

VERTEX PHARMACEUTICALS INC / MA  
Form 10-Q  
November 09, 2007

[QuickLinks](#) -- Click here to rapidly navigate through this document

---

---

**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, 2007**

**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**  
(State or other jurisdiction of  
incorporation or organization)

**04-3039129**  
(I.R.S. Employer  
Identification No.)

**130 WAVERLY STREET  
CAMBRIDGE, MASSACHUSETTS**  
(Address of principal executive offices)

**02139-4242**  
(zip code)

**(617) 444-6100**

(Registrant's telephone number, including area code)

---

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 is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large Accelerated Filer

Accelerated Filer

Non-Accelerated Filer

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

Edgar Filing: VERTEX PHARMACEUTICALS INC / MA - Form 10-Q

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**  
Class

132,297,777  
Outstanding at November 6, 2007

---

---

---

VERTEX PHARMACEUTICALS INCORPORATED

FORM 10-Q

FOR THE QUARTER ENDED SEPTEMBER 30, 2007

TABLE OF CONTENTS

<b>Part I. Financial Information</b>		
<i>Item 1.</i>	<i>Condensed Consolidated Financial Statements (unaudited)</i>	1
	Condensed Consolidated Balance Sheets September 30, 2007 and December 31, 2006	1
	Condensed Consolidated Statements of Operations Three and Nine Months Ended September 30, 2007 and 2006	2
	Condensed Consolidated Statements of Cash Flows Nine Months Ended September 30, 2007 and 2006	3
	Notes to Condensed Consolidated Financial Statements	4
<i>Item 2.</i>	<i>Management's Discussion and Analysis of Financial Condition and Results of Operations</i>	18
<i>Item 3.</i>	<i>Quantitative and Qualitative Disclosures About Market Risk</i>	38
<i>Item 4.</i>	<i>Controls and Procedures</i>	38
<b>Part II. Other Information</b>		
<i>Item 1A.</i>	<i>Risk Factors</i>	39
<i>Item 2.</i>	<i>Unregistered Sales of Equity Securities and Use of Proceeds</i>	40
<i>Item 5.</i>	<i>Other Information</i>	40
<i>Item 6.</i>	<i>Exhibits</i>	41

Signatures

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

"Vertex" is a registered trademark of Vertex. "Agenerase," "Lexiva" and "Telzir" are registered trademarks of GlaxoSmithKline plc. Other brands, names and trademarks contained in this Quarterly Report on Form 10-Q are the property of their respective owners.

**Part I. Financial Information****Item 1. Condensed Consolidated Financial Statements**

**Vertex Pharmaceuticals Incorporated**  
**Condensed Consolidated Balance Sheets**  
**(Unaudited)**

(In thousands, except share and per share amounts)

	September 30, 2007	December 31, 2006
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 253,979	\$ 213,171
Marketable securities, available for sale, current portion	248,571	491,455
Accounts receivable	34,658	62,923
Prepaid expenses	6,071	3,857
<b>Total current assets</b>	<b>543,279</b>	<b>771,406</b>
Marketable securities, available for sale, excluding current portion	11,902	57,126
Restricted cash	30,258	30,258
Property and equipment, net	68,900	61,535
Other assets	809	1,254
<b>Total assets</b>	<b>\$ 655,148</b>	<b>\$ 921,579</b>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 25,757	\$ 15,368
Accrued expenses and other current liabilities	96,157	91,359
Accrued interest		1,905
Deferred revenues, current portion	24,017	33,889
Accrued restructuring expense, current portion	5,592	4,735
Convertible subordinated notes		42,102
Convertible senior subordinated notes		59,648
Collaborator development loan (due May 2008), current portion	19,997	
Other obligations	14,188	2,008
<b>Total current liabilities</b>	<b>185,708</b>	<b>251,014</b>
Accrued restructuring expense, excluding current portion	30,537	28,338
Collaborator development loan (due May 2008), excluding current portion		19,997
Deferred revenues, excluding current portion	106,868	116,295
<b>Total liabilities</b>	<b>323,113</b>	<b>415,644</b>
Commitments and contingencies:		
Stockholders' equity:		
Preferred stock, \$0.01 par value; 1,000,000 shares authorized; none issued and outstanding at September 30, 2007 and December 31, 2006		
Common stock, \$0.01 par value; 200,000,000 shares authorized; 132,170,920 and 126,121,473 shares issued and outstanding at September 30, 2007 and	1,304	1,244

Edgar Filing: VERTEX PHARMACEUTICALS INC / MA - Form 10-Q

	September 30, 2007	December 31, 2006
	<u>                    </u>	<u>                    </u>
December 31, 2006, respectively		
Additional paid-in capital	1,832,425	1,702,128
Accumulated other comprehensive income (loss)	309	(962)
Accumulated deficit	(1,502,003)	(1,196,475)
	<u>                    </u>	<u>                    </u>
Total stockholders' equity	332,035	505,935
	<u>                    </u>	<u>                    </u>
Total liabilities and stockholders' equity	\$ 655,148	\$ 921,579
	<u>                    </u>	<u>                    </u>

The accompanying notes are an integral part of these condensed consolidated 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,	
	2007	2006	2007	2006
<b>Revenues:</b>				
Royalties	\$ 12,522	\$ 10,902	\$ 33,285	\$ 29,086
Collaborative and other research and development revenues	28,492	42,387	114,735	93,016
<b>Total revenues</b>	<b>41,014</b>	<b>53,289</b>	<b>148,020</b>	<b>122,102</b>
<b>Costs and expenses:</b>				
Royalty payments	3,562	3,113	10,232	8,993
Research and development expenses	128,949	96,115	397,714	262,567
Sales, general and administrative expenses	21,416	14,773	61,275	42,022
Restructuring expense	882	1,415	6,843	2,625
<b>Total costs and expenses</b>	<b>154,809</b>	<b>115,416</b>	<b>476,064</b>	<b>316,207</b>
<b>Loss from operations</b>	<b>(113,795)</b>	<b>(62,127)</b>	<b>(328,044)</b>	<b>(194,105)</b>
Interest income	7,256	5,330	24,801	13,231
Interest expense	(494)	(1,767)	(2,285)	(6,481)
Realized gain on sale of investment		7,663		7,663
Unrealized gain on warrants		4,250		4,250
Loss on exchange of convertible subordinated notes		(5,151)		(5,151)
<b>Loss before cumulative effect of a change in accounting principle</b>	<b>(107,033)</b>	<b>(51,802)</b>	<b>(305,528)</b>	<b>(180,593)</b>
Cumulative effect of a change in accounting principle SFAS 123(R)*				1,046
<b>Net loss</b>	<b>\$ (107,033)</b>	<b>\$ (51,802)</b>	<b>\$ (305,528)</b>	<b>\$ (179,547)</b>
Basic and diluted loss per common share before cumulative effect of a change in accounting principle	\$ (0.82)	\$ (0.46)	\$ (2.38)	\$ (1.65)
Basic and diluted cumulative effect of a change in accounting principle per common share				0.01
<b>Basic and diluted net loss per common share</b>	<b>\$ (0.82)</b>	<b>\$ (0.46)</b>	<b>\$ (2.38)</b>	<b>\$ (1.64)</b>
Basic and diluted weighted-average number of common shares outstanding	130,006	112,803	128,378	109,608

\*

In 2006, the Company adopted Financial Accounting Standards Board Statement No. 123(R), "Share-Based Payment," using a modified prospective method. See Note 3, "Stock-based Compensation," for further details.

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,	
	2007	2006
Cash flows from operating activities:		
Net loss	\$ (305,528)	\$ (179,547)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	20,008	18,993
Stock-based compensation expense	46,749	29,046
Other non-cash based compensation expense	3,287	2,507
Cumulative effect of a change in accounting principle		(1,046)
Loss on disposal of property and equipment		7
Realized loss (gain) on marketable securities	219	(7,641)
Unrealized gain on warrants		(4,250)
Charge for exchange of convertible subordinated notes		5,151
Changes in operating assets and liabilities:		
Accounts receivable	28,265	(22,019)
Prepaid expenses	(2,214)	(2,028)
Other assets		(1,995)
Accounts payable	10,389	934
Accrued expenses and other liabilities	16,978	25,373
Accrued restructuring	3,056	(10,228)
Accrued interest	(1,694)	(1,104)
Deferred revenues	(19,299)	129,659
Net cash used in operating activities	(199,784)	(18,188)
Cash flows from investing activities:		
Purchases of marketable securities	(317,156)	(173,555)
Sales and maturities of marketable securities	606,247	266,303
Expenditures for property and equipment	(27,216)	(25,229)
Restricted cash		4,090
Investments and other assets	(444)	221
Net cash provided by investing activities	261,431	71,830
Cash flows from financing activities:		
Issuances of common stock from employee benefit plans, net	21,238	38,441
Issuances of common stock from stock offering, net		313,292
Principal payments on convertible subordinated notes	(42,102)	
Debt exchange costs	(53)	(170)
Net cash (used in) provided by financing activities	(20,917)	351,563
Effect of changes in exchange rates on cash	78	181
Net increase in cash and cash equivalents	40,808	405,386
Cash and cash equivalents beginning of period	213,171	78,045
Cash and cash equivalents end of period	\$ 253,979	\$ 483,431



Nine Months Ended  
September 30,

---

Supplemental disclosure of cash flow information:

Cash paid for interest	\$	3,820	\$	7,212
		<hr/>		<hr/>

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

## Vertex Pharmaceuticals Incorporated

## Notes to Condensed Consolidated Financial Statements

(Unaudited)

**1. 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.

The condensed consolidated financial statements reflect the operations of the Company and its wholly-owned subsidiaries. All significant intercompany balances and transactions have been eliminated.

Certain information and footnote disclosures normally included in the Company's annual financial statements have been condensed or omitted. The interim financial statements, in the opinion of management, reflect all normal recurring adjustments (including accruals) necessary for a fair presentation of the financial position and results of operations for the interim periods ended September 30, 2007 and 2006.

The results of operations for the interim periods are not necessarily indicative of the results of operations to be expected for the fiscal year, although the Company expects to incur a substantial loss for the year ending December 31, 2007. These interim financial statements should be read in conjunction with the audited financial statements for the year ended December 31, 2006, which are contained in the Company's 2006 Annual Report on Form 10-K that was filed with the Securities and Exchange Commission on March 1, 2007.

**2. Accounting Policies***Basic and Diluted Net Loss per Common Share*

Basic net loss per share is based upon the weighted-average number of common shares outstanding during the period, excluding restricted stock that has been issued but is not yet vested. Diluted net loss per share 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 of adding such shares is dilutive. Common equivalent shares result from the assumed exercise of outstanding stock options (the proceeds of which are then assumed to have been used to repurchase outstanding stock using the treasury stock method), the assumed conversion of convertible notes and the vesting of unvested restricted shares of common stock. Common equivalent shares have not been included in the net loss per share calculations because the effect of including such shares would have been anti-dilutive. Total potential gross common equivalent shares consisted of the following (in thousands, except per share amounts):

	At September 30,	
	2007	2006
Stock options	15,914	15,084
Weighted-average exercise price, per share	\$ 28.24	\$ 26.16
Convertible notes		4,449
Weighted-average conversion price, per share	n/a	\$ 22.87
Unvested restricted shares	1,759	1,825

*Stock-based Compensation Expense*

The Company records stock-based compensation expense in accordance with Financial Accounting Standards Board ("FASB") Statement No. 123(R), "Share-Based Payment" ("SFAS 123(R)"). SFAS 123(R) requires companies to expense the fair value of employee stock options and other forms of stock-based employee compensation over the employees' service periods or the derived service period for awards with market conditions. Compensation expense is measured based on the fair value of the award at the grant date, including estimated forfeitures, and is adjusted to reflect actual forfeitures and the outcomes of certain conditions. Please refer to Note 3, "Stock-based Compensation," for further information.

*Research and Development Expenses*

All research and development expenses, including amounts funded by collaborators, are expensed as incurred. Research and development expenses are comprised of costs incurred in performing research and development activities, including salary and benefits; stock-based compensation expense; laboratory supplies and other direct expenses; contractual services, including clinical trial and pharmaceutical development costs; commercial supply investment in telaprevir; and infrastructure costs, including facilities costs and depreciation. Due to telaprevir's stage of development, costs related to the Company's investment in its commercial supply of telaprevir are considered a research and development expense. The Company's investment in its commercial supply of telaprevir is at risk if the Company does not obtain regulatory approval and successfully commercialize telaprevir.

In 2007 and 2006, the Company's collaborators have funded portions of the Company's research and development programs related to specific drug candidates and research targets. The following tables detail the research and development expenses incurred by the Company for collaborator-sponsored and Company-sponsored programs (collaborator-sponsored programs are those in which a collaborator has funded any portion of the related program expenses, including telaprevir, VX-702, VX-770, VX-809, kinases and certain cystic fibrosis research targets) for the three and nine months ended September 30, 2007 and 2006 (in thousands):

	For the Three Months Ended September 30, 2007			For the Three Months Ended September 30, 2006		
	Research	Development	Total	Research	Development	Total
Collaborator-sponsored	\$ 4,284	\$ 58,891	\$ 63,175	\$ 5,702	\$ 50,761	\$ 56,463
Company-sponsored	36,007	29,767	65,774	27,246	12,406	39,652
<b>Total</b>	<b>\$ 40,291</b>	<b>\$ 88,658</b>	<b>\$ 128,949</b>	<b>\$ 32,948</b>	<b>\$ 63,167</b>	<b>\$ 96,115</b>

  

	For the Nine Months Ended September 30, 2007			For the Nine Months Ended September 30, 2006		
	Research	Development	Total	Research	Development	Total
Collaborator-sponsored	\$ 14,919	\$ 198,115	\$ 213,034	\$ 34,855	\$ 121,591	\$ 156,446
Company-sponsored	107,986	76,694	184,680	70,786	35,335	106,121
<b>Total</b>	<b>\$ 122,905</b>	<b>\$ 274,809</b>	<b>\$ 397,714</b>	<b>\$ 105,641</b>	<b>\$ 156,926</b>	<b>\$ 262,567</b>

*Restructuring Expense*

The Company records costs and liabilities associated with exit and disposal activities, as defined in FASB Statement No. 146, "Accounting for Costs Associated with Exit or Disposal Activities" ("SFAS 146"), at fair value in the period the liability is incurred. In periods subsequent to initial measurement, changes to the liability are measured using the credit-adjusted risk-free discount rate applied in the initial period. In the three and nine months ended September 30, 2007 and 2006, the Company recorded costs and liabilities for exit and disposal activities related to a restructuring plan in accordance with SFAS 146. The liability is evaluated and adjusted as appropriate on at least a quarterly basis for changes in circumstances. Please refer to Note 6, "Restructuring Expense," for further information.

*Revenue Recognition*

The Company recognizes revenues in accordance with the Securities and Exchange Commission's ("SEC") Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements," as amended by SEC Staff Accounting Bulletin No. 104, "Revenue Recognition," and for revenue arrangements entered into after June 30, 2003, Emerging Issues Task Force Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables" ("EITF 00-21").

The Company's revenues are generated primarily through collaborative research, development and/or commercialization agreements. The terms of these agreements typically include payment to Vertex of one or more of the following: non-refundable, up-front license fees; funding of research and/or development efforts; milestone payments; and royalties on product sales.

Agreements containing multiple elements are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the customer and whether there is objective and reliable evidence of fair value of the undelivered obligation(s). The consideration received is allocated among the separate units based on their respective fair values or the residual method, and the applicable revenue recognition criteria are applied to each of the separate units.

The Company recognizes revenues from non-refundable, up-front license fees on a straight-line basis over the contracted or estimated period of performance, which is typically the research or development term. Research and development funding is recognized as earned, ratably over the period of effort.

Substantive milestones achieved in collaboration arrangements are recognized as earned when the corresponding payment is reasonably assured, subject to the following policies in those circumstances where the Company has obligations remaining after achievement of the milestone:

In those circumstances where collection of a substantive milestone payment is reasonably assured, the Company has remaining obligations to perform under the collaboration arrangement and the Company has sufficient evidence of fair value for its remaining obligations, management considers the milestone payment and the remaining obligations to be separate units of accounting. In these circumstances, the Company uses the residual method under EITF 00-21 to allocate revenue among the milestones and the remaining obligations.

In those circumstances where collection of a substantive milestone payment is reasonably assured, the Company has remaining obligations to perform under the collaboration arrangement and the Company does not have sufficient evidence of fair value for its remaining obligations, management considers the milestone payment and the remaining obligations under the contract as a single unit of accounting. In those circumstances where the collaboration does not require specific deliverables at specific times or at the end of the contract term, but rather the Company's obligations are satisfied over a period of time, substantive milestone payments are recognized over the period of performance. This typically results in a portion of the milestone payment being recognized as revenue on the date the milestone is achieved equal to the applicable percentage of the performance period that has elapsed as of the date the milestone is achieved, with the balance being deferred and recognized over the remaining period of performance.

The Company evaluates whether milestones are substantive at the inception of the agreement based on the contingent nature of the milestone, specifically reviewing factors such as the scientific and other risks that must be overcome to achieve the milestone as well as the level of effort and investment required. Milestones that are not considered substantive and do not meet the separation criteria are accounted for as license payments and recognized on a straight-line basis over the remaining period of performance.

Payments received or reasonably assured after performance obligations are met completely are recognized as revenue.

Royalty revenues are recognized based upon actual and estimated net sales of licensed products in licensed territories, as provided by the licensee, and are recognized in the period the sales occur. Differences between actual royalty revenues and estimated royalty revenues, which have not historically been significant, are reconciled and adjusted for in the quarter during which they become known.

### **3. Stock-based Compensation**

At September 30, 2007, the Company had four stock-based employee compensation plans: the 1991 Stock Option Plan, the 1994 Stock and Option Plan, the 1996 Stock and Option Plan and the 2006 Stock and Option Plan (collectively, the "Stock and Option Plans"), and one Employee Stock Purchase Plan (the "ESPP"). In connection with the Stock and Option Plans, the Company issues stock options and restricted stock awards with service conditions, which are generally the vesting periods of the awards. The Company also issues to certain members of senior management restricted stock awards that vest upon the earlier of the satisfaction of a market condition or a service condition ("PARS").

The Company records stock-based compensation expense in accordance with SFAS 123(R). SFAS 123(R) requires companies to recognize share-based payments to employees as compensation expense using the "fair value" method. The fair value of stock options and shares purchased pursuant to the ESPP is calculated using the Black-Scholes valuation model. The fair value of restricted stock awards is typically based on intrinsic value on the date of grant. Under the fair value recognition provisions of SFAS 123(R), stock-based compensation cost, measured at the grant date based on the fair value of the award, is recognized as expense ratably over the service period. The expense recognized over the service period includes an estimate of awards that will be forfeited.

For PARS awards, a portion of the fair value of the common stock on the date of grant is recognized ratably over a derived service period that is equal to the estimated time to satisfy the market condition. The portion of the fair value of the common stock that is recognized over the derived service period is based on the estimated probability that the award will vest as a result of the market condition. For the PARS awards granted in 2006 and 2007, the derived service period relating to each market condition was shorter than the four year service-based vesting period of the PARS. The difference between the fair value of the common stock on the date of grant and the value recognized over the derived service period is recognized ratably over the four year service-based vesting period of the PARS. The stock-based compensation expense recognized over each of the derived service periods and the four year service periods includes an estimate of awards that will be forfeited prior to the end of the derived service periods or the four year service periods, respectively.

Prior to adoption of SFAS 123(R), Vertex recorded the effect of forfeitures of restricted stock as they occurred. In connection with the adoption of SFAS 123(R) during the nine months ended September 30, 2006, Vertex recorded a \$1.0 million benefit from the cumulative effect of changing from recording forfeitures related to restricted stock awards as they occurred to estimating forfeitures during the service period.

The effect of recording stock-based compensation expense for the three and nine months ended September 30, 2007 and 2006 was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
<b>Stock-based compensation expense by type of award:</b>				
Stock options	\$ 8,479	\$ 6,972	\$ 29,865	\$ 22,374
Restricted shares	3,664	1,758	14,692	4,897
ESPP	829	544	2,192	1,775
<b>Total stock-based compensation expense</b>	<b>\$ 12,972</b>	<b>\$ 9,274</b>	<b>\$ 46,749</b>	<b>\$ 29,046</b>
<b>Effect of stock-based compensation expense by line item:</b>				
Research and development expenses	\$ 10,624	\$ 7,554	\$ 38,564	\$ 23,715
Sales, general and administrative expenses	2,348	1,720	8,185	5,331
<b>Total stock-based compensation expense</b>	<b>\$ 12,972</b>	<b>\$ 9,274</b>	<b>\$ 46,749</b>	<b>\$ 29,046</b>
Cumulative effect of a change in accounting principle SFAS 123(R)				(1,046)
<b>Net stock-based compensation expense included in net loss</b>	<b>\$ 12,972</b>	<b>\$ 9,274</b>	<b>\$ 46,749</b>	<b>\$ 28,000</b>

#### *Stock Options*

All stock options granted during the three and nine months ended September 30, 2007 and 2006 were granted with exercise prices equal to the fair market value of the Company's common stock on

the date of grant. The options granted during the three and nine months ended September 30, 2007 had a weighted-average grant date fair value, measured on the grant date, of \$15.10 and \$17.51, respectively, and the options granted during the three and nine months ended September 30, 2006 had a weighted-average grant date fair value, measured on the grant date, of \$20.05 and \$20.02, respectively.

In accordance with SFAS 123(R), the Company recorded stock-based compensation expense related to stock options of \$8.5 million and \$29.9 million, respectively, for the three and nine months ended September 30, 2007, and \$7.0 million and \$22.4 million, respectively, for the three and nine months ended September 30, 2006. The stock-based compensation expense related to stock options for the nine months ended September 30, 2007 included \$1.9 million related to stock options accelerated in connection with an executive officer's severance arrangement. As of September 30, 2007, there was \$75.4 million of total unrecognized compensation expense, net of estimated forfeitures, related to unvested options granted under the Company's Stock and Option Plans. The Company expects to recognize that expense over a weighted-average period of 2.80 years.

#### *Restricted Stock*

The Company recorded stock-based compensation expense related to restricted stock of \$3.7 million and \$14.7 million, respectively, for the three and nine months ended September 30, 2007, and \$1.8 million and \$4.9 million, respectively, for the three and nine months ended September 30, 2006. The stock-based compensation expense related to restricted stock for the nine months ended September 30, 2007 included \$1.4 million related to accelerated vesting of restricted stock awards in connection with an executive officer's severance arrangement.

As of September 30, 2007, there was \$29.5 million of total unrecognized stock-based compensation expense, net of estimated forfeitures, related to unvested restricted stock granted under the Company's Stock and Option Plans. The Company expects to recognize that expense over a weighted-average period of 2.49 years.

#### *Employee Stock Purchase Plan*

The stock-based compensation expense related to the ESPP was \$0.8 million and \$2.2 million, respectively, for the three and nine months ended September 30, 2007, and \$0.5 million and \$1.8 million, respectively, for the three and nine months ended September 30, 2006. As of September 30, 2007, there was \$1.1 million of total unrecognized compensation expense, net of estimated forfeitures, related to ESPP shares. The Company expects to recognize that expense during 2007 and 2008.

During the nine months ended September 30, 2007 and 2006, the Company issued 139,000 shares at an average price paid of \$25.80 per share, and 221,000 shares at an average price paid of \$13.20 per share, respectively, to employees under the ESPP. There were no shares issued to employees under the ESPP during the three months ended September 30, 2007 and 2006.

**4. Comprehensive Loss**

For the three and nine months ended September 30, 2007 and 2006, comprehensive loss was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Net loss	\$ (107,033)	\$ (51,802)	\$ (305,528)	\$ (179,547)
Changes in other comprehensive income (loss):				
Unrealized holding gains (losses) on marketable securities	866	(9,430)	1,193	1,447
Foreign currency translation adjustment	38	(67)	78	181
Total change in other comprehensive income (loss)	904	(9,497)	1,271	1,628
Total comprehensive loss	\$ (106,129)	\$ (61,299)	\$ (304,257)	\$ (177,919)

**5. Income Taxes**

The Company adopted FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes" an interpretation of FASB Statement No. 109 ("FIN 48") on January 1, 2007. FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with FASB Statement No. 109, "Accounting for Income Taxes." FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition.

At the adoption date and as of September 30, 2007, the Company had no material unrecognized tax benefits and no adjustments to liabilities or operations were required under FIN 48. The Company's practice was and continues to be to recognize interest and penalty expenses related to uncertain tax positions in income tax expense, which were zero at the adoption date and for the three and nine months ended September 30, 2007. Tax years 2004 through 2006 and 2003 through 2006 are subject to examination by the federal and state taxing authorities, respectively. There are no income tax examinations currently in process.



## 6. Restructuring Expense

In June 2003, Vertex adopted a plan to restructure its operations to coincide with its increasing internal emphasis on advancing drug candidates through clinical development to commercialization. The restructuring was designed to re-balance the Company's relative investments in research and development to better support the Company's long-term strategy. The restructuring plan included a workforce reduction, write-offs of certain assets and a decision not to occupy approximately 290,000 square feet of specialized laboratory and office space in Cambridge, Massachusetts under lease to Vertex (the "Kendall Square Lease"). The Kendall Square Lease commenced in January 2003 and has a 15-year term. In the second quarter of 2005, the Company revised its assessment of its real estate requirements and decided to use approximately 120,000 square feet of the facility subject to the Kendall Square Lease (the "Kendall Square Facility") beginning in 2006. The remaining rentable square footage of the Kendall Square Facility currently is subleased to third parties.

The Company continues to estimate the restructuring expense in accordance with SFAS 146. The net restructuring expenses incurred in 2006 and 2007 relate only to the portion of the building that the Company is not occupying and currently does not intend to occupy for its operations. The remaining lease obligations, which are associated with the portion of the Kendall Square Facility that the Company occupies and uses for its operations, are recorded as rental expense in the period incurred.

In estimating the expense and liability under its Kendall Square Lease obligation, the Company estimated (i) the costs to be incurred to satisfy rental and build-out commitments under the lease (including operating costs), (ii) the lead-time necessary to sublease the space, (iii) the projected sublease rental rates, and (iv) the anticipated durations of subleases. The Company validates its estimates and assumptions through consultations with independent third parties having relevant expertise. The Company uses a credit-adjusted risk-free rate of approximately 10% to discount the estimated cash flows. The Company reviews its estimates and assumptions on at least a quarterly basis, until the termination of the Kendall Square Lease, and will make whatever modifications management believes necessary, based on the Company's best judgment, to reflect any changed circumstances. The Company's estimates have changed in the past, and may change in the future, resulting in additional adjustments to the estimate of liability, and the effect of any such adjustments could be material. Because the Company's estimate of the liability includes the application of a discount rate to reflect the time-value of money, the estimate of the liability will increase each quarter simply as a result of the passage of time. Changes to the Company's estimate of the liability are recorded as additional restructuring expense/(credit).

For the three months ended September 30, 2007, the Company recorded net restructuring expense of \$0.9 million, which was primarily the result of the imputed interest cost relating to the restructuring liability. The activity related to the restructuring liability for the three months ended September 30, 2007 was as follows (in thousands):

	Liability as of June 30, 2007	Cash payments in third quarter of 2007	Cash received from subleases in third quarter of 2007	Charge in third quarter of 2007	Liability as of September 30, 2007
Lease restructuring liability	\$ 36,314	\$ (3,171)	\$ 2,104	\$ 882	\$ 36,129

Edgar Filing: VERTEX PHARMACEUTICALS INC / MA - Form 10-Q

For the nine months ended September 30, 2007, the Company recorded net restructuring expense of \$6.8 million, which was primarily the result of revising certain key estimates and assumptions in the first quarter of 2007 about building operating costs, for the remaining period of the lease commitment, as well as the imputed interest cost relating to the restructuring liability. The activity related to the restructuring liability for the nine months ended September 30, 2007 was as follows (in thousands):

	Liability as of December 31, 2006	Cash payments in the first nine months of 2007	Cash received from subleases in the first nine months of 2007	Charge in the first nine months of 2007	Liability as of September 30, 2007
Lease restructuring liability	\$ 33,073	\$ (9,637)	\$ 5,850	\$ 6,843	\$ 36,129

For the three months ended September 30, 2006, the Company recorded net restructuring expense of \$1.4 million, which was primarily attributable to the imputed interest cost relating to the restructuring liability. The activity related to the restructuring liability for the three months ended September 30, 2006 was as follows (in thousands):

	Liability as of June 30, 2006	Cash payments in the third quarter of 2006	Cash received from subleases in the third quarter of 2006	Charge in third quarter of 2006	Liability as of September 30, 2006
Lease restructuring liability	\$ 36,278	\$ (6,517)	\$ 1,578	\$ 1,415	\$ 32,754

For the nine months ended September 30, 2006, the Company recorded net restructuring expense of \$2.6 million, which was primarily attributable to the imputed interest cost relating to the restructuring liability. The activity related to the restructuring liability for the nine months ended September 30, 2006 was as follows (in thousands):

	Liability as of December 31, 2005	Cash payments in the first nine months of 2006	Cash received from subleases in the first nine months of 2006	Charge in the first nine months of 2006	Liability as of September 30, 2006
Lease restructuring liability	\$ 42,982	\$ (18,401)	\$ 5,548	\$ 2,625	\$ 32,754

## 7. Altus Investment

Altus Pharmaceuticals, Inc. ("Altus") completed its initial public offering in January 2006. As a result of investments Vertex had made in Altus while Altus was a private company, Vertex owned 817,749 shares of Altus common stock, and warrants to purchase 1,962,494 shares of Altus common stock (the "Altus Warrants"). In addition, the Company, as of the completion of the offering, held 450,000 shares of Altus redeemable preferred stock, which are not convertible into common stock and which are redeemable for \$10.00 per share plus accrued dividends at Vertex's option on or after December 31, 2010, or by Altus at any time. Dividends have been accruing at an annual rate of \$0.50 per share since the redeemable preferred stock was issued in 1999. Pursuant to a lock-up agreement, the Company was restricted from trading Altus securities for a period of six months following the initial public offering.

As a result of Altus' public offering, Altus common stock was classified on the Company's balance sheet as an available-for-sale investment and recorded at fair value, based on quoted market prices. Unrealized gains and losses on the Altus common stock were included as a component of accumulated other comprehensive income (loss), which is a separate component of stockholders' equity, until such gains and losses were realized.

In July 2006, after the trading restrictions had expired, the Company sold 817,749 shares of Altus common stock for \$11.7 million, resulting in a realized gain of \$7.7 million. Upon expiration of the trading restrictions in July 2006, the Company began accounting for the Altus Warrants as derivative instruments under FASB Statement No. 133, "Accounting for Derivative Instruments and Hedging Activities" ("SFAS 133"). In accordance with SFAS 133, in the third quarter of 2006, the Company recorded the Altus Warrants on its condensed consolidated balance sheets at a fair market value of \$19.1 million and recorded an unrealized gain on the fair market value of the Altus Warrants of \$4.3 million. In the fourth quarter of 2006, the Company sold the Altus Warrants for \$18.3 million, resulting in a realized loss of \$0.7 million. As a result of the Company's sales of Altus common stock and Altus Warrants, the Company recorded a net realized gain on a sale of investment of \$11.2 million in 2006.

## 8. Convertible Subordinated Notes

At December 31, 2006, the Company had \$42.1 million in aggregate principal amount of 5% Convertible Subordinated Notes due in September 2007 ("2007 Notes"). In the third quarter of 2007, the Company repaid the outstanding principal and accrued interest on the 2007 Notes. As a result of the repayment, no 2007 Notes were outstanding as of September 30, 2007. The 2007 Notes were convertible, at the option of the holder, into common stock at a price equal to \$92.26 per share. The 2007 Notes bore interest at the rate of 5% per annum, and the Company was required to make semi-annual interest payments on the outstanding principal balance of the 2007 Notes on March 19 and September 19 of each year.

At December 31, 2006, the Company had \$59.6 million in aggregate principal amount of 5.75% Convertible Senior Subordinated Notes due in February 2011 (the "2011 Notes") outstanding. In the first quarter of 2007, the Company called all of the 2011 Notes for redemption. In response and pursuant to the terms of the 2011 Notes, the holders of all the outstanding 2011 Notes converted, at a price equal to \$14.94 per share, their \$59.6 million in aggregate principal amount of 2011 Notes into 3,992,473 shares of the Company's common stock. The following items related to the conversion were

recorded as an offset to additional paid-in capital on the Company's condensed consolidated balance sheets: accrued interest, remaining unamortized issuance costs of the converted notes and issuance costs of the common stock. As a result of the conversions, no 2011 Notes were outstanding as of September 30, 2007. The 2011 Notes bore interest at the rate of 5.75% per annum, and the Company was required to make semi-annual interest payments on the outstanding principal balance of the 2011 Notes on February 15 and August 15 of each year.

In August 2006, the Company exchanged approximately 4.1 million shares of newly issued common stock for \$58.3 million in aggregate principal amount of then outstanding 2011 Notes plus all accrued and unpaid interest thereon. As a result of the exchange, the Company incurred a non-cash charge of \$5.2 million in the third quarter of 2006. This charge is related to the incremental shares issued in the transaction over the number that would have been issued upon the conversion of the 2011 Notes under the original conversion terms, at the original conversion price of \$14.94 per share.

## 9. Equity Offering

In September 2006, the Company completed a public offering of 10,000,000 shares of common stock, including the underwriters' over-allotment of 900,000 shares, at a price of \$33.00 per share. This transaction resulted in net proceeds of \$313.7 million to the Company.

## 10. Significant Revenue Arrangements

### *Janssen Pharmaceutica, N.V.*

In June 2006, the Company entered into a collaboration agreement with Janssen for the development, manufacture and commercialization of telaprevir, the Company's investigative hepatitis C virus protease inhibitor. Under the agreement, Janssen has agreed to be responsible for 50% of the drug development costs incurred under the development program for the parties' territories (North America for the Company, and the rest of the world, other than the Far East, for Janssen) and has exclusive rights to commercialize telaprevir in its territories including Europe, South America, the Middle East, Africa and Australia. Janssen made a \$165.0 million up-front license payment to the Company in July 2006. The up-front license payment is being amortized over the Company's estimated period of performance under the collaboration agreement. Under the agreement, Janssen agreed to make additional contingent milestone payments, which could total up to \$380.0 million if telaprevir is successfully developed, approved and launched as a product. As of September 30, 2007, the Company had earned \$30.0 million in contingent milestone payments under the agreement. The agreement also provides the Company with royalties on any sales of telaprevir in the Janssen territories, with a tiered royalty averaging in the mid-20% range, as a percentage of net sales in the Janssen territories, depending upon successful commercialization of telaprevir. Each of the parties will be responsible for drug supply in their respective territories. However, the agreement provides for the purchase by Janssen from the Company of materials required for Janssen's manufacture of the active pharmaceutical ingredient. In addition, Janssen will be responsible for certain third-party royalties on net sales in its territories. Janssen may terminate the agreement without cause at any time upon six months' notice to the Company.

During the three months ended September 30, 2007, the Company recognized \$20.4 million in revenues under the Janssen agreement, which included an amortized portion of the \$165.0 million up-front payment and net funding of reimbursable drug development costs. During the nine months ended September 30, 2007, the Company recognized \$86.0 million in revenues under the Janssen agreement, which included an amortized portion of the \$165.0 million up-front payment, net funding of reimbursable drug development costs and a \$15.0 million milestone payment that was earned by the Company in the first quarter of 2007.

*Merck & Co., Inc.*

In June 2004, the Company entered into a global collaboration with Merck to develop and commercialize MK-0457 (VX-680), the Company's lead Aurora kinase inhibitor, for the treatment of cancer, and to conduct research targeting the discovery of an additional Aurora kinase inhibitory compound or compounds to follow MK-0457 (VX-680). In 2005, Merck selected for development MK-6592 (VX-667), a second drug candidate covered by the collaboration agreement and in the first quarter of 2007, Merck selected for development VX-689, a third drug candidate covered by the collaboration. Under the agreement, Merck made two milestone payments totaling \$19.5 million in 2005, three milestone payments totaling \$36.3 million in 2006 and a milestone payment of \$9.0 million in the first quarter of 2007. Merck is responsible for worldwide clinical development and commercialization of all compounds developed under the collaboration and will pay the Company royalties on any product sales. Merck may terminate the agreement at any time without cause upon 90 days' advance written notice, except that six months' advance written notice is required for termination at any time when a product has marketing approval in a major market and the termination is not the result of a safety issue.

## **11. Guarantees**

As permitted under Massachusetts law, Vertex's Articles of Organization and Bylaws 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 are currently outstanding, and the Company believes the estimated fair value of these indemnification arrangements is minimal.

Vertex customarily agrees in the ordinary course of its business to indemnification provisions in agreements with clinical trials investigators and sites in its drug development programs, in sponsored research agreements with academic and not-for-profit institutions, in various comparable agreements involving parties performing services for the Company in the ordinary course of business, and in its real estate leases. The Company also customarily agrees to certain indemnification provisions in its drug discovery and development 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, 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 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 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.

On June 7, 2005 and September 14, 2006, the Company entered into Purchase Agreements with Merrill Lynch, Pierce, Fenner & Smith Incorporated, as the representative of the several underwriters named in such agreements, relating to the public offering and sale of shares of the Company's common stock. The Purchase Agreement relating to each offering requires the Company to indemnify the underwriters against any loss they may suffer by reason of the Company's breach of representations and warranties relating to that public offering, the Company's failure to perform certain covenants in those agreements, the inclusion of any untrue statement of material fact in the prospectus used in connection with that offering, the omission of any material fact needed to make those materials not misleading, and any actions taken by the Company or its representatives in connection with the offering. The representations, warranties and covenants in the Purchase Agreements are of a type customary in agreements of this sort. The Company believes the estimated fair value of these indemnification obligations is minimal.

## **12. 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 contingent liabilities accrued at September 30, 2007 or December 31, 2006.

## **13. New Accounting Pronouncements**

In June 2007, FASB ratified the consensus reached by the Emerging Issues Task Force on EITF Issue No. 07-3, "Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities" ("EITF 07-3"). EITF 07-3 addresses the diversity that exists with respect to the accounting for the non-refundable portion of a payment made by a research and development entity for future research and development activities. Under EITF 07-3, an entity would defer and capitalize non-refundable advance payments made for research and development

activities until the related goods are delivered or the related services are performed. EITF 07-3 will be effective for the Company beginning on January 1, 2008. The Company is currently evaluating the effect of EITF 07-3 on its consolidated financial statements.

In February 2007, FASB issued Statement No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115" ("SFAS 159"). SFAS 159 provides companies with an option to report selected financial assets and liabilities at fair value. Furthermore, SFAS 159 establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. SFAS 159 will be effective for the Company beginning on January 1, 2008. The Company is currently evaluating the effect of SFAS 159 on its consolidated financial statements.

In September 2006, FASB issued Statement No. 157, "Fair Value Measurements" ("SFAS 157"). SFAS 157 provides guidance for using fair value to measure assets and liabilities and requires additional disclosure about the use of fair value measures, the information used to measure fair value, and the effect fair value measurements have on earnings. SFAS 157 does not require any new fair value measurements. SFAS 157 will be effective for the Company beginning on January 1, 2008. The Company is currently evaluating the effect of SFAS 157 on its consolidated financial statements.

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

### Overview

We are in the business of discovering, developing and commercializing small molecule drugs for the treatment of serious diseases. We have built a drug discovery capability that integrates biology, chemistry, biophysics, automation and information technologies, with a goal of making the drug discovery process more efficient and productive. Our most advanced drug candidate, telaprevir, is being investigated for the treatment of hepatitis C virus, or HCV, infection in three major Phase 2b clinical trials. We are investing significant resources to expand our capabilities in clinical development, regulatory affairs, quality control and commercial operations and to build and manage a commercial supply chain in preparation for the Phase 3 development and the potential commercial launch of telaprevir. We have a number of other drug candidates, including candidates targeting cystic fibrosis, cancer, rheumatoid arthritis, bacterial infection and pain, that are being evaluated in preclinical studies or clinical trials either by us or in collaboration with other pharmaceutical companies. Our HIV protease inhibitor, fosamprenavir calcium, is being marketed by our collaborator GlaxoSmithKline plc as Lexiva in the United States and Telzir in Europe.

Our net loss for 2006 was \$206.9 million, or \$1.83 per basic and diluted common share, and our net loss for the nine months ended September 30, 2007 was \$305.5 million, or \$2.38 per basic and diluted common share. We expect to incur substantial operating losses in the future. In 2007, our research and development expenses have been higher than those in 2006, as we continue to incur research and development costs related to telaprevir and our other drug candidates, establish a commercial supply chain and build telaprevir commercial inventory to support markets where we expect to launch telaprevir, if approved, and build our general drug development and commercialization capabilities.

### *Business Focus*

We have elected to diversify our research and development activities across a relatively broad array of investment opportunities, due in part to the high risks associated with the biotechnology and pharmaceutical business. This diversification strategy requires more significant financial resources than would be required if we pursued a more limited approach. We are expending significant resources on development and commercialization of the drug candidates for which we currently have principal clinical development responsibility, in those markets where we have commercial rights. We rely on collaborators to develop and commercialize certain of our other drug candidates either worldwide or in the markets upon which we are not currently focused.

To date, we have relied on pharmaceutical company collaborators to develop and market our drug candidates that have advanced to late stage clinical trials or commercialization. Telaprevir is the first drug candidate for which we expect to perform all activities related to late stage development, drug supply, registration and commercialization in a major market. We have limited experience in Phase 3 clinical development, supply chain management, and pharmaceutical sales and marketing, and we are building those capabilities as we advance telaprevir through clinical development. Even though telaprevir is a Phase 2b drug candidate, we are planning for and investing significant resources now in preparation for Phase 3 clinical trials, application for marketing approval, commercial supply and sales and marketing. Our engagement in these resource-intensive activities could make it more difficult for us to maintain our portfolio focus, and puts significant investment at risk if we experience significant delays in our development program for telaprevir, or do not obtain regulatory approval and successfully commercialize telaprevir in North America. Although we attempt to stage our investments in each drug candidate to coincide to some degree with the occurrence of risk-reducing events associated with the development of that drug candidate, we may not be able through this approach to reduce significantly the overall financial risk associated with our drug development activities. There is no assurance that our



development of telaprevir will lead successfully to regulatory approval, or that obtaining regulatory approval will lead to commercial success.

In the past, we have sought collaborator funding for a significant portion of our research activities, which required that we grant to those collaborators significant rights to develop and commercialize drug candidates generated by that research. In the future, we expect that we will ourselves fund a greater proportion of our research programs than in past years, using internal funds rather than collaborator funds. We believe that this strategy will ultimately allow us to retain greater development control of, and commercial rights with respect to, those proprietary drug candidates that may meet our strategic internal investment criteria as in effect from time to time.

#### *Discovery and Development Process*

Several compounds that have been discovered by our research organization are currently in clinical development. We also have commenced preclinical activities with several novel compounds that recently have emerged from our drug discovery programs. We expect to initiate Phase 1 clinical trials for two of these compounds by the end of 2007. Discovery and development of a new pharmaceutical product is a lengthy and resource-intensive process, which may take 10 to 15 years or more. Throughout this entire process, potential drug candidates are subjected to rigorous evaluation, driven in part by stringent regulatory considerations, designed to generate information concerning efficacy, 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. The toxicity characteristics and profile of drug candidates at varying dose levels administered for varying periods of time also are monitored and evaluated during the nonclinical and clinical development process. Most chemical compounds that are investigated as potential drug candidates never progress into formal development, and most drug candidates that do advance into formal development never become commercial products. A drug candidate's failure to progress or advance may be the result of any one or more of a wide range of adverse experimental outcomes including, for example, the lack of sufficient efficacy against the disease target, the lack of acceptable absorption characteristics or other physical properties, difficulties in developing a cost-effective manufacturing or formulation method or the discovery of toxicities or side effects that are unacceptable for the disease indication being treated.

Given the uncertainties of the research and development process, it is not possible to predict with confidence which, if any, of our current research and development efforts will result in a marketable pharmaceutical product. We monitor the results of our discovery research, our nonclinical studies and clinical trials and frequently evaluate our portfolio investments in light of new data and scientific, business and commercial insights with the objective of balancing risk and potential. This process can result in relatively abrupt changes in focus and priority as new information becomes available and we gain additional insights into ongoing programs and potential new programs.

#### *Clinical Development Programs*

We are conducting three major Phase 2b clinical trials of telaprevir in patients infected with genotype 1 HCV. PROVE 1 is ongoing in the United States and PROVE 2 is ongoing in the European Union, both in treatment-naïve patients. PROVE 3 is ongoing in patients in North America and the European Union who did not achieve a sustained viral response with previous interferon-based treatments. We have completed enrollment of patients in all three of the PROVE clinical trials, bringing the total number of patients enrolled in the PROVE clinical trials to over 1,000. In the fourth quarter of 2007, we expect that a Phase 2 clinical trial will be initiated exploring the potential of twice-daily dosing of telaprevir in combination with pegylated interferon, or peg-IFN, and ribavirin, or RBV.

Together with our collaborator, Tibotec, we are in discussions with U.S. and European regulatory authorities to review clinical data and discuss how to evaluate telaprevir in future clinical trials. We expect to provide the results of our discussions with the United States Food and Drug Administration,

or FDA, once these discussions have been completed. The registration strategy for telaprevir and the timing of any New Drug Application, or NDA, will be dependent on discussions with the FDA on trial design and the timing of late stage development and on data from our ongoing and future clinical trials. Designing and coordinating large-scale clinical trials to determine the efficacy and safety of telaprevir and to support the submission of an NDA requires significant financial resources, along with extensive technical and regulatory expertise and infrastructure.

In the second quarter of 2007, we initiated a randomized, double-blind, placebo-controlled Phase 2a clinical trial of VX-770 to evaluate the safety, pharmacokinetics and specified biomarkers of cystic fibrosis transmembrane regulator activity in approximately 35 patients with cystic fibrosis with genotype G551D.

In the fourth quarter of 2007, we selected for development two compounds: a second-generation HCV protease inhibitor and VX-809, a cystic fibrosis corrector compound. We expect to begin Phase 1 clinical trials for both of these compounds by the end of 2007.

Each of our programs requires a significant investment of financial and personnel resources, time and expertise by us and/or any program collaborators to realize its full clinical and commercial value. Any one or more of our drug candidates may not advance to product registration. Each drug candidate could fail to progress or advance due to a wide range of adverse experimental outcomes, placing our investment in the drug candidate at risk. While we attempt to stage our investments to mitigate these financial risks, drug discovery and development by its nature is a very risky undertaking and staging of investment is not always possible or desirable. We expect to continue to evaluate and prioritize investment in our clinical development programs based on the emergence of new clinical and nonclinical data in each program for the remainder of 2007 and in subsequent years.

#### *Interim Data from PROVE 1 and PROVE 2 Clinical Trials*

In November 2007, at the Annual Meeting of the American Association for the Study of Liver Diseases, or AASLD, we presented interim data from our PROVE 1 and PROVE 2 clinical trials. In the treatment arms in which patients were treated with telaprevir plus peg-IFN and RBV for 12 weeks, followed by 12 weeks of treatment with peg-IFN and RBV alone, which we refer to as 24-week telaprevir-based treatment arms, 61% patients in PROVE 1 achieved sustained viral response at 24 weeks post-treatment and 65% of patients in PROVE 2 achieved sustained viral response at 12 weeks post-treatment. Patients achieve sustained viral response, or SVR, if they have undetectable HCV RNA levels less than 10 IU/mL as measured by the Roche TaqMan® assay on the relevant post-treatment measurement date. SVR 12 reports SVR at 12 weeks post-treatment, and SVR 24 reports SVR at 24 weeks post-treatment. The November 2007 interim analyses of telaprevir safety from PROVE 1 and PROVE 2, which are discussed below, appeared consistent with prior analyses, with the most common adverse events, regardless of treatment assignment, being fatigue, rash, headache and nausea. Gastrointestinal disorders, skin adverse events (rash and pruritus) and anemia were higher in the telaprevir arms than in the control arms over the dosing period.

#### *Viral Response*

SVR rates on an intent-to-treat basis for PROVE 1 and PROVE 2 for treatment arms for which data regarding SVR were available are set forth in the table below. SVR rates in the table below include patients who completed dosing in their treatment arm as well as patients who discontinued

Edgar Filing: VERTEX PHARMACEUTICALS INC / MA - Form 10-Q

treatment prior to completion of dosing, but who met the criteria for SVR 12 or SVR 24. In the-intent to-treat analysis, patients for whom SVR data was unavailable were counted as treatment failures.

	Number of Patients	Available Data	SVR Rate (Patients with HCV RNA <10 IU/mL)
<b>24 Week Treatment Arms</b>			
24-week telaprevir-based treatment arm (PROVE 1) telaprevir plus peg-IFN and RBV for 12 weeks, followed by 12 weeks of treatment with peg-IFN and RBV alone	79	SVR 24	61%
24-week telaprevir-based treatment arm (PROVE 2) telaprevir plus peg-IFN and RBV for 12 weeks, followed by 12 weeks of treatment with peg-IFN and RBV alone	81	SVR 12	65%

**12 Week Treatment Arms**

12-week treatment arm with RBV (PROVE 1) telaprevir plus peg-IFN and RBV for 12 weeks	17	SVR 24	35%
12-week treatment arm with RBV (PROVE 2) telaprevir plus peg-IFN and RBV for 12 weeks	82	SVR 24	59%
12-week treatment arm without RBV (PROVE 2) telaprevir plus peg-IFN for 12 weeks	78	SVR 24	29%

SVR data for the 48-week telaprevir-based treatment arm and control arms were not available at the time of the interim analysis. The following table sets forth on an intent-to-treat basis the percentage of patients that had undetectable HCV RNA less than 10 IU/mL at the end of treatment for PROVE 1 data in the 48-week trial arms or at 36 weeks on treatment for the PROVE 2 data.

	Number of Patients	Available Data	Patients with HCV RNA <10 IU/ml
<b>48 Week Treatment Arms</b>			
48-week telaprevir-based treatment arm (PROVE 1) telaprevir plus peg-IFN and RBV for 12 weeks, followed by 36 weeks of treatment with peg-IFN and RBV alone	79	End of Treatment	65%
48-week control arm (PROVE 1) 48 weeks of treatment with peg-IFN and RBV alone	75	End of Treatment	45%
48-week control arm (PROVE 2) 48 weeks of treatment with peg-IFN and RBV alone	82	36 weeks on Treatment	59%

Typically, following the completion of 48 weeks of treatment with peg-IFN and RBV alone, a certain proportion of patients with undetectable HCV RNA relapse. We expect that SVR results for the 48-week telaprevir-based treatment arm in PROVE 1 and for the control arms for PROVE 1 and PROVE 2, including viral relapse observed post-treatment, will be presented at a future medical meeting.

**Safety**

The types of adverse events that have been commonly observed with peg-IFN and RBV were seen across all treatment arms of PROVE 1 and PROVE 2. The most common adverse events, regardless of treatment assignment, were fatigue, rash, headache and nausea. Gastrointestinal disorders, skin adverse events (rash and pruritus) and anemia were higher in the telaprevir arms than in the control arm over the dosing period.

In PROVE 1, the overall discontinuation rate through 12 weeks was 18% across all telaprevir treatment arms and 3% in the control arm. This includes discontinuations due to adverse events, withdrawal of consent and patients lost to follow-up. The incidence of treatment discontinuations through week 12 due to adverse events was 13% and 2% in the telaprevir and control arms, respectively. The most common reason for discontinuation was rash, with 7% of patients discontinuing for this reason in the telaprevir arms during the first 12 weeks of treatment. After week 12, discontinuations due to adverse events were 8% in each of the telaprevir and control arms. Over the full course of the treatment period for all arms of the trial, the incidence of severe adverse events was 27% in the telaprevir arms and 24% in the control arm.

In PROVE 2, the overall discontinuation rate through 12 weeks was 14% across all telaprevir treatment arms and 6% in the control arm. This includes discontinuations due to adverse events, withdrawal of consent and patients lost to follow-up. The incidence of treatment discontinuations through week 12 due to adverse events was 10% and 3% in the telaprevir and control arms, respectively. As with PROVE 1, the most common reason for discontinuation was rash, with 7% of patients discontinuing due to rash in the telaprevir arms, compared to less than 1% in the control arm during the first 12 weeks of treatment. Through to week 12, the time of the interim safety analysis being reported, the incidence of severe adverse events was 17% in the telaprevir arms and 10% in the control arm.

The collection of adverse event and discontinuation data is ongoing in the PROVE clinical program.

### ***Rapid Viral Response***

In PROVE 1 and PROVE 2 combined, on an intent-to-treat basis, 77% of patients receiving telaprevir in combination with peg-IFN and RBV achieved a rapid viral response 79% in PROVE 1 and 75% in PROVE 2. Patients achieve rapid viral response, or RVR, if they have undetectable HCV RNA levels less than 10 IU/mL as measured by the Roche TaqMan® assay at 4 weeks after commencement of treatment. In the control arms of PROVE 1 and PROVE 2, 12% of patients achieved RVR 11% in PROVE 1 and 13% in PROVE 2. The result of statistical testing is often defined in terms of a "p-value," with a level of 0.05 or less considered to be a statistically significant difference. The difference between the RVR rates in the telaprevir arms and the control arms was statistically significant, with a p-value of less than 0.001 in both the PROVE 1 and the PROVE 2 trials.

For those patients who achieved RVR, completed 24 weeks of telaprevir-based therapy, and had data available for SVR analysis, 91% achieved an SVR 24 or SVR 12. We believe these data demonstrate a correlation between RVR and SVR in a 24-week telaprevir-based treatment regimen.

### ***Viral Breakthrough***

In PROVE 1, 91% of patients receiving telaprevir in combination with peg-IFN and RBV achieved undetectable HCV RNA on at least one occasion during treatment. The remaining 9% include patients who withdrew from treatment with detectable levels of HCV RNA or who did not achieve undetectable HCV RNA levels and whose HCV RNA levels increased at least 10-fold while on treatment. In PROVE 1 and PROVE 2 combined, 5% of patients receiving telaprevir in combination with peg-IFN and RBV experienced viral breakthrough in the first 12 weeks of treatment 7% in PROVE 1 and 2% in PROVE 2. Most viral breakthroughs occurred in the first month of treatment, and were generally associated with low interferon blood levels. After patients achieved undetectable HCV RNA, less than 2% of patients receiving telaprevir in combination with peg-IFN and RBV experienced viral breakthrough on treatment. We believe this low breakthrough rate after achieving a viral response reflects the impact of high blood levels of telaprevir that were achieved over the dosing regime tested. A patient who achieves undetectable levels less than 10 IU/mL is considered to have experienced viral breakthrough if the viral levels increase to more than 100 IU/mL during therapy. For patients who

do not achieve undetectable levels of plasma HCV RNA, the patient is considered to have experienced viral breakthrough if the patient's plasma HCV RNA increases by more than 10-fold from its lowest value during therapy.

### *Viral Relapse*

In PROVE 1 and PROVE 2 combined, the relapse rate for patients who completed 24 weeks of telaprevir-based treatment was 9% 2% in PROVE 1 and 14% in PROVE 2. In PROVE 1 and PROVE 2 combined, for those patients that achieved RVR and completed 24 weeks of therapy, 7% experienced viral relapse in the post-treatment period 2% in PROVE 1 and 11% in PROVE 2. Per protocol in PROVE 1, only patients who achieved an RVR and maintained undetectable HCV RNA from week 4 through week 20 were allowed to stop treatment at 24 weeks of therapy; no such criteria were utilized in PROVE 2. Following completion of treatment, no patient in PROVE 1 who received telaprevir in combination with peg-IFN and RBV relapsed after week 12 of the 24-week post-treatment period.

### *Financing Strategy*

At September 30, 2007, we had \$514.5 million of cash, cash equivalents and marketable securities and no outstanding convertible debt. Because we have incurred losses from our inception and expect to incur losses for the foreseeable future, we are dependent in large part on our continued ability to raise significant funding to finance operations and to meet our long-term contractual commitments and obligations. In the past, we have secured funds principally through capital market transactions, strategic collaborative agreements, proceeds from the disposition of assets, investment income and the issuance of stock under our employee benefit programs. In order to fund our research, development and manufacturing activities, particularly for later stage drug candidates including telaprevir, we expect to continue to pursue a general financing strategy that may lead us to undertake one or more additional capital transactions, which may or may not be similar to transactions in which we have engaged in the past. We cannot be sure that any such financing opportunities will be available on acceptable terms, if at all.

### *Collaborations*

Collaborations have been and will continue to be an important component of our business strategy. Our pipeline includes several drug candidates that are being developed by our collaborators, including:

Drug candidates that are being investigated by Merck & Co., Inc. for oncology indications under our Aurora kinase collaboration, including MK-0457 (VX-680) which is currently being evaluated in a 270-patient Phase 2 clinical trial in patients with treatment-resistant chronic myelogenous leukemia, or CML, and Philadelphia chromosome-positive acute lymphocytic leukemia, or PH+ ALL, containing the T315I BCR-ABL mutation.

A pre-clinical subtype-selective sodium channel modulator drug candidate for the treatment of pain, that was selected in mid-2007 by GlaxoSmithKline for further investigation.

AVN-944 (VX-944), a drug candidate for the treatment of advanced hematological malignancies, such as leukemia, lymphoma or myeloma, being investigated by our collaborator Avalon Pharmaceuticals, Inc.

In the third quarter of 2007, we completed a 12-week, 120-patient Phase 2a clinical trial to evaluate the safety, tolerability and anti-inflammatory effects of VX-702 dosed on a background of methotrexate in patients with rheumatoid arthritis and a Thorough QTc study on VX-702. Also in the third quarter of 2007, we concluded our agreement with Kissei Pharmaceutical Co., Ltd. for the development and commercialization of VX-702 in the Far East. We retain worldwide development and commercial rights to VX-702. We believe the results from the Phase 2a clinical trial and the Thorough

Q7c study support continued development of VX-702 and plan to seek a collaborator to further develop this compound.

### **Critical Accounting Policies and Estimates**

Our discussion and analysis of our financial condition and results of operations is based upon our condensed consolidated financial statements prepared in accordance with generally accepted accounting principles in the United States, or GAAP. 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 they become known. 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.

We believe that our application of the accounting policies for revenue recognition, research and development expenses, restructuring expense, and stock-based compensation expense, all of which are important to our financial condition and results of operations, require significant judgments and estimates on the part of management. Our accounting policies, including the ones discussed below, are more fully described in Note B, "Accounting Policies," to our consolidated financial statements included in our Annual Report on Form 10-K, which we filed with the Securities and Exchange Commission on March 1, 2007.

#### *Revenue Recognition*

We recognize revenues in accordance with the SEC's Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements," as amended by SEC Staff Accounting Bulletin No. 104, "Revenue Recognition," and for revenue arrangements entered into after June 30, 2003, Emerging Issues Task Force Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables" ("EITF 00-21").

Our revenues are generated primarily through collaborative research, development, manufacture and commercialization agreements. The terms of these agreements typically include payment to us of one or more of the following: non-refundable, up-front license fees; research and development funding; milestone payments and royalties on product sales.

Agreements containing multiple elements are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the collaborator and whether there is objective and reliable evidence of fair value of the undelivered obligation(s). The consideration received is allocated among the separate units based on each unit's fair value or using the residual method, and the applicable revenue recognition criteria are applied to each of the separate units.

We recognize revenues from non-refundable, up-front license fees on a straight-line basis over the contracted or estimated period of performance, which is typically the research or development term. Changes to our estimated or contracted period of performance are accounted for prospectively beginning in the period they become known. Research and development funding is recognized as earned, ratably over the period of effort.

## Edgar Filing: VERTEX PHARMACEUTICALS INC / MA - Form 10-Q

Substantive milestones achieved in collaboration arrangements are recognized as earned when the corresponding payment is reasonably assured, subject to the following policies in those circumstances where we have obligations remaining after achievement of the milestone:

In those circumstances where collection of a substantive milestone payment is reasonably assured, we have remaining obligations to perform under the collaboration arrangement and we have sufficient evidence of fair value for our remaining obligations, we consider the milestone payment and the remaining obligations to be separate units of accounting. In these circumstances, we use the residual method under EITF 00-21 to allocate revenue among the milestones and the remaining obligations.

In those circumstances where collection of a substantive milestone payment is reasonably assured, we have remaining obligations to perform under the collaboration arrangement, and we do not have sufficient evidence of fair value for our remaining obligations, we consider the milestone payment and the remaining obligations under the contract as a single unit of accounting. In those circumstances where the collaboration does not require specific deliverables at specific times or at the end of the contract term, but rather our obligations are satisfied over a period of time, substantive milestone payments are recognized over the period of performance. This typically results in a portion of the milestone payment being recognized as revenue on the date the milestone is achieved equal to the applicable percentage of the performance period that has elapsed as of the date the milestone is achieved, with the balance being deferred and recognized over the remaining period of performance.

We evaluate whether milestones are substantive at the inception of the agreement based on the contingent nature of the milestone, specifically reviewing factors such as the scientific and other risks that must be overcome to achieve the milestone as well as the level of effort and investment required. Milestones that are not considered substantive and do not meet the separation criteria are accounted for as license payments and recognized on a straight-line basis over the remaining period of performance.

Payments received or reasonably assured after performance obligations are met completely are recognized as revenue.

Royalty revenues are recognized based upon actual and estimated net sales of licensed products in licensed territories as provided by the licensee and are recognized in the period the sales occur. Differences between actual royalty revenues and estimated royalty revenues, which have not historically been significant, are reconciled and adjusted for in the quarter they become known.

### *Research and Development Expenses*

All research and development expenses, including amounts funded by research and development collaborations, are expensed as incurred. Research and development expenses are comprised of costs incurred in performing research and development activities, including salary and benefits; stock-based compensation expense; laboratory supplies and other direct expenses; contractual services, including clinical trial and pharmaceutical development costs; expenses associated with our commercial supply investment in telaprevir (which are considered research and development expenses due to telaprevir's stage of development); and infrastructure costs, including facilities costs and depreciation. When third-party service providers' billing terms do not coincide with our period-end, we are required to make estimates of the costs, including clinical trial costs, contract services and investment in commercial supply, incurred in a given accounting period and record accruals at period-end. We base our estimates on our knowledge of the research and development programs, services performed for the period, past history for related activities and the expected duration of the third-party service contract, where applicable.

### *Restructuring Expense*

We record liabilities associated with restructuring activities based on estimates of fair value in the period the liabilities are incurred, in accordance with Financial Accounting Standards Board Statement No. 146, "Accounting for Costs Associated with Exit or Disposal Activities" ("SFAS 146"). The liability for accrued restructuring expense of \$36.1 million at September 30, 2007 is related to that portion of our facility in Kendall Square, Cambridge, Massachusetts that we are not occupying and do not intend to occupy. This liability is calculated by applying our best estimate of our net ongoing obligation. As prescribed by SFAS 146, we use a probability-weighted discounted cash-flow analysis to calculate the amount of this liability. The probability-weighted discounted cash-flow analysis is based on management's assumptions and estimates of our ongoing lease obligations, including contractual rental commitments, build-out commitments and building operating costs, and estimates of income from subleases, based on the term and timing of such subleases. We discount the estimated cash flows using a discount rate of approximately 10%. These cash flow estimates are reviewed and may be adjusted in subsequent periods. Adjustments are based, among other things, on management's assessment of changes in factors underlying the estimates. Because our estimate of the liability includes the application of a discount rate to reflect the time-value of money, the estimate will increase simply as a result of the passage of time, even if all other factors remain unchanged.

Our estimates of our restructuring liability have changed in the past, and it is possible that our assumptions and estimates will change in the future, resulting in additional adjustments to the amount of the estimated liability. The effect of any such adjustments could be material. For example, we currently have two subleases for portions of the Kendall Square facility with remaining terms of four and five years, respectively, and we have made certain estimates and assumptions relating to future sublease terms following the expiration of the current subleases. Market variability may require adjustments to those assumptions in the future. We will review our assumptions and judgments related to the lease restructuring on at least a quarterly basis until the Kendall Square lease is terminated or expires, and make whatever modifications we believe are necessary, based on our best judgment, to reflect any changed circumstances.

### *Stock-based Compensation Expense*

We account for stock-based compensation in accordance with Statement of Financial Accounting Standards Board No. 123(R), "Share-Based Payment" ("SFAS 123(R)"). SFAS 123(R) requires us to measure compensation expense of stock-based compensation at the grant date, based on the fair value of the award, including estimated forfeitures, and to recognize that expense ratably over the employee's service period.

Under SFAS 123(R), we determine the fair value of awarded stock options and shares issued under the employee stock purchase plan using the Black-Scholes valuation model. The Black-Scholes valuation model requires us to make certain assumptions and estimates concerning our stock price volatility, the rate of return of risk-free investments, the expected term of the awards, and our anticipated dividends. In determining the amount of expense to be recorded, we also are required to exercise judgment to estimate forfeiture rates for awards, based on the probability that employees will complete the required service period. If actual forfeitures differ significantly from our estimates, our results could be materially affected.

## **Results of Operations**

### *Three Months Ended September 30, 2007 Compared with Three Months Ended September 30, 2006*

Our net loss for the three months ended September 30, 2007 was \$107.0 million, or \$0.82 per basic and diluted common share, compared to a net loss of \$51.8 million, or \$0.46 per basic and diluted common share, for the three months ended September 30, 2006. Included in the net loss for the



quarter ended September 30, 2007 is stock-based compensation expense of \$13.0 million and net restructuring expense of \$0.9 million. Included in the net loss for the quarter ended September 30, 2006 is stock-based compensation expense of \$9.3 million, net restructuring expense of \$1.4 million, loss on exchange of convertible subordinated notes of \$5.2 million and gains related to an investment of \$11.9 million.

Our net loss for the three months ended September 30, 2007 increased by \$55.2 million as compared to the three months ended September 30, 2006, and our revenues and expenses changed significantly period to period. The increased net loss was principally the result of increased development investment as we advanced our product candidates, and decreased revenues primarily due to a reduction in revenues recognized from research-based collaborations, as we have moved away from reliance on collaborator funding of our research operations. Our research and development expenses increased by \$32.8 million from the third quarter of 2006 to the third quarter of 2007. Overall, our total costs and expenses for the third quarter of 2007 increased by \$39.4 million as compared to the third quarter of 2006. There was a \$12.3 million decrease in revenues in the third quarter of 2007 compared to the third quarter of 2006. Our net loss per basic and diluted common share increased for the three months ended September 30, 2007 compared with the same period in 2006 as a result of the increased net loss partially offset by an increase in the basic and diluted weighted-average number of common shares outstanding from 112.8 million shares to 130.0 million shares.

### Revenues

Total revenues decreased to \$41.0 million for the three months ended September 30, 2007 compared to \$53.3 million in the three months ended September 30, 2006. In the third quarter of 2007, revenues were comprised of \$12.5 million in royalties and \$28.5 million in collaborative and other research and development revenues, as compared with \$10.9 million in royalties and \$42.4 million in collaborative and other research and development revenues in the third quarter of 2006.

Royalty revenues increased by \$1.6 million, or 15%, for the three months ended September 30, 2006 compared to the three months ended September 30, 2007. Royalties consist of Lexiva/Telzir (fosamprenavir calcium) royalty revenues and a small amount of Agenerase (amprenavir) royalty revenues. Royalty revenues are based on actual and estimated worldwide net sales of Lexiva/Telzir and Agenerase. The increase in royalty revenues was due to the increase in Lexiva/Telzir sales.

Collaborative and other research and development revenues decreased \$13.9 million, or 33%, in the third quarter of 2007 compared to the third quarter of 2006 primarily due to a reduction in revenues recognized from research-based collaborations, as we have moved away from reliance on collaborative funding of our research operations. The table presented below is a summary of revenues from collaborative arrangements for the three months ended September 30, 2007 and 2006:

	Three Months Ended September 30,	
	2007	2006
(In thousands)		
Collaborative and other research and development revenues:		
Janssen	\$ 20,419	\$ 25,420
Merck		2,525
Other	8,073	14,442
	<u>28,492</u>	<u>42,387</u>
Total collaborative and other research and development revenues	\$ 28,492	\$ 42,387

## Edgar Filing: VERTEX PHARMACEUTICALS INC / MA - Form 10-Q

In June 2006, we entered into a new major collaboration agreement with Janssen, which resulted in \$20.4 million and \$25.4 million, respectively, of revenues in the third quarter of 2007 and 2006, including in each period:

an amortized portion of the \$165.0 million up-front payment; and

net reimbursements from Janssen relating to telaprevir development costs.

During the final quarter of 2007, we expect to continue to recognize an amortized portion of the \$165.0 million up-front payment and net reimbursements from Janssen to fund a portion of the telaprevir development costs.

We recognized no revenues from Merck in the third quarter of 2007 compared to \$2.5 million in revenues from Merck in the third quarter of 2006. The Merck revenues in the third quarter of 2006 related to milestone payments and funding for the research program with Merck, which was completed during 2006.

Revenues from other collaborations decreased in the third quarter of 2007 as compared to the third quarter of 2006 primarily as a result of a decrease in revenues from our collaboration with Novartis.

We expect that for the foreseeable future the revenues and funding from collaborations that support our development-stage compounds, such as the Janssen and Merck collaborations, will provide a proportionately higher level of financial support for our research and development activities than revenues and funding from research collaboration agreements.

### **Costs and Expenses**

#### *Royalty Payments*

Royalty payments increased \$0.4 million, or 14%, to \$3.6 million in the three months ended September 30, 2007 from \$3.1 million in the three months ended September 30, 2006. Royalty payments relate to a royalty we pay to a third party on sales of Lexiva/Telzir and Agenerase. The increased royalty payments related to the increased royalty revenues we earned in the third quarter of 2007 as compared to the third quarter of 2006.

#### *Research and Development Expenses*

Research and development expenses increased \$32.8 million, or 34%, to \$128.9 million in the three months ended September 30, 2007, including stock-based compensation expense of \$10.6 million, from \$96.1 million in the three months ended September 30, 2006, including stock-based compensation expense of \$7.6 million. The increase in research and development expenses was primarily the result of increased development investment to support the global Phase 2b clinical development program for telaprevir, as well as a \$4.0 million increase in our investment in building commercial supply for telaprevir for use if telaprevir receives marketing approval, together with a \$3.1 million increase in stock-based compensation expense. The cost of developing the commercial supply for telaprevir is considered a research and development expense due to telaprevir's stage of development. Our investment in commercial supply of telaprevir is at risk if we do not obtain regulatory approval and successfully commercialize telaprevir. Development expenses increased by \$25.5 million, accounting for 78% of the aggregate increase in research and development expenses. Research expenses increased by \$7.3 million, of which \$1.1 million was increased stock-based compensation expense.

Research and development expenses consist primarily of salary and benefits; stock-based compensation expense; laboratory supplies and other direct expenses; contractual services, including clinical trial and pharmaceutical development costs; commercial supply investment in telaprevir; and infrastructure costs, including facilities costs and depreciation. Set forth below is a summary that

reconciles our total research and development expenses for the three months ended September 30, 2007 and 2006 (in thousands):

	Three Months Ended September 30,		\$ Change	% Change
	2007	2006		
<b>Research Expenses:</b>				
Salary and benefits	\$ 12,543	\$ 11,090	\$ 1,453	13%
Stock-based compensation expense	4,833	3,693	1,140	31%
Laboratory supplies and other direct expenses	5,813	5,015	798	16%
Contractual services	1,990	1,334	656	49%
Infrastructure costs	15,112	11,816	3,296	28%
<b>Total research expenses</b>	<b>\$ 40,291</b>	<b>\$ 32,948</b>	<b>\$ 7,343</b>	
<b>Development Expenses:</b>				
Salary and benefits	\$ 13,489	\$ 10,795	\$ 2,694	25%
Stock-based compensation expense	5,791	3,861	1,930	50%
Laboratory supplies and other direct expenses	7,315	5,081	2,234	44%
Contractual services	33,068	22,896	10,172	44%
Commercial supply investment in telaprevir	14,509	10,534	3,975	38%
Infrastructure costs	14,486	10,000	4,486	45%
<b>Total development expenses</b>	<b>\$ 88,658</b>	<b>\$ 63,167</b>	<b>\$ 25,491</b>	
<b>Total Research and Development Expenses:</b>				
Salary and benefits	\$ 26,032	\$ 21,885	\$ 4,147	19%
Stock-based compensation expense	10,624	7,554	3,070	41%
Laboratory supplies and other direct expenses	13,128	10,096	3,032	30%
Contractual services	35,058	24,230	10,828	45%
Commercial supply investment in telaprevir	14,509	10,534	3,975	38%
Infrastructure costs	29,598	21,816	7,782	36%
<b>Total research and development expenses</b>	<b>\$ 128,949</b>	<b>\$ 96,115</b>	<b>\$ 32,834</b>	

To date we have incurred in excess of \$2.1 billion in research and development costs associated with drug discovery and development. For the remainder of 2007, we expect to focus our development investment on telaprevir, while continuing to advance the development of our other drug candidates. We expect research and development expenses for the remainder of 2007 to be greater than in the corresponding period of 2006 due to increased investment in clinical development, as we advance our core programs, as well as increased costs for the investment in commercial supply of telaprevir drug product in advance of obtaining regulatory marketing approval.

The successful development of our drug candidates is highly uncertain and subject to a number of risk factors. The duration of clinical trials may vary substantially according to the type, complexity and novelty of the drug candidate. 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 preclinical, nonclinical and clinical activities at any step in the testing process may be adverse and lead to discontinuation or redirection of development activity. 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, preclinical studies, 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. The most significant costs associated with drug discovery and

development are those costs associated with Phase 2 and Phase 3 clinical trials. Given the uncertainties related to drug development, we are currently unable to reliably estimate when, if ever, our drug candidates will generate revenues and net cash inflows.

#### *Sales, General and Administrative Expenses*

Sales, general and administrative expenses increased \$6.6 million, or 45%, to \$21.4 million in the three months ended September 30, 2007 from \$14.8 million in the three months ended September 30, 2006. This increase is the result of increased headcount as we build our infrastructure to support the advancement of our business, together with increased stock-based compensation expense. We expect that our sales, general and administrative expenses for the remainder of 2007 will be significantly higher than in the corresponding period during 2006, because we are planning to build our capabilities in late-stage development, drug supply, registration and commercialization of pharmaceutical products, as we advance telaprevir through clinical development.

#### *Restructuring Expense*

Net restructuring expense for the three months ended September 30, 2007 was \$0.9 million compared to a net restructuring expense for the three months ended September 30, 2006 of \$1.4 million. The charge in both periods primarily related to imputed interest cost related to the restructuring liability.

The activity related to the restructuring liability for the three months ended September 30, 2007 was as follows (in thousands):

	Liability as of June 30, 2007	Cash payments in third quarter of 2007	Cash received from subleases in third quarter of 2007	Charge in third quarter of 2007	Liability as of September 30, 2007
Lease restructuring liability	\$ 36,314	\$ (3,171)	\$ 2,104	\$ 882	\$ 36,129

The activity related to the restructuring liability for the three months ended September 30, 2006 was as follows (in thousands):

	Liability as of June 30, 2006	Cash payments in the third quarter of 2006	Cash received from subleases in the third quarter of 2006	Charge in third quarter of 2006	Liability as of September 30, 2006
Lease restructuring liability	\$ 36,278	\$ (6,517)	\$ 1,578	\$ 1,415	\$ 32,754

In accordance with SFAS 146, we review our estimates and assumptions with respect to the Kendall Square lease on at least a quarterly basis, and will make whatever modifications we believe necessary to reflect any changed circumstances, based on our best judgment, until the termination of the lease. Our estimates have changed in the past, and may change in the future, resulting in additional adjustments to the estimate of liability, and the effect of any such adjustments could be material. Because our estimate of the liability includes the application of a discount rate to reflect the time-value of money, the estimate of the liability will increase each quarter simply as a result of the passage of time.

### **Non-Operating Items**

Interest income increased \$1.9 million, or 36%, to \$7.3 million for the three months ended September 30, 2007 from \$5.3 million for the three months ended September 30, 2006. The increase is a result of higher levels of invested funds and higher portfolio yields during the third quarter of 2007.

Interest expense decreased \$1.3 million, or 72%, to \$0.5 million for the three months ended September 30, 2007 from \$1.8 million for the three months ended September 30, 2006. The decrease resulted from our reduction of outstanding debt in 2006 and the first quarter of 2007.

In the third quarter of 2006, we sold 817,749 shares of the common stock of Altus Pharmaceuticals, Inc. for \$11.7 million, resulting in a realized gain of \$7.7 million. In addition, in the third quarter of 2006, we recorded an unrealized gain of \$4.3 million on the fair market value of warrants to purchase Altus common stock.

In the third quarter of 2006, we recorded a non-cash loss on exchange of convertible subordinated notes of \$5.2 million in connection with our issuance of common stock in exchange for a portion of our 5.75% Convertible Senior Subordinated Notes due February 2011. This charge related to the incremental shares issued in the transactions over the number of shares that would have been issued upon the conversion of the notes under their original terms.

### ***Nine Months Ended September 30, 2007 Compared with Nine Months Ended September 30, 2006***

Our net loss for the nine months ended September 30, 2007 was \$305.5 million, or \$2.38 per basic and diluted common share, compared to a net loss of \$179.5 million, or \$1.64 per basic and diluted common share, for the nine months ended September 30, 2006. Included in the net loss for the nine months ended September 30, 2007 is stock-based compensation expense of \$46.7 million and net restructuring expense of \$6.8 million. Included in the net loss for the nine months ended September 30, 2006 is stock-based compensation expense of \$29.0 million, net restructuring expense of \$2.6 million, loss on exchange of convertible subordinated notes of \$5.2 million, gains related to an investment of \$11.9 million and a benefit from the cumulative effect of an accounting change of \$1.0 million related to the adoption of SFAS 123(R) at the beginning of 2006.

## Edgar Filing: VERTEX PHARMACEUTICALS INC / MA - Form 10-Q

Our net loss for the nine months ended September 30, 2007 increased by \$126.0 million as compared to the nine months ended September 30, 2006, and our revenues and expenses changed significantly period to period. The increased net loss was principally the result of increased development investment as we advanced our product candidates. Our research and development expenses increased by \$135.1 million from the first nine months of 2006 to the first nine months of 2007. Overall, our total costs and expenses for the first nine months of 2007 increased by \$159.9 million as compared to the first nine months of 2006. These increased costs and expenses were partially offset by the \$25.9 million increase in revenues in the first nine months of 2007 compared to the first nine months of 2006. Our net loss per basic and diluted common share increased for the nine months ended September 30, 2007 compared with the same period in 2006 as a result of the increased net loss partially offset by an increase in the basic and diluted weighted-average number of common shares outstanding from 109.6 million shares to 128.4 million shares.

### Revenues

Total revenues increased to \$148.0 million for the nine months ended September 30, 2007 compared to \$122.1 million in the nine months ended September 30, 2006. In the nine months ended September 30, 2007, revenues were comprised of \$33.3 million in royalties and \$114.7 million in collaborative and other research and development revenues, as compared with \$29.1 million in royalties and \$93.0 million in collaborative and other research and development revenues in the nine months ended September 30, 2006.

Royalty revenues increased by \$4.2 million, or 14%, for the nine months ended September 30, 2006 compared to the nine months ended September 30, 2007. The increase in royalty revenues was due to the increase in Lexiva/Telzir sales.

Collaborative and other research and development revenues increased \$21.7 million, or 23%, in the first nine months of 2007 compared to the first nine months of 2006. The table presented below is a summary of revenues from collaborative arrangements for the nine months ended September 30, 2007 and 2006:

	<b>Nine Months Ended September 30,</b>	
	<b>2007</b>	<b>2006</b>
	<b>(In thousands)</b>	
Collaborative and other research and development revenues:		
Janssen	\$ 85,957	\$ 25,420
Merck	9,000	30,772
Other	19,778	36,824
Total collaborative and other research and development revenues	\$ 114,735	\$ 93,016

In June 2006, we entered into a new major collaboration agreement, with Janssen, which resulted in \$86.0 million and \$25.4 million of revenues in the first nine months of 2007 and 2006, respectively, including:

in each period, an amortized portion of the \$165.0 million up-front payment;

in each period, net reimbursements from Janssen relating to telaprevir development costs; and

in the nine months ended September 30, 2007, a milestone payment of \$15.0 million in connection with commencement of patient enrollment in the PROVE 3 clinical trial.

Our revenues from Merck decreased by \$21.8 million in the first nine months of 2007 compared to the first nine months of 2006. In the first nine months of 2007, all of our revenues related to the Merck



collaboration were the result of recognition of a milestone payment. In the first nine months of 2006, we recognized revenues related to both milestone payments and in connection with the research program with Merck, which was completed during 2006.

Revenues from other collaborations decreased in the first nine months of 2007 as compared to the first nine months of 2006 primarily as the result of the expiration during the second quarter of 2006 of the research collaboration with Novartis Pharma AG, together with the corresponding research funding.

### **Costs and Expenses**

#### *Royalty Payments*

Royalty payments increased \$1.2 million, or 14%, to \$10.2 million in the nine months ended September 30, 2007 from \$9.0 million in the nine months ended September 30, 2006. The increased royalty payments related to the increased royalty revenues we earned in the first nine months of 2007 as compared to the first nine months of 2006.

#### *Research and Development Expenses*

Research and development expenses increased \$135.1 million, or 51%, to \$397.7 million in the nine months ended September 30, 2007, including stock-based compensation expense of \$38.6 million, from \$262.6 million in the nine months ended September 30, 2006, including stock-based compensation expense of \$23.7 million. The increase in research and development expenses was primarily the result of increased development investment to support the global Phase 2b clinical development program for telaprevir, as well as a \$51.8 million increase in our investment in building commercial supply for telaprevir for use if telaprevir receives marketing approval, together with a \$14.8 million increase in stock-based compensation expense. Development expenses increased by \$117.9 million, accounting for 87% of the aggregate increase in research and development expenses. Research expenses increased by \$17.3 million, of which \$5.7 million was increased stock-based compensation expense.



Edgar Filing: VERTEX PHARMACEUTICALS INC / MA - Form 10-Q

Set forth below is a summary that reconciles our total research and development expenses for the nine months ended September 30, 2007 and 2006 (in thousands):

	Nine Months Ended September 30,		\$ Change	% Change
	2007	2006		
<b>Research Expenses:</b>				
Salary and benefits	\$ 37,706	\$ 33,605	\$ 4,101	12%
Stock-based compensation expense	17,736	12,021	5,715	48%
Laboratory supplies and other direct expenses	18,039	16,881	1,158	7%
Contractual services	5,554	4,915	639	13%
Infrastructure costs	43,870	38,219	5,651	15%
	<u>          </u>	<u>          </u>	<u>          </u>	
Total research expenses	\$ 122,905	\$ 105,641	\$ 17,264	
	<u>          </u>	<u>          </u>	<u>          </u>	
<b>Development Expenses:</b>				
Salary and benefits	\$ 36,815	\$ 29,042	\$ 7,773	27%
Stock-based compensation expense	20,828	11,694	9,134	78%
Laboratory supplies and other direct expenses	20,891	13,526	7,365	54%
Contractual services	91,601	61,247	30,354	50%
Commercial supply investment in telaprevir	65,047	13,218	51,829	392%
Infrastructure costs	39,627	28,199	11,428	41%
	<u>          </u>	<u>          </u>	<u>          </u>	
Total development expenses	\$ 274,809	\$ 156,926	\$ 117,883	
	<u>          </u>	<u>          </u>	<u>          </u>	
<b>Total Research and Development Expenses:</b>				
Salary and benefits	\$ 74,521	\$ 62,647	\$ 11,874	19%
Stock-based compensation expense	38,564	23,715	14,849	63%
Laboratory supplies and other direct expenses	38,930	30,407	8,523	28%
Contractual services	97,155	66,162	30,993	47%
Commercial supply investment in telaprevir	65,047	13,218	51,829	392%
Infrastructure costs	83,497	66,418	17,079	26%
	<u>          </u>	<u>          </u>	<u>          </u>	
Total research and development expenses	\$ 397,714	\$ 262,567	\$ 135,147	
	<u>          </u>	<u>          </u>	<u>          </u>	

*Sales, General and Administrative Expenses*

Sales, general and administrative expenses increased \$19.3 million, or 46%, to \$61.3 million in the nine months ended September 30, 2007 from \$42.0 million in the nine months ended September 30, 2006. This increase is the result of increased headcount as we build our infrastructure to support the advancement of our business, together with increased stock-based compensation expense.

*Restructuring Expense*

Net restructuring expense for the nine months ended September 30, 2007 was \$6.8 million compared to a net restructuring expense for the nine months ended September 30, 2006 of \$2.6 million. The increase in net restructuring expense for the nine months ended September 30, 2007 compared to the nine months ended September 30, 2006 was primarily the result of revising certain key estimates and assumptions about building operating costs for the remaining period of the lease commitment for our Kendall Square facility. The charge in both periods included imputed interest cost related to the restructuring liability.

## Edgar Filing: VERTEX PHARMACEUTICALS INC / MA - Form 10-Q

The activity related to the restructuring liability for the nine months ended September 30, 2007 was as follows (in thousands):

	Liability as of December 31, 2006	Cash payments in the first nine months of 2007	Cash received from subleases in the first nine months of 2007	Charge in the first nine months of 2007	Liability as of September 30, 2007
Lease restructuring liability	\$ 33,073	\$ (9,637)	\$ 5,850	\$ 6,843	\$ 36,129

The activity related to the restructuring liability for the nine months ended September 30, 2006 was as follows (in thousands):

	Liability as of December 31, 2005	Cash payments in the first nine months of 2006	Cash received from subleases in the first nine months of 2006	Charge in the first nine months of 2006	Liability as of September 30, 2006
Lease restructuring liability	\$ 42,982	\$ (18,401)	\$ 5,548	\$ 2,625	\$ 32,754

### Non-Operating Items

Interest income increased \$11.6 million, or 87%, to \$24.8 million for the nine months ended September 30, 2007 from \$13.2 million for the nine months ended September 30, 2006. The increase is a result of higher levels of invested funds and higher portfolio yields during the first nine months of 2007.

Interest expense decreased \$4.2 million, or 65%, to \$2.3 million for the nine months ended September 30, 2007 from \$6.5 million for the nine months ended September 30, 2006. The decrease resulted from our reduction of outstanding debt in 2006 and the first quarter of 2007.

In the nine months ended September 30, 2006, we sold 817,749 shares of the common stock of Altus for \$11.7 million, resulting in a realized gain of \$7.7 million. In addition, in the nine months ended September 30, 2006, we recorded an unrealized gain of \$4.3 million on the fair market value of warrants to purchase Altus common stock.

In the nine months ended September 30, 2006, we recorded a non-cash loss on exchange of convertible subordinated notes of \$5.2 million in connection with our issuance of common stock in exchange for a portion of our 5.75% Convertible Senior Subordinated Notes due February 2011. These charges related to the incremental shares issued in the transactions over the number of shares that would have been issued upon the conversion of the notes under their original terms.

In connection with the adoption of SFAS 123(R) during the nine months ended September 30, 2006, we recorded a \$1.0 million benefit from the cumulative effect of changing from recording forfeitures related to restricted stock awards as they occurred to estimating forfeitures during the service period.

### Liquidity and Capital Resources

We have incurred operating losses since our inception and historically have financed our operations principally through public and private offerings of our equity and debt securities, strategic collaborative agreements that include research and/or development funding, development milestones

and royalties on the sales of products, investment income and proceeds from the issuance of stock under our employee benefit programs.

At September 30, 2007, we had cash, cash equivalents and marketable securities of \$514.5 million, a decrease of \$247.3 million from \$761.8 million at December 31, 2006. The decrease is primarily the result of expenses relating to our clinical development activities. Capital expenditures for property and equipment during the nine months ended September 30, 2007 were \$27.2 million.

At September 30, 2007, we had \$20.0 million in loans outstanding under the loan facility established under our collaboration with Novartis, which is repayable, without interest, in May 2008. In the third quarter of 2007, we repaid \$42.1 million in aggregate principal amount of 5% Convertible Subordinated Notes due September 2007. During the first quarter of 2007, holders of \$59.6 million in aggregate principal amount of our 5.75% Convertible Senior Subordinated Notes due February 2011 converted their 2011 Notes into 3,992,473 shares of our common stock at a price of \$14.94 in principal amount per share. As a result of the conversion of the 2011 Notes in the first quarter of 2007 and the repayment of the 2007 Notes in the third quarter of 2007, no convertible debt was outstanding as of September 30, 2007.

Our lease restructuring liability of \$36.1 million at September 30, 2007 relates to the portion of the Kendall Square facility that we are not occupying and do not intend to occupy and includes net lease obligations, recorded at net present value. In the nine months ended September 30, 2007, we made cash payments of \$9.6 million against the lease restructuring liability and received \$5.9 million in sublease rental payments. In the fourth quarter of 2007, we expect to make cash payments of \$3.2 million against the lease restructuring liability, and receive \$1.9 million in sublease rental payments. We review our estimates underlying the lease restructuring liability on at least a quarterly basis, and the amount of the liability, and consequently any expected future payment, could change with any change in our estimates.

We expect to continue to make significant investments in our pipeline, particularly in clinical trials of telaprevir and our other drug candidates, in our effort to prepare for potential registration, regulatory approval and commercial launch of our existing and future drug candidates. We also expect to continue to make a significant investment in the commercial supply of telaprevir in order to manufacture sufficient quantities of drug product in advance of obtaining regulatory marketing approval to support a timely commercial product launch if we are successful in completing the development of telaprevir and obtaining marketing approval. We expect to incur losses on a quarterly and annual basis for the foreseeable future.

The adequacy of our available funds to meet our future operating and capital requirements will depend on many factors, including the number, breadth and prospects of our discovery and development programs, the costs and timing of obtaining regulatory approvals for any of our drug candidates and our decisions regarding manufacturing and commercial investments. Collaborations have been and will continue to be an important component of our business strategy.

As part of our strategy for managing our capital structure, we have from time to time adjusted the amount and maturity of our debt obligations through new issues, privately negotiated transactions and market purchases and engaged in equity offerings, depending on market conditions and our perceived needs at the time. We expect to continue pursuing a general financial strategy that may lead us to undertake one or more additional capital transactions. Any such capital transactions may or may not be similar to transactions in which we have engaged in the past.

We expect that it will be necessary to raise additional funds through public offerings or private placements of our securities or other methods of financing in order to complete the development of telaprevir. We will continue to manage our capital structure and 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 2006 Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission on March 1, 2007. As a result of the conversion of \$59.6 million of our 2011 Notes into shares of common stock in the first quarter of 2007 and our repayment of \$42.1 million in aggregate principal amount of 2007 Notes in the third quarter of 2007, we no longer have any convertible debt.

### **New Accounting Pronouncements**

In June 2007, Financial Accounting Standards Board ("FASB") ratified the consensus reached by the Emerging Issues Task Force on EITF Issue No. 07-3, "Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities" ("EITF 07-3"). EITF 07-3 addresses the diversity that exists with respect to the accounting for the non-refundable portion of a payment made by a research and development entity for future research and development activities. Under EITF 07-3, an entity would defer and capitalize non-refundable advance payments made for research and development activities until the related goods are delivered or the related services are performed. EITF 07-3 will be effective for us beginning on January 1, 2008. We currently are evaluating the effect of EITF 07-3 on our consolidated financial statements.

In February 2007, FASB issued Statement No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115" ("SFAS 159"). SFAS 159 provides companies with an option to report selected financial assets and liabilities at fair value. Furthermore, SFAS 159 establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. SFAS 159 will be effective for us beginning on January 1, 2008. We are currently evaluating the effect of SFAS 159 on our consolidated financial statements.

In September 2006, FASB issued Statement No. 157, "Fair Value Measurements" ("SFAS 157"). SFAS 157 provides guidance for using fair value to measure assets and liabilities and requires additional disclosure about the use of fair value measures, the information used to measure fair value, and the effect fair value measurements have on earnings. SFAS 157 does not require any new fair value measurements. SFAS 157 will be effective for us beginning on January 1, 2008. We currently are evaluating the effect of SFAS 157 on our consolidated financial statements.

We adopted FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes - an interpretation of FASB Statement No. 109" ("FIN 48") on January 1, 2007. FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with FASB Statement No. 109, "Accounting for Income Taxes." FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. At the adoption date and as of September 30, 2007, we had no material unrecognized tax benefits and no adjustments to liabilities or operations were required under FIN 48. Our practice was and continues to be to recognize interest and penalty expenses related to uncertain tax positions in income tax expense, which were zero at the adoption date and for the three and nine months ended September 30, 2007. Tax years 2004 through 2006 and 2003 through 2006 are subject to examination by the federal and state taxing authorities, respectively. There are no income tax examinations currently in process.

**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 until it is required to fund operations, including our research and development activities. 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 notes and money market instruments. 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. 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.

**Item 4. Controls and Procedures**

*Evaluation of Disclosure Controls and Procedures*

Our chief executive officer and chief financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this Quarterly Report on Form 10-Q, have concluded that, based on such evaluation, as of September 30, 2007, 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 Securities and Exchange Commission 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 Exchange Act Rules 13a-15(f) and 15d-15(f)) occurred during the third quarter of 2007 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**Part II. Other Information**

**Item 1A. Risk Factors**

Information regarding risk factors appears in Item 1A of our 2006 Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission on March 1, 2007. There have been no material changes from the risk factors previously disclosed in that Annual Report on Form 10-K.

***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 or incorporate 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 clinical trials, development timelines and regulatory authority filings for telaprevir and other drug candidates under development by us and our collaborators;

our expectations regarding the number of patients that will be evaluated, and the data that will be generated by ongoing and planned clinical trials, and the ability to use that data for the design and initiation of further clinical trials, including the Phase 3 clinical trials of telaprevir, and to support regulatory filings, including potentially an NDA for telaprevir;

our expectations regarding the scope and timing of ongoing and potential future clinical trials, including the ongoing Phase 2b clinical trials and expected Phase 3 clinical program for telaprevir, the ongoing clinical trials of VX-770, and expected Phase 1 clinical trials for VX-809 and our second-generation HCV protease inhibitor;

our expectations regarding the efforts our collaborators, including Merck, Janssen and GlaxoSmithKline, will devote towards the clinical and preclinical development of the drug candidates that have been selected for further development;

our plans to fund a greater proportion of our research programs than in past years with internal funds, and our beliefs regarding the benefits of this strategy;

our expectations regarding presenting SVR results for remaining treatment arms at a future medical meeting;

our business strategy;

our planned investments in our drug development and commercialization capabilities and telaprevir;

the establishment, development and maintenance of collaborative relationships;

our ability to use our research programs to identify and develop new potential drug candidates;

our estimates regarding obligations associated with a lease of a facility in Kendall Square, Cambridge, Massachusetts; and

our liquidity.

Any or all of our forward-looking statements in this Quarterly Report may turn out to be wrong. They can be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties. Many factors mentioned in our discussion in this Quarterly Report will be important in determining future results. Consequently, no forward-looking statement can be guaranteed. Actual future results may vary materially.



Without limiting the foregoing, the words "believes," "anticipates," "plans," "expects" and similar expressions are intended to identify forward-looking statements. There are a number of factors that could cause actual events or results to differ materially from those indicated by such forward-looking statements, many of which are beyond our control, including the factors set forth under "Item 1A. Risk Factors" of our Annual Report on Form 10-K, as updated or supplemented by "Part II Item 1A Risk Factors" of subsequent Quarterly Reports on Form 10-Q. In addition, 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

The table set forth below shows all repurchases of securities by us during the three months ended September 30, 2007:

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as part of publicly announced Plans or Programs	Maximum Number of Shares that may yet be purchased under publicly announced Plans or Programs
July 1, 2007 to July 31, 2007	17,649	\$ 10.20		
August 1, 2007 to August 31, 2007	13,816	\$ 0.01		
September 1, 2007 to September 30, 2007	3,352	\$ 0.01		

The repurchases were made under the following two programs:

Under the terms of our 1996 Stock and Option Plan and 2006 Stock and Option Plan, we may award shares of restricted stock to our employees and consultants. These shares of restricted stock typically are subject to a lapsing right of repurchase by us. We may exercise this right of repurchase in the event that a restricted stock recipient's service to us is terminated. If we exercise this right, we are required to repay the purchase price paid by or on behalf of the recipient for the repurchased restricted shares, which typically is the par value per share of \$0.01. Repurchased shares are returned to the applicable Stock and Option Plan under which they were issued. Shares returned to the 2006 Stock and Option Plan are available for future awards under the terms of that plan.

In addition, in the third quarter of 2007, with respect to certain outstanding grants of restricted stock that vested during such period, we repurchased shares of restricted stock from our employees. Under this program, we offered to repurchase from certain of our employees a number of shares of restricted stock with a value, based on the fair market value on the vesting date, equal to our minimum statutory income tax withholding obligation on account of the employees' newly vested shares. In the third quarter of 2007, we repurchased 6,116 shares under this program at a price of \$29.42 per share. Repurchased shares under this program are not available for future awards under the 2006 Stock and Option Plan.

## Item 5. Other Information

Effective November 8, 2007, we adopted the Vertex Pharmaceuticals Incorporated 2007 New Hire Stock and Option Plan. Under the plan, we may issue to new employees stock and option awards up to



an aggregate of 750,000 shares of our common stock. In accordance with NASDAQ Marketplace Rules, we will disclose in a press release the material terms of any actual grants that we may make under the 2007 New Hire Stock and Option Plan. The 2007 New Hire Stock and Option Plan will expire on June 1, 2008.

**Item 6. Exhibits**

Exhibit No.	Description
10.1	Vertex Pharmaceuticals Incorporated 2007 New Hire Stock and Option Plan.*
10.2	Change of Control Letter entered into between Vertex Pharmaceuticals Incorporated and Lisa Kelly on July 12, 2007.*
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	Certifications of the Chief Executive Officer and Chief Financial Officer under Section 906 of the Sarbanes-Oxley Act of 2002.

\*  
Management contract, compensatory plan or arrangement.

**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.

November 9, 2007

VERTEX PHARMACEUTICALS INCORPORATED

By: /s/ IAN F. SMITH

---

Ian F. Smith  
*Executive Vice President and Chief Financial  
Officer (principal financial officer and duly  
authorized officer)*

---

QuickLinks

VERTEX PHARMACEUTICALS INCORPORATED FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2007 TABLE OF CONTENTS

Item 1. Condensed Consolidated Financial Statements

Vertex Pharmaceuticals Incorporated Condensed Consolidated Balance Sheets (Unaudited) (In thousands, except share and per share amounts)

Vertex Pharmaceuticals Incorporated Condensed Consolidated Statements of Operations (Unaudited) (In thousands, except per share amounts)

Vertex Pharmaceuticals Incorporated Condensed Consolidated Statements of Cash Flows (Unaudited) (In thousands)

Vertex Pharmaceuticals Incorporated Notes to Condensed Consolidated Financial Statements (Unaudited)

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Item 4. Controls and Procedures

Signatures