agreements

We have entered into collaborations with biotechnology and pharmaceutical companies in order to acquire rights or to license drug candidates or technologies that enhance our pipeline and/or our research capabilities. Over the last several years, we entered into collaboration agreements with a number of companies, including Affinia Therapeutics Inc., Arbor Biotechnologies, Inc., CRISPR, Kymera Therapeutics, Inc., Moderna, and Molecular Templates, Inc. Generally, when we in-license a technology or drug candidate, we make upfront payments to the collaborator, assume the costs of the program and/or agree to make contingent payments, which could consist of milestone, royalty and option payments. Most of these collaboration payments are expensed as research and development expenses; however, depending on many factors, including the structure of the collaboration, the significance of the in-licensed drug candidate to the collaborator’s operations and the other activities in which our collaborators are engaged, the accounting for these transactions can vary significantly. In the

nine months ended September 30, 2020 and 2019, our research and development expenses included $143.3 million and $261.6 million, respectively, related to upfront and milestones payments pursuant to our collaboration agreements.

Out-License Agreements

We also have out-licensed internally developed programs to collaborators who are leading the development of these programs. These out-license arrangements include our agreement with Merck KGaA, Darmstadt, Germany, which licensed oncology research and development programs from us in early 2017. Pursuant to these out-licensing arrangements, our collaborators are responsible for the research, development and commercialization costs associated with these programs, and we are entitled to receive contingent milestone and/or royalty payments. As a result, we do not expect to incur significant expenses in connection with these programs and have the potential for future collaborative and royalty revenues resulting from these programs.

Please refer to Note C, "Collaborative Arrangements," for further information regarding our in-license agreements and out-license agreements.

Strategic Investments

In connection with our business development activities, we have periodically made equity investments in our collaborators. As of September 30, 2020, we held strategic equity investments in public companies and certain private companies, and we plan to make additional strategic equity investments in the future. While we invest the majority of our cash, cash equivalents and marketable securities in instruments that meet specific credit quality standards and limit our exposure to any one issue or type of instrument, our strategic investments are maintained and managed separately from our other cash, cash equivalents and marketable securities. Any changes in the fair value of equity investments with readily determinable fair values (including publicly traded securities) are recorded to other income (expense), net in our condensed consolidated statement of operations. For equity investments without readily determinable fair values including equity investments in private companies, each reporting period we are required to re-evaluate the carrying value of the investment, which may result in other income (expense).

In the nine months ended September 30, 2020 and 2019, we recorded within other income (expense), net gains of $140.9 million and $68.9 million, respectively, related to changes in the fair value of our strategic investments, and from sales of certain equity investments. To the extent that we continue to hold strategic investments, particularly strategic investments in publicly traded companies, we will record other income (expense) related to these strategic investments on a quarterly basis. Due to the increased volatility of the global markets, including as a result of COVID-19, and the high volatility of stocks in the biotechnology industry, we expect the value of these strategic investments to fluctuate and that the increases or decreases in the fair value of these strategic investments will continue to have material impacts on our net income (expense) and our profitability on a quarterly and/or annual basis.

RESULTS OF OPERATIONS

	Three Months Ended September 30,		Increase/(Decrease)		Nine Months Ended September 30,		Increase/(Decrease)	
	2020	2019	$	%	2020	2019	$	%
	(in thousands, except percentages and per share amounts)							
Revenues	$ 1,538,271	$ 949,828	$ 588,443	62 %	$ 4,577,863	$ 2,749,556	$ 1,828,307	66 %
Operating costs and expenses	866,030	850,495	15,535	2 %	2,467,365	2,103,455	363,910	17 %
Income from operations	672,241	99,333	572,908	577 %	2,110,498	646,101	1,464,397	227 %
Other non-operating income (expense), net	73,630	(28,667)	102,297	**	117,677	71,868	45,809	64 %
Provision for income taxes	78,437	13,148	65,289	497 %	120,718	124,393	(3,675)	(3)%
Net income	$ 667,434	$ 57,518	$ 609,916	1,060 %	$ 2,107,457	$ 593,576	$ 1,513,881	255 %
Net income per diluted common share	$ 2.53	$ 0.22			$ 7.98	$ 2.28		
Diluted shares used in per share calculations	264,079	260,473			264,031	260,182		

** Not meaningful

Net Income

Our net income increased in the third quarter of 2020 as compared to the third quarter of 2019 primarily due to increased revenues resulting from the U.S. approval of TRIKAFTA in the fourth quarter of 2019 and continued uptake of our medicines in ex-U.S. markets. Our net income in the third quarter of 2020 as compared to the third quarter of 2019 also increased due to an increase in the fair value of our strategic investments and decreased collaborative research and development payments, partially offset by increased cost of sales consistent with increased product revenues, increased sales, general and administrative expenses to support our business and an increased provision for income taxes due to our increasing profitability.

Our net income increased in the nine months ended September 30, 2020 as compared to the nine months ended September 30, 2019 primarily due to increased revenues partially offset by increased operating costs and expenses. The increased revenues were primarily due to the U.S. approval of TRIKAFTA in the fourth quarter of 2019 and continued uptake of our medicines in ex-U.S. markets. The increased operating expenses were primarily due to increased cost of sales consistent with increased product revenues, increased investment in research and development and increased sales, general and administrative expenses to support our business.

Revenues

	Three Months Ended September 30,		Increase/(Decrease)		Nine Months Ended September 30,		Increase/(Decrease)	
	2020	2019	$	%	2020	2019	$	%
	(in thousands, except percentages)							
Product revenues, net	$ 1,536,271	$ 949,828	$ 586,443	62 %	$ 4,575,863	$ 2,747,461	$ 1,828,402	67 %
Collaborative and royalty revenues	2,000	—	2,000	**	2,000	2,095	(95)	(5) %
Total revenues	$ 1,538,271	$ 949,828	$ 588,443	62 %	$ 4,577,863	$ 2,749,556	$ 1,828,307	66 %

** Not meaningful

Product Revenues, Net

	Three Months Ended September 30,		Increase/(Decrease)		Nine Months Ended September 30,		Increase/(Decrease)	
	2020	2019	$	%	2020	2019	$	%
	(in thousands, except percentages)							
TRIKAFTA/KAFTRIO	$ 960,308	$ —	$ 960,308	**	$ 2,773,256	$ —	$ 2,773,256	**
SYMDEKO/SYMKEVI	156,178	403,714	(247,536)	(61) %	501,066	1,085,821	(584,755)	(54) %
ORKAMBI	225,919	296,711	(70,792)	(24) %	692,038	906,159	(214,121)	(24) %
KALYDECO	193,866	249,403	(55,537)	(22) %	609,503	755,481	(145,978)	(19) %
Total product revenues, net	$ 1,536,271	$ 949,828	$ 586,443	62 %	$ 4,575,863	$ 2,747,461	$ 1,828,402	67 %

** Not meaningful

In the third quarter and nine months ended September 30, 2020, our net product revenues increased by $586.4 million and $1.83 billion, respectively, as compared to the third quarter and nine months ended September 30, 2019. The increase in total net product revenues in the third quarter of 2020 and nine months ended September 30, 2020 was primarily due to the launch of TRIKAFTA, which was approved in the United States in the fourth quarter of 2019. Decreases in revenues for our other products were the result of patients in the United States switching from these medicines to TRIKAFTA, partially offset by label expansions and expanded access to our medicines in ex-U.S markets. In the third quarter and nine months ended September 30, 2020, our net product revenues included $313.7 million and $955.4 million, respectively, from ex-U.S. markets. In the third quarter and nine months ended September 30, 2019, our net product revenues included $239.5 million and $697.6 million, respectively, from ex-U.S. markets. In the third quarter of 2020, KAFTRIO was approved in the E.U., which we anticipate will positively affect our net product revenues in the future.

Collaborative and Royalty Revenues

Our collaborative and royalty revenues were $2.0 million in the third quarter and nine months ended September 30, 2020, respectively. We did not record any collaborative and royalty revenues in the third quarter of 2019. In the nine months ended September 30, 2019, our collaborative and royalty revenues were $2.1 million. Our collaborative revenues have historically fluctuated significantly from one period to another and may continue to fluctuate in the future. Our future royalty revenues will be dependent on if, and when, our collaborators, including Merck KGaA, Darmstadt, Germany, are able to successfully develop drug candidates that we have out-licensed to them.

Operating Costs and Expenses

	Three Months Ended September 30,		Increase/(Decrease)		Nine Months Ended September 30,		Increase/(Decrease)	
	2020	2019	$	%	2020	2019	$	%
	(in thousands, except percentages)							
Cost of sales	$ 186,182	$ 131,914	$ 54,268	41 %	$ 533,199	$ 362,746	$ 170,453	47 %
Research and development expenses	493,497	555,948	(62,451)	(11) %	1,362,953	1,274,529	88,424	7 %
Sales, general and administrative expenses	184,551	159,674	24,877	16 %	558,613	463,221	95,392	21 %
Change in fair value of contingent consideration	1,800	2,959	(1,159)	(39) %	12,600	2,959	9,641	326 %
Total costs and expenses	$ 866,030	$ 850,495	$ 15,535	2 %	$ 2,467,365	$ 2,103,455	$ 363,910	17 %

Cost of Sales

Our cost of sales primarily consists of the cost of producing inventories that corresponded to product revenues for the reporting period, plus the third-party royalties payable on our net sales of our products. Pursuant to our agreement with the CFF, our tiered third-party royalties on sales of TRIKAFTA/KAFTRIO, SYMDEKO/SYMKEVI, KALYDECO and ORKAMBI, calculated as a percentage of net sales, range from the single digits to the sub-teens, with royalties on sales of TRIKAFTA/KAFTRIO slightly lower than for our other products. Over the last several years, our cost of sales has been increasing due to increased net product revenues. Our cost of sales as a percentage of our net product revenues was approximately 12% and 14% in the third quarter of 2020 and 2019, respectively. Our cost of sales as a percentage of our net product revenues was approximately 12% and 13% in the nine months ended September 30, 2020 and 2019, respectively.

Research and Development Expenses

	Three Months Ended September 30,		Increase/(Decrease)		Nine Months Ended September 30,		Increase/(Decrease)	
	2020	2019	$	%	2020	2019	$	%
	(in thousands, except percentages)							
Research expenses	$ 186,152	$ 302,418	$ (116,266)	(38) %	$ 477,560	$ 537,509	$ (59,949)	(11) %
Development expenses	307,345	253,530	53,815	21 %	885,393	737,020	148,373	20 %
Total research and development expenses	$ 493,497	$ 555,948	$ (62,451)	(11) %	$ 1,362,953	$ 1,274,529	$ 88,424	7 %

Our research and development expenses include internal and external costs incurred for research and development of our drugs and drug candidates and expenses related to certain technology that we acquire or license through business development transactions. We do not assign our internal costs, such as salary and benefits, stock-based compensation expense, laboratory supplies and other direct expenses and infrastructure costs, to individual drugs or drug candidates, because the employees within our research and development groups typically are deployed across multiple research and development programs. These internal costs are significantly greater than our external costs, such as the costs of services provided to us by clinical research organizations and other outsourced research, which we allocate by individual program. All research and development costs for our drugs and drug candidates are expensed as incurred.

Since January 2018, we have incurred approximately $4.5 billion in research and development expenses associated with drug discovery and development. The successful development of our drug candidates is highly uncertain and subject to a number of risks. In addition, the duration of clinical trials may vary substantially according to the type, complexity and novelty of the drug candidate and the disease indication being targeted. The FDA and comparable agencies in foreign countries impose substantial requirements on the introduction of therapeutic pharmaceutical products, typically requiring lengthy and detailed laboratory and clinical testing procedures, sampling activities and other costly and time-consuming procedures. Data obtained from nonclinical and clinical activities at any step in the testing process may be adverse and lead to discontinuation or redirection of development activities. Data obtained from these activities also are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The duration and cost of discovery, nonclinical studies and clinical trials may vary significantly over the life of a project and are difficult to predict. Therefore, accurate and meaningful estimates of the ultimate costs to bring our drug candidates to market are not available.

In 2019 and the nine months ended September 30, 2020, costs related to our CF programs represented the largest portion of our development costs. Any estimates regarding development and regulatory timelines for our drug candidates are highly subjective and subject to change. Until we have data from Phase 3 clinical trials, we cannot make a meaningful estimate regarding when, or if, a clinical development program will generate revenues and cash flows.

Research Expenses

	Three Months Ended September 30,		Increase/(Decrease)		Nine Months Ended September 30,		Increase/(Decrease)	
	2020	2019	$	%	2020	2019	$	%
	(in thousands, except percentages)							
Research Expenses:								
Salary and benefits	$ 32,145	$ 33,767	$ (1,622)	(5) %	$ 97,513	$ 80,644	$ 16,869	21 %
Stock-based compensation expense	15,301	16,170	(869)	(5) %	68,206	50,843	17,363	34 %
Outsourced services and other direct expenses	27,911	27,721	190	1 %	79,837	78,707	1,130	1 %
Collaborative payments	80,050	198,979	(118,929)	(60) %	143,300	251,179	(107,879)	(43) %
Infrastructure costs	30,745	25,781	4,964	19 %	88,704	76,136	12,568	17 %
Total research expenses	$ 186,152	$ 302,418	$ (116,266)	(38) %	$ 477,560	$ 537,509	$ (59,949)	(11) %

We expect to continue to invest in our research programs with a focus on identifying drug candidates with the goal of creating transformative medicines for serious diseases. Our research expenses decreased by 38% in the third quarter of 2020 as compared to the third quarter of 2019 primarily due to a decrease in collaborative payments. Our research expenses decreased by 11% in the nine months ended September 30, 2020 as compared to the nine months ended September 30, 2019, primarily due to a decrease in collaborative payments partially offset by increased expenses to support our cell and genetic therapy programs.

Development Expenses

	Three Months Ended September 30,		Increase/(Decrease)		Nine Months Ended September 30,		Increase/(Decrease)	
	2020	2019	$	%	2020	2019	$	%
	(in thousands, except percentages)							
Development Expenses:								
Salary and benefits	$ 73,698	$ 59,552	$ 14,146	24 %	$ 221,828	$ 178,254	$ 43,574	24 %
Stock-based compensation expense	45,469	36,334	9,135	25 %	135,526	117,008	18,518	16 %
Outsourced services and other direct expenses	133,595	107,439	26,156	24 %	374,926	298,908	76,018	25 %
Collaborative payments	—	5,000	(5,000)	**	—	10,440	(10,440)	**
Infrastructure costs	54,583	45,205	9,378	21 %	153,113	132,410	20,703	16 %
Total development expenses	$ 307,345	$ 253,530	$ 53,815	21 %	$ 885,393	$ 737,020	$ 148,373	20 %

** Not meaningful

Our development expenses increased by 21% in the third quarter of 2020 as compared to the third quarter of 2019 and increased by 20% in the nine months ended September 30, 2020 as compared to the nine months ended September 30, 2019, primarily due to increased expenses related to our diverse pipeline, including clinical trials, headcount and infrastructure costs.

Sales, General and Administrative Expenses

	Three Months Ended September 30,		Increase/(Decrease)		Nine Months Ended September 30,		Increase/(Decrease)	
	2020	2019	$	%	2020	2019	$	%
	(in thousands, except percentages)							
Sales, general and administrative expenses	$ 184,551	$ 159,674	$ 24,877	16 %	$ 558,613	$ 463,221	$ 95,392	21 %

Sales, general and administrative expenses increased by 16% in the third quarter of 2020 as compared to the third quarter of 2019 and increased by 21% in the nine months ended September 30, 2020 as compared to the nine months ended September 30, 2019, primarily due to increased global support for our medicines, including incremental investment to support the launch of our triple combination regimen and increased support for our CF pipeline products and other disease areas.

Contingent Consideration

In the third quarter and nine months ended September 30, 2020, the increase in the fair value of contingent consideration potentially payable to Exonics' former equity holders was $1.8 million and $12.6 million, respectively. In each of the third quarter and nine months ended September 30, 2019, the increase in the fair value of contingent consideration potentially payable to Exonics' former equity holders was $3.0 million.

Other Non-Operating Income (Expense), Net

Interest Income

Interest income decreased from $17.6 million and $51.3 million in the third quarter and nine months ended September 30, 2019, respectively, to $3.1 million and $19.9 million in the third quarter and nine months ended September 30, 2020, respectively, primarily due to a decrease in prevailing market interest rates. Our future interest income will be dependent on the amount of, and prevailing market interest rates on, our outstanding cash equivalents and marketable securities.

Interest Expense

Interest expense was $13.9 million and $41.9 million in the third quarter and nine months ended September 30, 2020, respectively, as compared to $14.5 million and $44.3 million in the third quarter and nine months ended September 30, 2019, respectively. The majority of our interest expense in these periods was related to imputed interest expense associated with our leased corporate headquarters in Boston. Our future interest expense will be dependent on whether, and to what extent, we borrow amounts under our credit facilities.

Other Income (Expense), Net

Other income (expense), net was income of $84.4 million and $139.6 million in the third quarter and nine months ended September 30, 2020, respectively, as compared to an expense of $31.7 million and income of $64.8 million in the third quarter and nine months ended September 30, 2019, respectively. Our other income (expense), net in these periods was primarily related to changes in the fair value of our strategic investments, as well as realized gains from sales of certain investments. We expect that due to the volatility of the stock price of biotechnology companies, our other income (expense), net will fluctuate in future periods based on increases or decreases in the fair value of our strategic investments.

Income Taxes

Our provision for income taxes was $78.4 million and $120.7 million in the third quarter and nine months ended September 30, 2020, respectively, as compared to $13.1 million and $124.4 million in the third quarter and nine months ended September 30, 2019, respectively. Our effective tax rate for the nine months ended September 30, 2020 was lower than the U.S. statutory rate primarily due to (i) discrete tax benefits associated with the $209.0 million transfer of intellectual property rights to the United Kingdom, the write-off of a long-term intercompany receivable, and an increase in the United Kingdom's corporate tax rate; and (ii) excess tax benefits related to stock-based compensation. Our effective tax rate for the nine months ended September 30, 2019 was lower than the U.S. statutory rate primarily due to excess tax benefits related to stock-based compensation. We released our valuation allowance on the majority of our net operating losses and other deferred tax assets in the fourth quarter of 2018. Starting in 2019, we began recording a provision for income taxes on our pre-tax income using an effective tax rate approximating statutory rates. We expect to utilize our remaining previously benefited U.S. net operating losses in 2020. As a result, a larger portion of our tax provision will represent a cash tax payable in future periods.

LIQUIDITY AND CAPITAL RESOURCES

The following table summarizes the components of our financial condition as of September 30, 2020 and December 31, 2019:

	September 30, 2020	December 31, 2019	Increase/(Decrease) $	Increase/(Decrease) %
	(in thousands)			
Cash, cash equivalents and marketable securities	$ 6,151,058	$ 3,808,294	$ 2,342,764	62 %
Working Capital				
Total current assets	7,458,456	4,822,829	2,635,627	55 %
Total current liabilities	(2,004,026)	(1,334,827)	669,199	50 %
Total working capital	$ 5,454,430	$ 3,488,002	$ 1,966,428	56 %

As of September 30, 2020, total working capital was $5.5 billion, which represented an increase of $2.0 billion from $3.5 billion as of December 31, 2019. The increase in total working capital in the nine months ended September 30, 2020 was primarily related to $2.8 billion of cash provided by operations partially offset by $408.0 million of cash used to repurchase our common stock pursuant to the share repurchase program that we announced in July 2019 and expenditures for property and equipment of $212.1 million.

Sources of Liquidity

As of September 30, 2020, we had cash, cash equivalents and marketable securities of $6.2 billion, which represented an increase of $2.3 billion from $3.8 billion as of December 31, 2019. We intend to rely on our existing cash, cash equivalents and marketable securities together with cash flows from product sales as our primary source of liquidity.

We may borrow up to a total of $2.5 billion pursuant to two revolving credit facilities. We may repay and reborrow amounts under these revolving credit agreements without penalty. Subject to certain conditions, we may request that the borrowing capacity for each of the credit agreements be increased by an additional $500.0 million, for a total of $3.5 billion collectively.

Other possible sources of future liquidity include commercial debt, public and private offerings of our equity and debt securities, strategic sales of assets or businesses and financial transactions. Negative covenants in our credit agreement may prohibit or limit our ability to access these sources of liquidity.

Future Capital Requirements

We have significant future capital requirements, including:

- significant expected operating expenses to conduct research and development activities and to operate our organization; and
- substantial facility and capital lease obligations.

In addition:

- We have entered into certain collaboration agreements with third parties that include the funding of certain research, development and commercialization efforts with the potential for future milestone and royalty payments by us upon the achievement of pre-established developmental and regulatory targets and/or commercial targets, and we may enter into additional business development transactions, including acquisitions, collaborations and equity investments, that require additional capital.
- In 2019, we reached an agreement with the French government and agreed to repay a portion of the amounts we have collected under the ORKAMBI early access programs in France to the French government in the fourth quarter of 2020 based on the difference between the invoiced amount and the final amount for ORKAMBI distributed through these programs as reflected in the structure of the agreement with the French government.
- To the extent we borrow amounts under the credit agreements we entered into in 2019 and 2020, we would be required to repay any outstanding principal amounts in 2024 or 2022, respectively.

- As of September 30, 2020, $56.0 million remained available to fund repurchases under our share repurchase program.

We expect that cash flows from our products together with our current cash, cash equivalents and marketable securities will be sufficient to fund our operations for at least the next twelve months and do not expect COVID-19 to have an adverse effect on our liquidity. The adequacy of our available funds to meet our future operating and capital requirements will depend on many factors, including the amounts of future revenues generated by our products, and the potential introduction of one or more of our other drug candidates to the market, the level of our business development activities and the number, breadth, cost and prospects of our research and development programs.

Financing Strategy

We may raise additional capital by borrowing under credit agreements, through public offerings or private placements of our securities or securing new collaborative agreements or other methods of financing. We will continue to manage our capital structure and will consider all financing opportunities, whenever they may occur, that could strengthen our long-term liquidity profile. There can be no assurance that any such financing opportunities will be available on acceptable terms, if at all.

CONTRACTUAL COMMITMENTS AND OBLIGATIONS

Our commitments and obligations were reported in our Annual Report on Form 10-K for the year ended December 31, 2019, which was filed with the Securities and Exchange Commission, or SEC, on February 13, 2020. There have been no material changes from the contractual commitments and obligations previously disclosed in that Annual Report on Form 10-K.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Our discussion and analysis of our financial condition and results of operations are based upon our condensed consolidated financial statements prepared in accordance with generally accepted accounting principles in the United States. The preparation of these financial statements requires us to make certain estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of revenues and expenses during the reported periods. These items are monitored and analyzed by management for changes in facts and circumstances, and material changes in these estimates could occur in the future. Changes in estimates are reflected in reported results for the period in which the change occurs. We base our estimates on historical experience and various other assumptions that we believe to be reasonable under the circumstances. Actual results may differ from our estimates if past experience or other assumptions do not turn out to be substantially accurate. During the nine months ended September 30, 2020, there were no material changes to our critical accounting policies as reported in our Annual Report on Form 10-K for the year ended December 31, 2019, which was filed with the SEC on February 13, 2020.

RECENT ACCOUNTING PRONOUNCEMENTS

For a discussion of recent accounting pronouncements, please refer to Note A, “Basis of Presentation and Accounting Policies.”

Item 3. Quantitative and Qualitative Disclosures About Market Risk

As part of our investment portfolio, we own financial instruments that are sensitive to market risks. The investment portfolio is used to preserve our capital. None of these market risk-sensitive instruments are held for trading purposes. We do not have derivative financial instruments in our investment portfolio.

Interest Rate Risk

We invest our cash in a variety of financial instruments, principally securities issued by the U.S. government and its agencies, investment-grade corporate bonds and commercial paper, and money market funds. These investments are denominated in U.S. Dollars. All of our interest-bearing securities are subject to interest rate risk and could decline in value if interest rates fluctuate, including potential fluctuations as a result of COVID-19. Substantially all of our investment portfolio consists of marketable securities with active secondary or resale markets to help ensure portfolio liquidity, and we have implemented guidelines limiting the term-to-maturity of our investment instruments. Due to the conservative nature of these instruments, we do not believe that we have a material exposure to interest rate risk. If interest rates were to increase or decrease by 1%, the fair value of our investment portfolio would increase or decrease by an immaterial amount.

We entered into a credit agreement in each of 2019 and 2020. Loans under these credit agreements bear interest, at our option, at either a base rate or a Eurocurrency rate, in each case plus an applicable margin based on our consolidated leverage ratio (the ratio of our total consolidated funded indebtedness to our consolidated EBITDA for the most recently completed four fiscal quarter period). Pursuant to the credit agreement that we entered into in 2019, the applicable margin on base rate loans ranges from 0.125% to 0.500% and the applicable margin on Eurocurrency loans ranges from 1.125% to 1.500%. Pursuant to the credit agreement that we entered into in 2020, the applicable margin on base rate loans ranges from 0.500% to 0.875% and the applicable margin on Eurocurrency loans ranges from 1.500% to 1.875%. We do not believe that changes in interest rates related to either credit agreement would have a material effect on our financial statements. As of September 30, 2020, we had no principal or interest outstanding under either of our existing credit facilities. A portion of our "Interest expense" in the fourth quarter of 2020 will be dependent on whether, and to what extent, we borrow amounts under these existing facilities.

Foreign Exchange Market Risk

As a result of our foreign operations, we face exposure to movements in foreign currency exchange rates, primarily the Euro and British Pound against the U.S. Dollar. Fluctuations in the global markets, including as a result of COVID-19, may have a positive or negative effect on our foreign exchange rate exposure. The current exposures arise primarily from cash, accounts receivable, intercompany receivables and payables, payables and accruals and inventories. Both positive and negative effects to our net revenues from international product sales from movements in exchange rates are partially mitigated by the natural, opposite effect that exchange rates have on our international operating costs and expenses.

We have a foreign currency management program with the objective of reducing the effect of exchange rate fluctuations on our operating results and forecasted revenues and expenses denominated in foreign currencies. We currently have cash flow hedges for the Euro, British Pound, Canadian Dollar and Australian Dollar related to a portion of our forecasted product revenues that qualify for hedge accounting treatment under U.S. GAAP. We do not seek hedge accounting treatment for our foreign currency forward contracts related to monetary assets and liabilities that impact our operating results. As of September 30, 2020, we held foreign exchange forward contracts that were designated as cash flow hedges with notional amounts totaling $966.6 million representing a net liability at fair value of $32.1 million on our condensed consolidated balance sheet.

Although not predictive in nature, we believe a hypothetical 10% threshold reflects a reasonably possible near-term change in exchange rates. Assuming that the September 30, 2020 exchange rates were to change by a hypothetical 10%, the fair value recorded on our condensed consolidated balance sheet related to our foreign exchange forward contracts that were designated as cash flow hedges as of September 30, 2020 would change by approximately $96.7 million. However, since these contracts hedge a specific portion of our forecasted product revenues denominated in certain foreign currencies, any change in the fair value of these contracts is recorded in "Accumulated other comprehensive loss" on our condensed consolidated balance sheet and is reclassified to earnings in the same periods during which the underlying product revenues affect earnings. Therefore, any change in the fair value of these contracts that would result from a hypothetical 10% change in exchange rates would be entirely offset by the change in value associated with the underlying hedged product revenues

resulting in no impact on our future anticipated earnings and cash flows with respect to the hedged portion of our forecasted product revenues.

Equity Price Risk

Information required by this section is incorporated by reference from the discussion in the "Strategic Investments" section of this Part I, Item 2, "Management's Discussion and Analysis of Financial Condition and Results of Operations."

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management (under the supervision and with the participation of our chief executive officer and chief financial officer), after evaluating the effectiveness 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) as of the end of the period covered by this Quarterly Report on Form 10-Q, has concluded that, based on such evaluation, as of September 30, 2020 our disclosure controls and procedures were effective and designed to provide reasonable assurance that the information required to be disclosed is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Changes in Internal Controls Over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended) occurred during the three months ended September 30, 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. Other Information

Item 1. Legal Proceedings

We are not currently subject to any material legal proceedings.

Item 1A. Risk Factors

Information regarding risk factors appears in Part I, Item 1A. "Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2019, which was filed with the SEC on February 13, 2020. There have been no material changes from the risk factors previously disclosed in the Annual Report on Form 10-K, except as discussed in Part II, Item 1A. "Risk Factors" in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, which was filed with the SEC on May 1, 2020 and our Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, which was filed with the SEC on July 31, 2020 and is being updated below.

We are subject to risks associated with the spread of COVID-19.

COVID-19 has broadly affected the global economy, resulted in significant travel and work restrictions in many regions and has put a significant strain on healthcare resources. COVID-19 has had, and we expect it will continue to have, an impact on our operations and an impact on the operations of our collaborators, third-party contractors and other entities, including governments, governmental agencies and payors, with which we interact. To date, the most significant effect on our business operations has been the requirement that a majority of our employees work remotely. We have re-initiated enrollment and dosing in all of our ongoing clinical trials and initiated new clinical trials despite some earlier temporary pauses to enrollment and dosing caused by COVID-19.

We continue to monitor local COVID-19 trends and government guidance for each of our site locations and have begun to re-open certain of our sites utilizing a phased, site-specific approach. There can be no assurance that these re-openings will continue or that, due to additional waves of increased infections, updated government guidance or other considerations, we will not be required to temporarily close or ramp-down sites that had re-opened or to pause enrollment and dosing at clinical trial sites. Any site closure or pause of a clinical trial could harm our operations and delay the development of our product candidates.

In the future, the economic impacts of the COVID-19 pandemic could affect our business directly or indirectly, including potentially affecting the net prices for our products through changes in our payor mix as a result of increased unemployment in the United States or increased pressure on healthcare costs. The effects on our research, development, manufacturing and commercialization activities will be dependent on, among other things, the severity and duration of the COVID-19 pandemic, and any worsening of the global economic environment as a result thereof, as well as the impact of the pandemic on our third-party manufacturers, suppliers, distributors, subcontractors and customers. While the ultimate impact of COVID-19 on our business is highly uncertain, any negative impacts that materialize could materially adversely affect our operations, financial performance and stock price. Any negative impacts of COVID-19, alone or in combination with others, could exacerbate other risk factors discussed in Part I, "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2019. The full extent to which the COVID-19 pandemic will negatively affect our operations, financial performance and stock price will depend on future developments that are highly uncertain and cannot be predicted, including the scope and duration of the pandemic and actions taken by governmental authorities and other third parties in response to the pandemic.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q and, in particular, our Management's Discussion and Analysis of Financial Condition and Results of Operations set forth in Part I, Item 2, contain a number of forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding:

- our expectations regarding the amount of, timing of, and trends with respect to our financial performance, including revenues, costs and expenses and other gains and losses, including those related to net product revenues;
- our expectations regarding the effect of COVID-19 on, among other things, our financial performance, liquidity, business and operations, including manufacturing, supply chain, research and development activities and pipeline programs;
- our expectations regarding clinical trials, development timelines, regulatory authority filings, submissions and potential approvals and label expansions for ivacaftor, lumacaftor, tezacaftor, elexacaftor, and any combination regimen;

- our ability to obtain reimbursement for our medicines in the U.S. and ex-U.S. markets and our ability to launch, commercialize and market our medicines or any of our other drug candidates for which we obtain regulatory approval;
- our expectations regarding the timing and structure of clinical trials of our drugs, drug candidates and other pipeline programs and the expected timing of our receipt of data from our ongoing and planned clinical trials;
- the data that will be generated by ongoing and planned clinical trials and the ability to use that data to advance compounds, continue development or support regulatory filings;
- our beliefs regarding the support provided by clinical trials and preclinical and nonclinical studies of our drug candidates and other pipeline programs for further investigation, clinical trials or potential use as a treatment;
- our expectations regarding the potential benefits and commercial potential of our product candidates, including the potential approach to treating specific diseases;
- our plan to continue investing in our research and development programs, including anticipated timelines for our programs, and our strategy to develop our pipeline programs, alone or with third party-collaborators;
- the potential future benefits of our acquisitions and collaborations;
- the establishment, development and maintenance of collaborative relationships, including potential milestone payments or other obligations;
- potential business development activities, including the identification of potential collaborative partners or acquisition targets;
- potential fluctuations in foreign currency exchange rates;
- our expectations regarding our provision for or benefit from income taxes and the utilization of our deferred tax assets, including the impact of the Coronavirus Aid, Relief and Economic Security Act;
- our ability to use our research programs to identify and develop new drug candidates to address serious diseases and significant unmet medical needs; and
- our liquidity and our expectations regarding the possibility of raising additional capital.

Any or all of our forward-looking statements in this Quarterly Report on Form 10-Q may turn out to be wrong. There are a number of assumptions, risks, and uncertainties, known or unknown, which could cause actual events or results to differ materially from those indicated by our forward-looking statements, including the risks and uncertainties described under "Risk Factors" in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2019, which was filed with the SEC on February 13, 2020, our Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, which was filed with the SEC on May 1, 2020, our Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, which was filed with the SEC on July 31, 2020 and in this Quarterly Report on Form 10-Q. These are factors and uncertainties that we think could cause our actual results to differ materially from expected results. Other factors and uncertainties besides those listed there could also adversely affect us.

Without limiting the foregoing, the words "believes," "anticipates," "plans," "intends," "expects," "could," "may," "potential," "will," "estimate" and similar expressions are intended to identify forward-looking statements. The forward-looking statements contained herein represent our estimate only as of the date of this filing and should not be relied upon as representing our estimate as of any subsequent date. While we may elect to update these forward-looking statements at some point in the future, we specifically disclaim any obligation to do so to reflect actual results, changes in assumptions or changes in other factors affecting such forward-looking statements.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Issuer Repurchases of Equity Securities

In July 2019, our Board of Directors approved a share repurchase program (the "2019 Share Repurchase Program"), pursuant to which we are authorized to repurchase up to $500.0 million of our common stock between August 1, 2019 and December 31, 2020. The table set forth below shows repurchases of securities by us during the three months ended September 30, 2020 under our 2019 Share Repurchase Program.

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs (1)	Approximate Dollar Value of Shares that May Yet be Purchased Under the Plans or Programs (1)
July 1, 2020 to July 31, 2020	—	$—	—	$164,001,989
August 1, 2020 to August 31, 2020	310,562	$270.48	310,562	$80,002,649
September 1, 2020 to September 30, 2020	92,157	$260.42	92,157	$56,003,011
Total	402,719	$268.17	402,719	$56,003,011

(1) Under our 2019 Share Repurchase Program, we are authorized to purchase shares from time to time through open market or privately negotiated transactions. Such purchases may be made pursuant to Rule 10b5-1 plans or other means as determined by our management and in accordance with the requirements of the Securities and Exchange Commission.

Item 6. Exhibits

Exhibit Number	Exhibit Description
10.1	Credit Agreement, dated as of September 18, 2020, by and among Vertex Pharmaceuticals Incorporated, Bank of America, N.A. and the other lenders party thereto.
31.1	Certification of the Chief Executive Officer under Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Chief Financial Officer under Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Chief Executive Officer and the Chief Financial Officer under Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation
101.LAB	XBRL Taxonomy Extension Labels
101.PRE	XBRL Taxonomy Extension Presentation
101.DEF	XBRL Taxonomy Extension Definition
104	Cover Page Interactive Data File—the cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.

SIGNATURES

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.

Vertex Pharmaceuticals Incorporated

October 30, 2020 By: /s/ Charles F. Wagner, Jr.

Charles F. Wagner, Jr.

Executive Vice President, Chief Financial Officer
(principal financial officer and
duly authorized officer)