VERTEX PHARMACEUTICALS INC / MA Form 10-Q October 28, 2010

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# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# **FORM 10-Q**

ý QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2010

OR

o 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 ý No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T ( $\S232.405$  of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  $\circ$  No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ý

Accelerated filer o

Non-accelerated filer o

Smaller reporting company o

(Do not check if a smaller reporting company)

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

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

203,194,222

Outstanding at October 21, 2010

# VERTEX PHARMACEUTICALS INCORPORATED FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2010

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

"Vertex" is a registered trademark of Vertex. "Lexiva," "Telzir" and "Agenerase" 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. Financial Statements**

# **Vertex Pharmaceuticals Incorporated**

# **Condensed Consolidated Balance Sheets**

#### (unaudited)

# (in thousands, except share and per share amounts)

|   | Sep | otember 30,<br>2010 | De | ecember 31,<br>2009 |
|---|-----|---------------------|----|---------------------|
| Assets  |     |                     |    |                     |
| Current assets:   |     |                     |    |                     |
| Cash and cash equivalents   | \$  | 569,901             | \$ | 446,658             |
| Marketable securities, available for sale                         |     | 633,110             |    | 838,255             |
| Accounts receivable   |     | 4,964               |    | 9,601               |
| Prepaid expenses and other current assets                         |     | 18,464              |    | 12,512              |
| Total current assets  |     | 1,226,439           |    | 1,307,026           |
| Restricted cash   |     | 34,090              |    | 30,313              |
| Property and equipment, net                                       |     | 65,439              |    | 62,279              |
| Intangible assets   |     | 518,700             |    | 518,700             |
| Goodwill  |     | 26,102              |    | 26,102              |
| Other assets  |     | 18,059              |    | 11,068              |
| Total assets  | \$  | 1,888,829           | \$ | 1,955,488           |
| Liabilities and Stockholders' Equity Current liabilities:         |     |                     |    |                     |
| Accounts payable  | \$  | 24,644              | \$ | 36,989              |
| Accrued expenses and other current liabilities                    | Ψ   | 127,969             | Ψ  | 118,753             |
| Accrued interest  |     | 112                 |    | 571                 |
| Deferred revenues, current portion                                |     | 98,977              |    | 74,956              |
| Accrued restructuring expense, current portion                    |     | 5,894               |    | 6,316               |
| Convertible senior subordinated notes (due 2013), current portion |     | 2,02                |    | 32,071              |
| Secured notes (due 2012), current portion                         |     | 45,280              |    | 32,071              |
| Other obligations   |     | 8,691               |    | 15,227              |
| Total current liabilities   |     | 311,567             |    | 284,883             |
| Deferred revenues, excluding current portion                      |     | 177,962             |    | 225,575             |
| Accrued restructuring expense, excluding current                  |     |                     |    |                     |
| portion   |     | 27,344              |    | 27,701              |
| Convertible senior subordinated notes (due 2015)                  |     | 400,000             |    |                     |
| Secured notes (due 2012), excluding current portion               |     | 87,225              |    | 121,765             |
| Liability related to sale of potential future milestone payments  |     | 72,123              |    | 38,207              |
| Deferred tax liability  |     | 160,278             |    | 160,278             |
| Deterred tax frability  |     | 100,278             |    | 100,278             |

| Other liabilities                                   |           | 2,234       |         | 733         |  |  |  |  |
|---|-----------|-------------|---------|-------------|--|--|--|--|
| Total liabilities                                   | 1,238,733 |             | 859,142 |             |  |  |  |  |
| Commitments and contingencies                       |           |             |         |             |  |  |  |  |
| Stockholders' equity:                               |           |             |         |             |  |  |  |  |
| Preferred stock, \$0.01 par value; 1,000,000 shares |           |             |         |             |  |  |  |  |
| authorized; none issued and outstanding at          |           |             |         |             |  |  |  |  |
| September 30, 2010 and December 31, 2009            |           |             |         |             |  |  |  |  |
| Common stock, \$0.01 par value; 300,000,000         |           |             |         |             |  |  |  |  |
| shares authorized at September 30, 2010 and         |           |             |         |             |  |  |  |  |
| December 31, 2009; 203,100,532 and                  |           |             |         |             |  |  |  |  |
| 199,955,023 shares issued and outstanding at        |           |             |         |             |  |  |  |  |
| September 30, 2010 and December 31, 2009,           |           |             |         |             |  |  |  |  |
| respectively  |           | 2,012       |         | 1,982       |  |  |  |  |
| Additional paid-in capital                          |           | 3,912,778   |         | 3,784,787   |  |  |  |  |
| Accumulated other comprehensive loss                |           | (677)       |         | (640)       |  |  |  |  |
| Accumulated deficit                                 |           | (3,264,017) |         | (2,689,783) |  |  |  |  |
|   |           |             |         |             |  |  |  |  |
| Total stockholders' equity                          |           | 650,096     |         | 1,096,346   |  |  |  |  |
|   |           |             |         |             |  |  |  |  |
| Total liabilities and stockholders' equity          | \$        | 1,888,829   | \$      | 1,955,488   |  |  |  |  |

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 Mon<br>Septem |    |           |    | Nine Mont<br>Septem |    |           |  |  |
|---------------------------------|----|---------------------|----|-----------|----|---------------------|----|-----------|--|--|
|                                 |    | 2010                |    | 2009      |    | 2010                |    | 2009      |  |  |
| Revenues:                       |    |                     |    |           |    |                     |    |           |  |  |
| Royalty revenues                | \$ | 8,173               | \$ | 7,834     | \$ | 21,842              | \$ | 19,891    |  |  |
| Collaborative revenues          |    | 15,622              |    | 17,123    |    | 56,004              |    | 48,109    |  |  |
| Total revenues                  |    | 23,795              |    | 24,957    |    | 77,846              |    | 68,000    |  |  |
| Costs and expenses:             |    | 23,773              |    | 21,557    |    | 77,010              |    | 00,000    |  |  |
| Royalty expenses                |    | 3,228               |    | 3,712     |    | 9,681               |    | 10,555    |  |  |
| Research and development        |    | 2,22                |    | 5,712     |    | ,,001               |    | 10,000    |  |  |
| expenses                        |    | 170,434             |    | 132,132   |    | 468,528             |    | 415,044   |  |  |
| Sales, general and              |    | 170,101             |    | 102,102   |    | .00,020             |    | .10,0     |  |  |
| administrative expenses         |    | 48,855              |    | 36,572    |    | 125,322             |    | 97,618    |  |  |
| Restructuring expense           |    | 866                 |    | 774       |    | 3,758               |    | 4,283     |  |  |
| Acquisition-related expenses    |    |                     |    |           |    | - ,                 |    | 7,793     |  |  |
| T                               |    |                     |    |           |    |                     |    | .,        |  |  |
| Total costs and expenses        |    | 223,383             |    | 173,190   |    | 607,289             |    | 535,293   |  |  |
| ·                               |    | ,                   |    | ,         |    | ,                   |    | ĺ         |  |  |
| Loss from operations            |    | (199,588)           |    | (148,233) |    | (529,443)           |    | (467,293) |  |  |
| Interest income                 |    | 493                 |    | 595       |    | 1,432               |    | 4,683     |  |  |
| Interest expense                |    | (3,951)             |    | (1,927)   |    | (11,589)            |    | (8,630)   |  |  |
| Change in fair value of         |    | (= ,= = = )         |    | (-,)      |    | (,,                 |    | (0,000)   |  |  |
| derivative instruments          |    | (5,911)             |    |           |    | (34,634)            |    |           |  |  |
| Loss on exchange of             |    | ( , , ,             |    |           |    |                     |    |           |  |  |
| convertible senior subordinated |    |                     |    |           |    |                     |    |           |  |  |
| notes (due 2013)                |    |                     |    |           |    |                     |    | (12,294)  |  |  |
| ,                               |    |                     |    |           |    |                     |    | , , ,     |  |  |
| Net loss                        | \$ | (208,957)           | \$ | (149,565) | \$ | (574,234)           | \$ | (483,534) |  |  |
|                                 |    |                     |    |           |    |                     |    |           |  |  |
| Basic and diluted net loss per  |    |                     |    |           |    |                     |    |           |  |  |
| common share                    | \$ | (1.04)              | \$ | (0.84)    | \$ | (2.87)              | \$ | (2.86)    |  |  |
| Common share                    | Ψ  | (1.0.1)             | Ψ  | (0.0.1)   | Ψ  | (2.07)              | Ψ  | (2.00)    |  |  |
| Basic and diluted               |    |                     |    |           |    |                     |    |           |  |  |
| weighted-average number of      |    |                     |    |           |    |                     |    |           |  |  |
| common shares outstanding       |    | 200,887             |    | 178,735   |    | 200,080             |    | 169,137   |  |  |
| common bliares outstanding      |    | 200,007             |    | 170,733   |    | 200,000             |    | 107,137   |  |  |

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 Mont<br>Septem |                 |
|--|---------------------|-----------------|
|  | 2010                | 2009            |
| Cash flows from operating activities:                  |                     |                 |
| Net loss   | \$<br>(574,234)     | \$<br>(483,534) |
| Adjustments to reconcile net loss to net cash used in  |                     |                 |
| operating activities:                                  |                     |                 |
| Depreciation and amortization expense                  | 22,254              | 21,724          |
| Stock-based compensation expense                       | 67,550              | 68,996          |
| Other non-cash based compensation expense              | 4,914               | 4,585           |
| Secured notes (due 2012) discount amortization         |                     |                 |
| expense  | 10,021              |                 |
| Change in fair value of derivative instruments         | 34,634              |                 |
| Loss on exchange of convertible senior                 |                     | 12.201          |
| subordinated notes (due 2013)                          |                     | 12,294          |
| Loss on disposal of property and equipment             | 22                  | 2,233           |
| Other non-cash expenses, net                           | (241)               |                 |
| Changes in operating assets and liabilities, excluding |                     |                 |
| the effect of an acquisition:                          |                     | 12.220          |
| Accounts receivable                                    | 4,641               | 13,328          |
| Prepaid expenses and other current assets              | (5,955)             | (2)             |
| Accounts payable                                       | (12,315)            | (32,104)        |
| Accrued expenses and other liabilities                 | 4,060               | (1,740)         |
| Accrued restructuring expense                          | (779)               | (706)           |
| Accrued interest                                       | (319)               | (2,395)         |
| Deferred revenues                                      | (23,592)            | 72,062          |
|  |                     |                 |
| Net cash used in operating activities                  | (469,339)           | (325,259)       |
| Cash flows from investing activities:                  |                     |                 |
| Purchases of marketable securities                     | (774,530)           | (374,767)       |
| Sales and maturities of marketable securities          | 979,791             | 517,240         |
| Payment for the acquisition of ViroChem, net of cash   |                     |                 |
| acquired   |                     | (87,422)        |
| Expenditures for property and equipment                | (23,626)            | (15,918)        |
| Increase in restricted cash                            | (3,777)             | (55)            |
| Increase in other assets                               | (862)               | (33)            |
|  |                     |                 |
| Net cash provided by investing activities              | 176,996             | 39,045          |
| Cash flows from financing activities:                  |                     |                 |
| Issuances of common stock from employee benefit        |                     |                 |
| plans  | 23,987              | 24,960          |
| Issuances of common stock from stock offerings, net    |                     | 313,250         |
| Issuance of secured notes (due 2012)                   |                     | 122,217         |
| Issuance of convertible senior subordinated notes      |                     |                 |
| (due 2015), net  | 391,645             |                 |
| Debt conversion/exchange costs                         | (22)                | (85)            |
|  |                     |                 |
| Net cash provided by financing activities              | 415,610             | 460,342         |
|  |                     |                 |

| Effect of changes in exchange rates on cash   |    | (24)    |    | (4,110) |
|---|----|---------|----|---------|
| Net increase in cash and cash equivalents   |    | 123,243 |    | 170,018 |
| Cash and cash equivalents beginning of period   |    | 446,658 |    | 389,115 |
| Cash and cash equivalents end of period   | \$ | 569,901 | \$ | 559,133 |
| Supplemental disclosure of cash flow information:   |    |         |    |         |
| Cash paid for interest  | \$ | 761     | \$ | 10,248  |
| Conversion/exchange of convertible senior   | \$ | 22.071  | ¢  | 142 500 |
| subordinated notes (due 2013) for common stock Accrued interest offset to additional paid-in capital on | Ф  | 32,071  | \$ | 143,500 |
| conversion/exchange of convertible senior   |    | 4.40    |    | • 000   |
| subordinated notes (due 2013) Unamortized debt issuance costs of  | \$ | 140     | \$ | 2,099   |
| converted/exchanged convertible senior subordinated   |    |         |    |         |
| notes (due 2013) offset to additional paid-in capital   | \$ | 624     | \$ | 3,476   |
| Fair value of common stock issued to acquire  | \$ |         | \$ | 200 557 |
| ViroChem  | Ф  |         | Ф  | 290,557 |

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

### **Vertex Pharmaceuticals Incorporated**

#### **Notes to Condensed Consolidated Financial Statements**

#### (unaudited)

#### A. Basis of Presentation

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, 2010 and 2009.

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, 2010. These interim financial statements should be read in conjunction with the audited financial statements for the year ended December 31, 2009, which are contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2009 that was filed with the Securities and Exchange Commission on February 19, 2010.

#### **B.** Accounting Policies

Basic and Diluted Net Loss per Common Share

Basic net loss per common share is based upon the weighted-average number of common shares outstanding during the period, excluding restricted stock and restricted stock units that have been issued but are not yet vested. Diluted net loss per common 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 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 vesting of unvested restricted stock and restricted stock units. Common equivalent shares have not been included in the net loss per common share calculations because the effect would have been anti-dilutive. Total potential gross common equivalent shares consisted of the following:

|  | At Septer           | in thousands, except per share amounts) 22,267 19,08 32.09 \$ 30.5 8,192 6,22 |        |  |
|--|---------------------|---|--------|--|
|  | 2010<br>(in thousan | ıds, e  |        |  |
|  | per share           | amoi  | unts)  |  |
| Stock options  | 22,267              |   | 19,087 |  |
| Weighted-average exercise price (per share)          | \$<br>32.09         | \$  | 30.59  |  |
| Convertible notes                                    | 8,192               |   | 6,223  |  |
| Conversion price (per share)                         | \$<br>48.83         | \$  | 23.14  |  |
| Unvested restricted stock and restricted stock units | 1,938               |   | 1,823  |  |
|  | 4                   | 5   |        |  |

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#### **Vertex Pharmaceuticals Incorporated**

#### **Notes to Condensed Consolidated Financial Statements (Continued)**

#### (unaudited)

#### **B.** Accounting Policies (Continued)

Stock-based Compensation Expense

The Company expenses the fair value of employee stock options and other forms of stock-based employee compensation over the associated employee service period or, for awards with market conditions, the derived service period. For awards with performance conditions, the Company makes estimates regarding the likelihood of satisfaction of the performance conditions that affect the period over which the expense is recognized. Compensation expense is determined 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 market and performance conditions. Please refer to Note C, "Stock-based Compensation Expense," for further information.

# Research and Development Expenses

All research and development expenses, including amounts funded by research and development collaborations, are expensed as incurred. The Company defers and capitalizes nonrefundable advance payments made by the Company for research and development activities until the related goods are delivered or the related services are performed.

Research and development expenses are comprised of costs incurred by the Company 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 its drug candidates; and infrastructure costs, including facilities costs and depreciation expense. The Company evaluates periodically whether a portion of its commercial supply investment may be capitalized as inventory. Generally, inventory may be capitalized if it is probable that future revenues will be generated from the sale of the inventory and that these revenues will exceed the cost of the inventory. The Company is continuing to expense all of its commercial supply investment due to the high risk inherent in drug development.

The Company's collaborators funded portions of the Company's research and development programs related to specific drug candidates and research targets, including telaprevir, in the three and nine months ended September 30, 2010 and 2009. The Company's collaborative revenues, including amortization of up-front license fees received in prior periods, were \$15.6 million and \$17.1 million, respectively, for the three months ended September 30, 2010 and 2009 and \$56.0 million and \$48.1 million, respectively, for the nine months ended September 30, 2010 and 2009. The Company's research and development expenses allocated to programs in which a collaborator funded at least a portion of the research and development expenses were approximately \$42 million and approximately \$33 million, respectively, for the three months ended September 30, 2010 and 2009 and approximately \$119 million in each of the nine month periods ended September 30, 2010 and 2009.

#### Restructuring Expense

The Company records costs and liabilities associated with exit and disposal activities based on estimates of fair value in the period the liabilities are 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. Liabilities are evaluated and adjusted as appropriate for changes in

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#### **Vertex Pharmaceuticals Incorporated**

#### **Notes to Condensed Consolidated Financial Statements (Continued)**

#### (unaudited)

#### **B.** Accounting Policies (Continued)

circumstances at least on a quarterly basis. Please refer to Note H, "Restructuring Expense," for further information.

Revenue Recognition

#### **Collaborative Revenues**

The Company's revenues are generated primarily through collaborative research, development and/or commercialization agreements. The terms of these agreements typically include payment to the Company of one or more of the following: nonrefundable, up-front license fees; funding of research and/or development activities; payments for services the Company provides through its third-party manufacturing network; milestone payments; and royalties on product sales. Each of these types of payments results in collaborative revenues, except for revenues from royalties on product sales, which are classified as royalty revenues.

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 the fair value of the undelivered obligation(s). The consideration received is allocated among the separate units either on the basis of each unit's fair value or using the residual method, and the applicable revenue recognition criteria are applied to each of the separate units.

## Up-front Fees

The Company recognizes revenues from nonrefundable, up-front license fees on a straight-line basis over the contracted or estimated period of performance, which is typically the period over which the research and development is expected to occur or manufacturing services are expected to be provided. In order to estimate the period of performance, the Company is required to make estimates regarding the drug development and commercialization timelines for compounds being developed pursuant to the applicable agreement. The Company's estimates regarding the period of performance under certain of its collaboration agreements have changed in the past and may change in the future.

#### Milestones

At the inception of each agreement that includes milestone payments, the Company evaluates whether each milestone is substantive on the basis of 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. The Company recognizes revenues related to substantive milestones in full in the period in which the substantive milestone is achieved, if payment is reasonably assured and the Company's performance obligations are fully satisfied. If the Company has obligations remaining after the achievement of the milestone, the Company considers whether it has sufficient evidence of the fair value of its remaining obligations. If (A) a milestone is not considered substantive or (B) the Company has remaining obligations after the achievement of a substantive milestone and does not have sufficient evidence of the fair value of those obligations, the Company recognizes the applicable milestone over the remaining period of performance.

#### **Vertex Pharmaceuticals Incorporated**

#### **Notes to Condensed Consolidated Financial Statements (Continued)**

#### (unaudited)

#### **B.** Accounting Policies (Continued)

Research and Development Activities/Manufacturing Services

Under certain of its collaboration agreements, the Company is entitled to reimbursement from its collaborators for specified research and development expenses and/or payments for specified manufacturing services that the Company provides through its third-party manufacturing network. The Company considers the nature and contractual terms of the arrangement and the nature of the Company's business operations in order to determine whether research and development funding will result in collaborative revenues or an offset to research and development expenses. The Company typically recognizes the revenues related to these reimbursable expenses and manufacturing services in the period in which the reimbursable expenses are incurred or the manufacturing services are provided.

# **Royalty Revenues**

Royalty revenues typically are recognized based upon actual and estimated net sales of licensed products in licensed territories, as provided by the licensee, and generally are recognized in the period the sales occur. The Company reconciles and adjusts for differences between actual royalty revenues and estimated royalty revenues in the quarter they become known. These differences historically have not been significant.

The Company has sold its rights to certain royalties on sales of HIV protease inhibitors and recognizes the revenues related to this sale as royalty revenues. In the circumstance where the Company has sold its rights to future royalties under a license agreement and also maintains continuing involvement in the royalty arrangement (but not significant continuing involvement in the generation of the cash flows due to the purchaser of the future royalty rights), the Company defers recognition of the proceeds it receives for the royalty stream and recognizes these deferred revenues over the life of the license agreement. The Company recognizes these deferred revenues pursuant to the units-of-revenue method. Under this method, the amount of deferred revenues to be recognized as royalty revenues in each period is calculated by multiplying the following: (1) the royalty payments due to the purchaser for the period by (2) the ratio of the remaining deferred revenue amount to the total estimated remaining royalty payments due to the purchaser over the term of the agreement. The Company's estimates regarding the estimated remaining royalty payments due to the purchaser have changed in the past and may change in the future.

#### Financial Transaction Expenses

Issuance costs incurred to complete the Company's convertible senior subordinated note offerings and the financial transactions that the Company entered into in September 2009 are deferred and included in other assets on the Company's condensed consolidated balance sheets. The issuance costs are amortized using the effective interest rate method over the term of the related debt or financial instrument. The amortization expense related to the issuance costs is included in interest expense on the condensed consolidated statements of operations.

The Company defers direct and incremental costs associated with the sale of its rights to future royalties. These costs are included in other assets on the Company's condensed consolidated balance sheets and are amortized in the same manner and over the same period during which the related deferred revenues are recognized as royalty revenues. The amortization expense related to these

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#### **Vertex Pharmaceuticals Incorporated**

#### **Notes to Condensed Consolidated Financial Statements (Continued)**

#### (unaudited)

#### **B.** Accounting Policies (Continued)

transaction expenses is included in royalty expenses on the condensed consolidated statements of operations.

Expenses incurred in connection with common stock issuances are recorded as an offset to additional paid-in capital on the condensed consolidated balance sheets.

#### **Business Combinations**

The Company assigns the value of the consideration transferred to acquire a business to the tangible assets and identifiable intangible assets acquired and liabilities assumed on the basis of their fair values at the date of acquisition. The Company assesses the fair value of assets, including intangible assets such as in-process research and development assets, using a variety of methods. Each asset is measured at fair value from the perspective of a market participant. The present-value models used to estimate the fair values of in-process research and development assets incorporate significant assumptions regarding the estimates market participants would make in order to evaluate an asset: including market participants' assumptions regarding the probability of completing in-process research and development projects, which would require obtaining regulatory approval for marketing of the associated drug candidate; market participants' estimates regarding the timing of and the expected costs to complete in-process research and development projects; market participants' estimates of future cash flows from potential product sales; and the appropriate discount rates for market participants. Transaction costs and restructuring costs associated with the transaction are expensed as incurred.

#### In-process Research and Development Assets

In-process research and development assets acquired in a business combination are recorded as of the acquisition date at fair value and accounted for as indefinite-lived intangible assets. These assets are maintained on the Company's condensed consolidated balance sheets until either the project underlying them is completed or the assets become impaired. If a project is completed, the carrying value of the related intangible asset is amortized over the remaining estimated life of the asset beginning in the period in which the project is completed. If a project becomes impaired or is abandoned, the carrying value of the related intangible asset is written down to its fair value and an impairment charge is taken in the period in which the impairment occurs. In-process research and development assets are tested for impairment on an annual basis as of October 1, or earlier if impairment indicators are present.

# Goodwill

The difference between the purchase price and the fair value of assets acquired and liabilities assumed in a business combination is allocated to goodwill. Goodwill is evaluated for impairment on an annual basis as of October 1, or earlier if impairment indicators are present.

#### Derivative Instruments and Embedded Derivatives

The Company has entered into financial transactions involving a free-standing derivative instrument and embedded derivatives. These financial transactions include arrangements involving secured notes, the sale of potential future milestone payments and convertible notes. The embedded

#### **Vertex Pharmaceuticals Incorporated**

#### **Notes to Condensed Consolidated Financial Statements (Continued)**

#### (unaudited)

## **B.** Accounting Policies (Continued)

derivatives are required to be bifurcated from the host instruments because the derivatives are not clearly and closely related to the host instruments. The Company determines the fair value of each derivative instrument or embedded derivative on the date of issuance. The estimates of the fair value of these derivatives, particularly with respect to derivatives related to the achievement of milestones in the development of specific drug candidates, include significant assumptions regarding the estimates market participants would make in order to evaluate the derivative. Changes in the fair value of these derivatives are evaluated on a quarterly basis. Please refer to Note L, "September 2009 Financial Transactions," for further information.

# C. Stock-based Compensation Expense

The Company issues stock options, restricted stock and restricted stock units with service conditions, which are generally the vesting periods of the awards. The Company also issues, to certain members of senior management, restricted stock and restricted stock units that vest upon the earlier of the satisfaction of (i) market or performance conditions or (ii) a service condition, and stock options that vest upon the earlier of the satisfaction of (1) performance conditions or (2) a service condition. In the second and third quarters of 2010, based on the advancement of the Company's telaprevir registration program and the completion of the Company's September 2010 convertible debt offering, the Company recognized a portion of the stock-based compensation expense related to certain grants that contain performance conditions and a service condition over an implicit service period that is shorter than the service period over which the Company had been recognizing the expense. The implicit service period is the period that will be required to meet the performance condition based on the Company's estimates.

The stock options, restricted stock and restricted stock units issued by the Company are granted under the Company's stock and option plans. In addition, the Company issues shares pursuant to an employee stock purchase plan ("ESPP"). On May 13, 2010, the Company's shareholders approved an increase in the number of shares of common stock authorized for issuance under the Company's Amended and Restated 2006 Stock and Option Plan by 12,000,000 shares, from 21,602,380 shares to 33,602,380 shares.

The effect of stock-based compensation expense during the three and nine months ended September 30, 2010 and 2009 was as follows:

# **Vertex Pharmaceuticals Incorporated**

#### **Notes to Condensed Consolidated Financial Statements (Continued)**

#### (unaudited)

#### C. Stock-based Compensation Expense (Continued)

The stock-based compensation expense by type of award during the three and nine months ended September 30, 2010 and 2009 was as follows:

|   | Three Months Ended September 30, |    |          |      | Ended<br>30, |      |        |
|---|----------------------------------|----|----------|------|--------------|------|--------|
|   | 2010 2009                        |    | 2010     |      |              | 2009 |        |
|   |                                  |    | (in thou | ısan | ds)          |      |        |
| Stock-based compensation expense by type of |                                  |    |          |      |              |      |        |
| award:                                      |                                  |    |          |      |              |      |        |
| Stock options                               | \$<br>16,177                     | \$ | 14,180   | \$   | 47,380       | \$   | 51,044 |
| Restricted stock and restricted stock units | 6,164                            |    | 4,901    |      | 16,654       |      | 14,606 |
| ESPP share issuances                        | 1,427                            |    | 1,053    |      | 3,516        |      | 3,346  |
|   |                                  |    |          |      |              |      |        |
| Total stock-based compensation expense      |                                  |    |          |      |              |      |        |
| included in net loss                        | \$<br>23,768                     | \$ | 20,134   | \$   | 67,550       | \$   | 68,996 |

The stock-based compensation expense for the nine months ended September 30, 2009 included \$9.2 million related to accelerated vesting and the modification of stock options and \$1.3 million related to accelerated vesting of restricted stock awards, in each case in connection with Dr. Joshua Boger's transition arrangement. The stock-based compensation expense for the three and nine months ended September 30, 2009 also included \$2.0 million and \$3.5 million, respectively, related to accelerated vesting of stock options and \$0.6 million and \$0.9 million, respectively, related to accelerated vesting of restricted stock awards, in each case in connection with certain other executive officers' severance arrangements. The following table sets forth the unrecognized stock-based compensation expense, net of estimated forfeitures, as of September 30, 2010 by type of award and the weighted-average period over which that expense is expected to be recognized for the Company's stock options, restricted stock and restricted stock units, and ESPP share issuances:

|   | As of September 30, 2010                                 |   |  |  |  |  |  |
|---|--|---|--|--|--|--|--|
|   | Unrecognized Expense,<br>Net of<br>Estimated Forfeitures | Weighted-average<br>Recognition<br>Period |  |  |  |  |  |
|   | (in thousands)   | (in years)                                |  |  |  |  |  |
| Type of award:                              |  |   |  |  |  |  |  |
| Stock options                               | 133,489  | 2.82                                      |  |  |  |  |  |
| Restricted stock and restricted stock units | 39,860   | 2.42                                      |  |  |  |  |  |
| ESPP share issuances                        | 1,678  | 0.48                                      |  |  |  |  |  |
|   | 11   |   |  |  |  |  |  |

# **Vertex Pharmaceuticals Incorporated**

#### **Notes to Condensed Consolidated Financial Statements (Continued)**

#### (unaudited)

# D. Marketable Securities

A summary of cash, cash equivalents and marketable securities is shown below:

| September 30, 2010   | Amortized<br>Cost |           | Cost Gains |          | Gross<br>Unrealized<br>Losses |       | Fair<br>Value   |
|--|-------------------|-----------|------------|----------|-------------------------------|-------|-----------------|
|  |                   |           |            | (in thou | ısanı                         | ds)   |                 |
| Cash and cash equivalents                                      |                   |           |            |          |                               |       |                 |
| Cash and money market funds                                    | \$                | 506,520   | \$         |          | \$                            |       | \$<br>506,520   |
| U.S. Treasury securities                                       |                   | 60,483    |            |          |                               | (2)   | 60,481          |
| Government-sponsored enterprise securities                     |                   | 2,900     |            |          |                               |       | 2,900           |
| Total cash and cash equivalents                                | \$                | 569,903   | \$         |          | \$                            | (2)   | \$<br>569,901   |
| Marketable securities  |                   |           |            |          |                               |       |                 |
| U.S. Treasury securities (due within 1 year)                   | \$                | 28,094    | \$         | 3        | \$                            |       | \$<br>28,097    |
| Government-sponsored enterprise securities (due within 1 year) |                   | 604,935   |            | 83       |                               | (5)   | 605,013         |
| Total marketable securities                                    | \$                | 633,029   | \$         | 86       | \$                            | (5)   | \$<br>633,110   |
| Total cash, cash equivalents and marketable securities         | \$                | 1,202,932 | \$         | 86       | \$                            | (7)   | \$<br>1,203,011 |
| December 31, 2009  |                   |           |            |          |                               |       |                 |
| Cash and cash equivalents                                      |                   |           |            |          |                               |       |                 |
| Cash and money market funds                                    | \$                | 251,005   | \$         |          | \$                            |       | \$<br>251,005   |
| U.S. Treasury securities                                       |                   | 20,198    |            |          |                               | (5)   | 20,193          |
| Government-sponsored enterprise securities                     |                   | 175,455   |            | 8        |                               | (3)   | 175,460         |
| Total cash and cash equivalents                                | \$                | 446,658   | \$         | 8        | \$                            | (8)   | \$<br>446,658   |
| Marketable securities  |                   |           |            |          |                               |       |                 |
| U.S. Treasury securities (due within 1 year)                   | \$                | 223,422   | \$         |          | \$                            | (99)  | \$<br>223,323   |
| Government-sponsored enterprise securities (due within 1 year) |                   | 614,869   |            | 81       |                               | (18)  | 614,932         |
| Total marketable securities                                    | \$                | 838,291   | \$         | 81       | \$                            | (117) | \$<br>838,255   |
| Total cash, cash equivalents and marketable securities         | \$                | 1,284,949 | \$         | 89       | \$                            | (125) | \$<br>1,284,913 |

The Company reviews investments in marketable securities for other-than-temporary impairment whenever the fair value of an investment is less than amortized cost and evidence indicates that an investment's carrying amount is not recoverable within a reasonable period of time. To determine whether an impairment is other-than-temporary, the Company considers the intent to sell, or whether it is more likely than not that the Company will be required to sell, the investment before recovery of the investment's amortized cost basis. Evidence considered in this assessment includes reasons for the impairment, compliance with the Company's investment policy, the severity and the duration of the impairment and changes in value subsequent to period end.

#### **Vertex Pharmaceuticals Incorporated**

#### **Notes to Condensed Consolidated Financial Statements (Continued)**

#### (unaudited)

#### D. Marketable Securities (Continued)

As of September 30, 2010, the Company had five government-sponsored enterprise securities that were in a gross unrealized loss position and no marketable securities in any other category that were in a gross unrealized loss position. The following table summarizes the fair value and gross unrealized losses related to marketable securities, aggregated by investment category and length of time that individual securities have been in a continuous gross unrealized loss position as of September 30, 2010:

|  |    | Less than<br>Fair<br>Value | Unr | onths<br>Gross<br>realized<br>Loss | Gros<br>l Fair Unreali<br>Value Loss |    |    |        |    | oss<br>alized<br>oss |
|--|----|----------------------------|-----|------------------------------------|--------------------------------------|----|----|--------|----|----------------------|
| Government-sponsored enterprise securities | \$ | 53,783                     | \$  | (5)                                |                                      | \$ | \$ | 53,783 | \$ | (5)                  |
| Total                                      | \$ | 53,783                     | \$  | (5)                                | \$                                   | \$ | \$ | 53,783 | \$ | (5)                  |

The following table summarizes the fair value and gross unrealized losses related to marketable securities, aggregated by investment category and length of time that individual securities have been in a continuous gross unrealized loss position as of December 31, 2009:

|                          |    | Less than 1   | l2 m | onths                     | 12 mon                  | ths or more                              |    | Tot           | tal |                           |
|--------------------------|----|---------------|------|---------------------------|-------------------------|--|----|---------------|-----|---------------------------|
|                          |    | Fair<br>Value |      | Gross<br>realized<br>Loss | Fair<br>Value<br>(in th | Gross<br>Unrealized<br>Loss<br>housands) |    | Fair<br>Value | Uni | Gross<br>realized<br>Loss |
| U.S. Treasury securities | \$ | 221,412       | \$   | (99)                      | \$                      | ¢  | Ф  | 221 412       | ¢   | (00)                      |
| Government-sponsored     | Ф  | 221,412       | Ф    | (99)                      | Ф                       | \$                                       | \$ | 221,412       | \$  | (99)                      |
| enterprise securities    |    | 118,950       |      | (18)                      |                         |  |    | 118,950       |     | (18)                      |
| Total                    | \$ | 340,362       | \$   | (117)                     | \$                      | \$                                       | \$ | 340,362       | \$  | (117)                     |

In the three months ended September 30, 2010 and 2009, the Company had proceeds of \$461.7 million and \$171.8 million, respectively, from sales and maturities of available-for-sale securities. In the nine months ended September 30, 2010 and 2009, the Company had proceeds of \$979.8 million and \$517.2 million, respectively, from sales and maturities of available-for-sale securities.

Realized gains and losses are determined using the specific identification method and are included in interest income on the condensed consolidated statements of operations. There were no gross realized gains and losses for the three and nine months ended September 30, 2010 and 2009.

#### E. Fair Value of Financial Instruments

The fair value of the Company's financial assets and liabilities reflects the Company's estimate of amounts that it would have received in connection with the sale of the assets or paid in connection with the transfer of the liabilities in an orderly transaction between market participants at the measurement date. In connection with measuring the fair value of its assets and liabilities, the Company seeks to maximize the use of observable inputs (market data obtained from sources independent from the Company) and to minimize the use of unobservable inputs (the Company's

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#### **Vertex Pharmaceuticals Incorporated**

#### **Notes to Condensed Consolidated Financial Statements (Continued)**

#### (unaudited)

#### E. Fair Value of Financial Instruments (Continued)

assumptions about how market participants would price assets and liabilities). The following fair value hierarchy is used to classify assets and liabilities based on the observable inputs and unobservable inputs used in order to value the assets and liabilities:

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

The Company's investment strategy is focused on capital preservation. The Company invests in instruments that meet credit quality standards as outlined in the Company's investment policy guidelines. These guidelines also limit the amount of credit exposure to any one issue or type of instrument. Beginning in the fourth quarter of 2007, the Company began to shift its investments to instruments that carry less exposure to market volatility and liquidity pressures. As of September 30, 2010, the Company's investments are in money market funds and short-term government guaranteed or supported securities.

As of September 30, 2010, all of the Company's financial assets that were subject to fair value measurements were valued using observable inputs. The Company's financial assets that were valued based on Level 1 inputs consist of a money market fund, U.S. Treasuries and government-sponsored enterprise securities, which are government-supported. The money market fund in which the Company invests also holds government-sponsored enterprise securities. During the three and nine months ended September 30, 2010 and 2009, the Company did not record an other-than-temporary impairment charge related to its financial assets. The Company's financial liabilities that were subject to fair value measurement relate to the financial transactions that the Company entered into in September 2009 and are valued based on Level 3 inputs. Please refer to Note L, "September 2009 Financial Transactions."

# **Vertex Pharmaceuticals Incorporated**

#### **Notes to Condensed Consolidated Financial Statements (Continued)**

#### (unaudited)

# E. Fair Value of Financial Instruments (Continued)

The following table sets forth the Company's financial assets and liabilities subject to fair value measurements as of September 30, 2010:

Fair Value Measurements as of

#### 

| U.S. Treasury securities                      | 60,481          | 60,481          |                 |
|---|-----------------|-----------------|-----------------|
| Government-sponsored enterprise securities    | 2,900           | 2,900           |                 |
| Marketable securities:                        |                 |                 |                 |
| U.S. Treasury securities                      | 28,097          | 28,097          |                 |
| Government-sponsored enterprise securities    | 605,013         | 605,013         |                 |
| Restricted cash                               | 34,090          | 34,090          |                 |
| Total   | \$<br>1,202,260 | \$<br>1,202,260 | \$<br>\$        |
| Financial liabilities carried at fair value:  |                 |                 |                 |
| Embedded derivative related to 2012 Notes     | \$<br>11,170    | \$              | \$<br>\$ 11,170 |
| Liability related to sale of potential future |                 |                 |                 |
| milestone payments                            | 72,123          |                 | 72,123          |
|   |                 |                 |                 |
| Total   | \$<br>83,293    | \$              | \$<br>\$ 83,293 |

The following table is a reconciliation of financial liabilities measured at fair value using significant unobservable inputs (Level 3):

|  | - ,    | onths Ended<br>ber 30, 2010 |
|--|--------|-----------------------------|
|  | (in th | housands)                   |
| Balance, December 31, 2009                     | \$     | 48,659                      |
| Change in fair value of derivative instruments |        | 34,634                      |
| Balance, September 30, 2010                    | \$     | 83,293                      |

As of September 30, 2010, the Company had \$400.0 million outstanding in aggregate principal amount of 3.35% convertible senior subordinated notes due 2015 (the "2015 Notes") on its condensed consolidated balance sheet. At September 30, 2010, these 2015 Notes had a fair value of approximately \$404 million as obtained from a quoted market source.

#### **Vertex Pharmaceuticals Incorporated**

#### **Notes to Condensed Consolidated Financial Statements (Continued)**

#### (unaudited)

#### F. Comprehensive Loss

For the three and nine months ended September 30, 2010 and 2009, comprehensive loss was as follows:

|  |    | Three Mon<br>Septem |      |           | Nine Mont<br>Septem |      |           |
|--|----|---------------------|------|-----------|---------------------|------|-----------|
|  |    | 2010                | 2009 | 2010      |                     | 2009 |           |
|  |    |                     |      |           |                     |      |           |
| Net loss   |    |                     |      |           |                     |      |           |
| Changes in other comprehensive income (loss):              | \$ | (208,957)           | \$   | (149,565) | \$<br>(574,234)     | \$   | (483,534) |
| Unrealized holding gains (losses) on marketable securities |    | (52)                |      | (206)     | 116                 |      | (3,042)   |
| Foreign currency translation adjustment                    |    | (67)                |      | (327)     | (153)               |      | (241)     |
|  |    |                     |      |           |                     |      |           |
| Total change in other comprehensive loss                   |    | (119)               |      | (533)     | (37)                |      | (3,283)   |
|  |    |                     |      |           |                     |      |           |
| Total comprehensive loss                                   | \$ | (209,076)           | \$   | (150,098) | \$<br>(574,271)     | \$   | (486,817) |

#### G. Income Taxes

At September 30, 2010 and December 31, 2009, the Company had no material unrecognized tax benefits and no adjustments to liabilities or operations were required. The Company does not expect that its unrecognized tax benefits will materially increase within the next twelve months. The Company did not recognize any material interest or penalties related to uncertain tax positions at September 30, 2010 and December 31, 2009.

The Company files United States federal income tax returns and income tax returns in various state, local and foreign jurisdictions. The Company is no longer subject to any tax assessment from an income tax examination in the United States before 2007 and any other major taxing jurisdiction for years before 2005, except where the Company has net operating losses or tax credit carryforwards that originate before 2005. The Company currently is not under examination by any jurisdiction for any tax year.

# H. 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. At that time, 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") for its operations, beginning in 2006. The remaining rentable square footage of the Kendall Square Facility currently is subleased to third parties.

#### **Vertex Pharmaceuticals Incorporated**

#### **Notes to Condensed Consolidated Financial Statements (Continued)**

#### (unaudited)

#### H. Restructuring Expense (Continued)

The restructuring expense incurred in the three and nine months ended September 30, 2010 and 2009 relates only to the portion of the Kendall Square Facility that the Company is not occupying and 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 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, and intends to continue such reviews until the termination of the Kendall Square Lease, and will make whatever modifications the Company 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 the liability, and the effect of any such adjustments could be material. Changes to the Company's estimate of the liability are recorded as additional restructuring expense/(credit). In addition, because the Company's estimate of the liability includes the application of a discount rate to reflect the time-value-of-money, the Company will record imputed interest costs related to the liability each quarter. These costs are included in restructuring expense on the Company's condensed consolidated statements of operations.

For the three months ended September 30, 2010, the Company recorded 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, 2010 was as follows (in thousands):

|                     | oility as of<br>une 30,<br>2010 | pa<br>in t | Cash nyments the third narter of 2010 | recei<br>sub<br>th<br>qu | Cash ved from leases in e third arter of 2010 | in t<br>qua |     | ability as of otember 30, 2010 |
|---------------------|---------------------------------|------------|---------------------------------------|--------------------------|---|-------------|-----|--------------------------------|
| Lease restructuring |                                 |            |                                       |                          |   |             |     |                                |
| liability           | \$<br>33,924                    | \$         | (3,754)                               | \$                       | 2,202   | \$          | 866 | \$<br>33,238                   |

For the three months ended September 30, 2009, the Company recorded restructuring expense of \$0.8 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, 2009 was as follows (in thousands):

|                     | Ju | ility as of<br>ine 30,<br>2009 | pa<br>in t<br>qu | Cash syments the third arter of 2009 | rece<br>sul<br>in t<br>qu | Cash ived from bleasese the third arter of 2009 | in tl<br>qua |     | ability as of otember 30, 2009 |
|---------------------|----|--------------------------------|------------------|--------------------------------------|---------------------------|---|--------------|-----|--------------------------------|
| Lease restructuring |    |                                |                  |                                      |                           |   |              |     |                                |
| liability           | \$ | 34,050                         | \$               | (3,772)                              | \$                        | 2,306   | \$           | 774 | \$<br>33,358                   |

#### **Vertex Pharmaceuticals Incorporated**

#### **Notes to Condensed Consolidated Financial Statements (Continued)**

#### (unaudited)

#### H. Restructuring Expense (Continued)

For the nine months ended September 30, 2010, the Company recorded restructuring expense of \$3.8 million, which was partially due to revisions in the second quarter of 2010 to key estimates and assumptions related to the exercise by a sublessee of an option to continue subleasing a portion of the Kendall Square Facility through 2015 and changes to certain assumptions for the period from 2015 to 2018, and partially the result of the imputed interest cost relating to the restructuring liability. The activity related to the restructuring liability for the nine months ended September 30, 2010 was as follows (in thousands):

|                               | Liability<br>Decembe<br>2009 | as of a | Cash payments in the first nine months of 2010 | Cas<br>received<br>subleas<br>the firs<br>month<br>201 | I from<br>ses in<br>t nine<br>is of | in t | harge<br>he first<br>nine<br>nths of<br>2010 | oility as of<br>ember 30,<br>2010 |
|-------------------------------|------------------------------|---------|--|--|-------------------------------------|------|--|-----------------------------------|
| Lease restructuring liability | \$ 34                        | ,017    | \$ (11,169)                                    | \$   | 6,632                               | \$   | 3,758  | \$<br>33,238                      |

For the nine months ended September 30, 2009, the Company recorded restructuring expense of \$4.3 million, which was the result of incremental lease obligations related to the revision in the first quarter of 2009 of certain key estimates and assumptions about facility operating costs 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, 2009 was as follows (in thousands):

|                               | oility as of ember 31, 2008 | in | Cash ayments the first ne months of 2009 | su<br>the | Cash<br>eived from<br>bleases in<br>e first nine<br>nonths of<br>2009 | in i | Charge<br>the first<br>nine<br>onths of<br>2009 | bility as of<br>tember 30,<br>2009 |  |
|-------------------------------|-----------------------------|----|--|-----------|---|------|---|------------------------------------|--|
| Lease restructuring liability | \$<br>34.064                | \$ | (11.529)                                 | \$        | 6.540   | \$   | 4.283   | \$<br>33,358                       |  |

# I. Equity and Debt Offerings and Debt Exchanges and Conversions

February 2009 Equity Offering

In February 2009, the Company completed an offering of 10,000,000 shares of common stock (the "February 2009 Equity Offering"), which were sold at a price of \$32.00 per share. This offering resulted in \$313.3 million of net proceeds to the Company. The underwriting discount of \$6.4 million and other expenses of \$0.3 million related to the February 2009 Equity Offering were recorded as an offset to additional paid-in capital.

December 2009 Equity Offering

In December 2009, the Company completed an offering of 13,000,000 shares of common stock (the "December 2009 Equity Offering"), which were sold at a price of \$38.50 per share. This offering resulted in \$488.1 million of net proceeds to the Company. The underwriting discount of \$12.1 million and other expenses of \$0.3 million related to the December 2009 Equity Offering were recorded as an offset to additional paid-in capital.

#### **Vertex Pharmaceuticals Incorporated**

#### **Notes to Condensed Consolidated Financial Statements (Continued)**

(unaudited)

#### I. Equity and Debt Offerings and Debt Exchanges and Conversions (Continued)

2009 Debt Exchanges and 2010 Debt Conversions

As of January 1, 2009, the Company had outstanding \$287.5 million in aggregate principal amount of 4.75% convertible senior subordinated notes due 2013 (the "2013 Notes"). The 2013 Notes were convertible, at the option of the holder, into common stock at a price equal to \$23.14 per share or 43.22 shares of common stock per \$1,000 in principal amount of the 2013 Notes, subject to adjustment. The 2013 Notes bore interest at the rate of 4.75% per annum, and the Company was required to make semi-annual interest payments on the outstanding principal balance of the 2013 Notes on February 15 and August 15 of each year. The Company had the right to redeem the 2013 Notes, in whole or in part, on or after February 15, 2010, at the redemption prices stated in the indenture, plus accrued and unpaid interest to, but excluding, the redemption date. The 2013 Notes would have matured on February 15, 2013.

In the second quarter of 2009, the Company exchanged \$143.5 million in aggregate principal amount of the 2013 Notes, plus accrued interest, for 6,601,000 shares of newly-issued common stock. In order to induce the holders of the 2013 Notes to enter into these exchanges, the Company agreed to issue 46 shares of common stock for each \$1,000 in principal amount of the 2013 Notes, which was 2.78 more shares of common stock per \$1,000 in principal amount than were provided for upon conversion pursuant to the terms of the 2013 Notes. As a result of these exchanges, the Company incurred a non-cash charge of \$12.3 million in the second quarter of 2009 related to the incremental shares that were issued to the holders of the 2013 Notes. In addition, accrued interest of \$2.1 million and unamortized debt issuance costs of the 2013 Notes of \$3.5 million were recorded as an offset to additional paid-in capital.

In the fourth quarter of 2009, the Company exchanged \$111.9 million in aggregate principal amount of the 2013 Notes, plus accrued interest, for 4,980,838 shares of newly-issued common stock. In order to induce the holders of the 2013 Notes to enter into these exchanges, the Company agreed to issue 44.5 shares of common stock for each \$1,000 in principal amount of the 2013 Notes, which was 1.28 more shares of common stock per \$1,000 in principal amount than were provided for upon conversion pursuant to the terms of the 2013 Notes. As a result of these exchanges, the Company incurred a non-cash charge of \$5.8 million in the fourth quarter of 2009 related to the incremental shares that were issued to the holders of the 2013 Notes. In addition, accrued interest of \$1.3 million and unamortized debt issuance costs of the 2013 Notes of \$2.4 million were recorded as an offset to additional paid-in capital.

In the first quarter of 2010, the Company announced that it would redeem the remaining \$32.1 million in aggregate principal amount of the 2013 Notes on March 19, 2010. Instead, the holders of the remaining 2013 Notes elected to convert their 2013 Notes, pursuant to the original terms of the 2013 Notes, into 1,386,006 shares of newly-issued common stock in full satisfaction of the 2013 Notes. Accrued interest of \$0.1 million and unamortized debt issuance costs of the 2013 Notes of \$0.6 million were recorded as an offset to additional paid-in capital.

September 2010 Convertible Debt Offering

On September 28, 2010, the Company completed an offering of \$400.0 million in aggregate principal amount of 3.35% convertible senior subordinated notes due 2015. This offering resulted in net

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#### **Vertex Pharmaceuticals Incorporated**

#### **Notes to Condensed Consolidated Financial Statements (Continued)**

#### (unaudited)

#### I. Equity and Debt Offerings and Debt Exchanges and Conversions (Continued)

proceeds of \$391.6 million to the Company. The underwriting discount of \$8.0 million and other expenses of \$0.4 million related to this offering were recorded as debt issuance costs and are included in other assets on the Company's condensed consolidated balance sheet. The 2015 Notes were issued pursuant to and are governed by the terms of an indenture (as supplemented, the "Indenture").

The 2015 Notes are convertible at any time, at the option of the holder, into common stock at a price equal to approximately \$48.83 per share, or 20.4794 shares of common stock per \$1,000 principal amount of the 2015 Notes, subject to adjustment. The 2015 Notes bear interest at the rate of 3.35% per annum, and the Company is required to make semi-annual interest payments on the outstanding principal balance of the 2015 Notes on April 1 and October 1 of each year, beginning on April 1, 2011. The 2015 Notes mature on October 1, 2015.

Prior to October 1, 2013, if the closing price of the Company's common stock has exceeded 130% of the then applicable conversion price for at least 20 trading days within a period of 30 consecutive trading days, the Company may redeem the 2015 Notes at its option, in whole or in part, at a redemption price equal to 100% of the principal amount of the 2015 Notes to be redeemed. If the Company elects to redeem the 2015 Notes prior to October 1, 2013, or the holder elects to convert the 2015 Notes after receiving notice of such redemption, the Company will be obligated to make an additional payment, payable in cash or, subject to certain conditions, shares of the Company's common stock, so that the Company's total interest payments on the 2015 Notes being redeemed and such additional payment shall equal three years of interest. On or after October 1, 2013, the Company may redeem the 2015 Notes at its option, in whole or in part, at the redemption prices stated in the Indenture plus accrued and unpaid interest, if any, to, but excluding, the redemption date.

Holders may require the Company to repurchase some or all of their 2015 Notes upon the occurrence of certain fundamental changes of Vertex, as set forth in the Indenture, at 100% of the principal amount of the 2015 Notes to be repurchased, plus any accrued and unpaid interest, if any, to, but excluding, the repurchase date.

If a fundamental change occurs that is also a specific type of change of control under the Indenture, the Company will pay a make-whole premium upon the conversion of the 2015 Notes in connection with any such transaction by increasing the applicable conversion rate on such 2015 Notes. The make-whole premium will be in addition to, and not in substitution for, any cash, securities or other assets otherwise due to holders of the 2015 Notes upon conversion. The make-whole premium will be determined by reference to the Indenture and is based on the date on which the fundamental change becomes effective and the price paid, or deemed to be paid, per share of the Company's common stock in the transaction constituting the fundamental change, subject to adjustment.

Based on the Company's evaluation of the 2015 Notes, the Company determined that the 2015 Notes contain a single embedded derivative. This embedded derivative relates to potential penalty interest payments that could be imposed on the Company for a failure to comply with its securities reporting obligations pursuant to the 2015 Notes. This embedded derivative required bifurcation because it was not clearly and closely related to the host instrument. The Company has determined that the value of this embedded derivative was nominal as of September 28, 2010 and September 30, 2010.

#### **Vertex Pharmaceuticals Incorporated**

#### **Notes to Condensed Consolidated Financial Statements (Continued)**

#### (unaudited)

#### J. Collaborative Arrangements

Janssen Pharmaceutica, N.V.

In June 2006, the Company entered into a collaboration agreement with Janssen Pharmaceutica, N.V. ("Janssen") for the development, manufacture and commercialization of telaprevir. 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. The Company's estimates regarding the period of performance under the Janssen collaboration agreement were adjusted in 2007, in the third quarter of 2009 and in the first quarter of 2010, as a result of changes in the global development plan for telaprevir, which contemplates the conduct of certain development activities in the post-approval period, if telaprevir is approved for marketing. These adjustments were made on a prospective basis beginning in the periods in which the changes were identified and resulted in a decrease in the amount of revenues the Company recognized from the Janssen agreement by \$2.6 million per quarter for the first adjustment, by \$1.1 million per quarter for the second adjustment and by \$1.4 million per quarter for the third adjustment. As of September 30, 2010, there was \$71.5 million in deferred revenues related to this up-front license payment that will be recognized over the remaining estimated period of performance.

Under the agreement, Janssen agreed to make contingent milestone payments, which could have totaled up to \$380.0 million for successful development, approval and launch of telaprevir as a product. As of September 30, 2010, the Company had earned \$100.0 million of these contingent milestone payments. The remaining \$280.0 million in milestones under the Company's agreement with Janssen include \$100.0 million related to the regulatory filing with and approval of telaprevir by the European Medicines Agency, and \$150.0 million related to the launch of telaprevir in the European Union. On September 30, 2009, the Company entered into two financial transactions related to the \$250.0 million in milestones related to the filing, approval and launch of telaprevir in the European Union. Please refer to Note L, "September 2009 Financial Transactions." No revenues from milestone payments were recognized in the three or nine month periods ended September 30, 2010 or 2009.

Under the collaboration agreement for telaprevir, each party incurs internal and external reimbursable expenses related to the telaprevir development program and is reimbursed for 50% of these expenses. The Company recognizes the full amount of the reimbursable costs it incurs as research and development expenses on its condensed consolidated statements of operations and recognizes the net amount that Janssen is obligated to pay the Company with respect to reimbursable expenses, after offsetting reimbursable expenses incurred by Janssen, as collaborative revenues.

In addition, the collaboration agreement requires the Company to provide Janssen certain services through the Company's third-party manufacturing network. Reimbursements from Janssen for manufacturing services are recorded as collaborative revenues.

The collaboration agreement with Janssen 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

#### **Vertex Pharmaceuticals Incorporated**

#### **Notes to Condensed Consolidated Financial Statements (Continued)**

#### (unaudited)

#### J. Collaborative Arrangements (Continued)

percentage of net sales in the Janssen territories. Each of the parties will be responsible for drug supply in their respective territories. In addition, Janssen will be responsible for certain third-party royalties on net sales in its territories. Janssen may terminate the agreement (A) prior to the receipt of marketing approval for telaprevir, without cause at any time upon six months' notice to the Company or (B) if marketing approval has been obtained, upon the later of (i) one year's advance notice and (ii) such period as may be required to assign and transfer to the Company specified filings and approvals.

During the three and nine months ended September 30, 2010 and 2009, the Company recognized the following collaborative revenues attributable to the Janssen collaboration:

|  | Т  | hree Mo<br>Septer | <br>         |      | Nine M<br>End<br>Septem | ded |        |
|--|----|-------------------|--------------|------|-------------------------|-----|--------|
|  |    | 2010              | 2009         |      | 2010                    |     | 2009   |
|  |    |                   | (in tho      | usan | ids)                    |     |        |
| Amortized portion of up-front payment                                  | \$ | 3,107             | \$<br>4,488  | \$   | 9,321                   | \$  | 15,708 |
| Net reimbursement for telaprevir development costs                     |    | 1,148             | 5,583        |      | 7,055                   |     | 24,288 |
| Reimbursement for manufacturing services                               |    | 311               | 161          |      | 6,536                   |     | 161    |
| Total collaborative revenues attributable to the Janssen collaboration | \$ | 4,566             | \$<br>10,232 | \$   | 22,912                  | \$  | 40,157 |

#### Mitsubishi Tanabe Pharma Corporation

In June 2004, the Company entered into a collaboration agreement (the "MTPC Agreement") with Mitsubishi Tanabe Pharma Corporation ("Mitsubishi Tanabe"), pursuant to which Mitsubishi Tanabe agreed to provide financial and other support for the development and commercialization of telaprevir. Under the terms of the agreement, Mitsubishi Tanabe has the right to develop and commercialize telaprevir in Japan and certain other Far East countries. The MTPC Agreement provided for payments by Mitsubishi Tanabe to the Company through Phase 2 clinical development, including an up-front license fee, development-stage milestone payments and reimbursement of certain drug development costs for telaprevir.

On July 30, 2009, the Company and Mitsubishi Tanabe amended the MTPC Agreement. Under the amended agreement, Mitsubishi Tanabe paid the Company \$105.0 million in the third quarter of 2009, and the Company may receive a further contingent milestone payment ranging from between \$15.0 million to \$65.0 million. The amended agreement provides to Mitsubishi Tanabe a fully-paid license to commercialize telaprevir to treat HCV infection in Japan and specified other countries in the Far East, as well as rights to manufacture telaprevir for sale in its territory. Mitsubishi Tanabe is responsible for its own development and manufacturing costs in its territory. Mitsubishi Tanabe may terminate the agreement at any time without cause upon 60 days' prior written notice to the Company.

Prior to the amendment, the Company recognized revenues based on an amortized portion of the 2004 up-front payment, milestones, if any, and reimbursement of certain of the Company's expenses incurred in telaprevir development. The \$105.0 million payment that the Company received in the third quarter of 2009 pursuant to the amended agreement is a nonrefundable, up-front license fee and revenues related to this payment are being recognized on a straight-line basis over the Company's

#### **Vertex Pharmaceuticals Incorporated**

#### **Notes to Condensed Consolidated Financial Statements (Continued)**

#### (unaudited)

#### J. Collaborative Arrangements (Continued)

expected period of performance under the amended agreement. As of September 30, 2010, there was \$60.5 million in deferred revenues related to this up-front license payment that will be recognized over the remaining period of performance. In connection with the amendment to the MTPC Agreement, the Company agreed to supply manufacturing services to Mitsubishi Tanabe through the Company's third-party manufacturing network. As of September 30, 2010, there was \$27.0 million in deferred revenues related to manufacturing services that Mitsubishi Tanabe has paid for, but which have not been completed.

During the three and nine months ended September 30, 2010 and 2009, the Company recognized the following collaborative revenues attributable to the Mitsubishi Tanabe collaboration:

|  | Т              | \$ 9,558 \$ 6,386<br>505<br>1,498 |  |       | End | led    |      |       |
|--|----------------|-----------------------------------|--|-------|-----|--------|------|-------|
|  | 2010 2009 2010 |                                   |  |       |     |        | 2009 |       |
|  |                |                                   | September 30,         September 30,           2010         2009         2010         2009           (in thousands)           9,558         \$ 6,386         \$ 28,674         \$ 6,4           505         1,2           1,498         3,976 |       |     |        |      |       |
| Amortized portion of up-front payment  | \$             | 9,558                             | \$   | 6,386 | \$  | 28,674 | \$   | 6,469 |
| Reimbursement for telaprevir development costs                                   |                |                                   |  | 505   |     |        |      | 1,265 |
| Payments for manufacturing services  |                | 1,498                             |  |       |     | 3,976  |      |       |
|  |                |                                   |  |       |     |        |      |       |
| Total collaborative revenues attributable to the Mitsubishi Tanabe collaboration | \$             | 11,056                            | \$   | 6,891 | \$  | 32,650 | \$   | 7,734 |

### K. Acquisition of ViroChem Pharma Inc.

On March 12, 2009, the Company acquired 100% of the outstanding equity of ViroChem Pharma Inc. ("ViroChem"), a privately-held biotechnology company based in Canada, for \$100.0 million in cash and 10,733,527 shares of the Company's common stock. Vertex acquired ViroChem in order to add two clinical development-stage HCV polymerase inhibitors to Vertex's HCV drug development portfolio. At the time of the acquisition, ViroChem was also engaged in research activities related to viral diseases and was developing an early-stage drug candidate for the treatment of patients with HIV infection. The transaction was accounted for under the acquisition method of accounting. All of the assets acquired and liabilities assumed in the transaction were recognized at their acquisition-date fair values, while transaction costs and restructuring costs associated with the transaction were expensed as incurred. The intangible assets and goodwill related to the ViroChem acquisition are tested for impairment on an annual basis as of October 1, or earlier if impairment indicators are present.

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#### **Vertex Pharmaceuticals Incorporated**

#### **Notes to Condensed Consolidated Financial Statements (Continued)**

#### (unaudited)

#### K. Acquisition of ViroChem Pharma Inc. (Continued)

All of the intangible assets acquired in the ViroChem acquisition related to in-process research and development assets. These in-process research and development assets primarily related to ViroChem's two clinical development-stage HCV polymerase inhibitors, VX-222 and VX-759, which accounted for \$412.9 million and \$105.8 million, respectively, of the intangible assets reflected on the Company's condensed consolidated balance sheets as of September 30, 2010 and December 31, 2009. The Company's condensed consolidated balance sheets also reflect goodwill that relates to the potential synergies from the possible development of combination therapies involving telaprevir and the acquired drug candidates. No impairment has been found for VX-222 or VX-759 or goodwill since the acquisition date.

In addition, the Company considered ViroChem's other clinical drug candidates and determined that VCH-286, ViroChem's lead HIV drug candidate, had an estimated fair value of \$7.2 million at the acquisition date, based on development costs through the acquisition date. Pursuant to the Company's 2009 annual impairment analysis, the Company determined that VCH-286's fair value was zero, resulting in a \$7.2 million impairment charge in the fourth quarter of 2009.

The deferred tax liability of \$160.3 million as of September 30, 2010 and December 31, 2009 primarily relates to the tax impact of future amortization or impairments associated with the identified intangible assets acquired from ViroChem, which are not deductible for tax purposes. In connection with the impairment charge for VCH-286, the Company also recorded an adjustment of \$2.2 million to the deferred tax liability in the fourth quarter of 2009.

In connection with the acquisition of ViroChem, the Company incurred \$7.8 million in expenses in the first quarter of 2009, which are reflected as acquisition-related expenses on the condensed consolidated statement of operations in the nine months ended September 30, 2009. These costs include transaction expenses as well as a restructuring charge the Company incurred in March 2009 when it determined it would restructure ViroChem's operations in order to focus on ViroChem's HCV development programs. As a result of this restructuring plan, which was completed in the second quarter of 2009, Vertex recorded a \$2.1 million expense related to employee severance, benefits and related costs in the first quarter of 2009.

## L. September 2009 Financial Transactions

2012 Notes

On September 30, 2009, the Company sold \$155.0 million in aggregate principal amount of secured notes due 2012 (the "2012 Notes") for an aggregate of \$122.2 million pursuant to a note purchase agreement with Olmsted Park S.A. (the "Purchaser"). The 2012 Notes were issued pursuant to, and the 2012 Notes are governed by the terms of, an indenture entered into on September 30, 2009 between the Company and U.S. Bank National Association, as trustee and collateral agent. In connection with the issuance of the 2012 Notes, the Company granted a security interest to the Purchaser with respect to \$155.0 million of future telaprevir milestone payments that the Company is eligible to earn from Janssen for the future filing, approval and launch of telaprevir in the European Union.

The 2012 Notes were issued at a discount and do not pay current interest prior to maturity. The 2012 Notes will mature on October 31, 2012, subject to earlier mandatory redemption to the extent specified milestone events set forth in the Company's collaboration with Janssen occur prior to

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#### **Vertex Pharmaceuticals Incorporated**

#### **Notes to Condensed Consolidated Financial Statements (Continued)**

#### (unaudited)

#### L. September 2009 Financial Transactions (Continued)

October 31, 2012. \$100.0 million of these potential milestone payments relate to the regulatory filing with and approval of telaprevir by the European Medicines Agency, and \$55.0 million of these potential milestone payments relate to the launch of telaprevir in the European Union. The Company will be required to redeem the portion of the 2012 Notes equal to each milestone payment as each such milestone payment is earned under the Janssen collaboration.

The holders of the 2012 Notes have the right to cause the Company to repay all or any part of the 2012 Notes at 100% of the principal amount of the 2012 Notes to be repurchased if a change of control of the Company occurs. The Company may also redeem all or any part of the 2012 Notes at any time at 100% of the principal amount of the 2012 Notes to be redeemed. Upon certain events of default occurring and continuing, either the trustee or the holders of not less than 25% in aggregate principal amount of the 2012 Notes then outstanding may declare the principal of the 2012 Notes immediately due and payable. In the case of certain events of bankruptcy, insolvency or reorganization relating to the Company, the principal amount of the 2012 Notes shall automatically become immediately due and payable.

The Company has determined that the 2012 Notes contain an embedded derivative related to the potential mandatory redemption or early repayment of the 2012 Notes at the principal amount prior to their maturity date. The Company bifurcated the embedded derivative from the 2012 Notes because the features of the embedded derivative were not clearly and closely related to the 2012 Notes.

The Company determines the fair value of the embedded derivative based on a probability-weighted model of the discounted value that market participants would ascribe to the potential mandatory redemption and early repayment features of the 2012 Notes. The Company records quarterly interest expense related to the 2012 Notes determined using the effective interest rate method. The fair value of this embedded derivative is evaluated quarterly, with any changes in the fair value of the embedded derivative resulting in a corresponding loss or gain. Changes in the fair value of the embedded derivative that result in a loss increase the liability each quarter by an amount corresponding to the loss and changes in the fair value of the embedded derivative that result in a gain decrease the liability each quarter by an amount corresponding to the gain. The liabilities related to the 2012 Notes, including the embedded derivative, are reflected together on the Company's condensed consolidated balance sheets. As of September 30, 2010, a portion of these liabilities, corresponding to the portion of the 2012 Notes that will be repaid in connection with achieving the first potential milestone, is reflected as a current liability. The balance of the liabilities related to the 2012 Notes is reflected as a long-term liability.

#### Sale of Future Milestone Payments

On September 30, 2009, the Company entered into two purchase agreements with the Purchaser pursuant to which the Company sold its rights to an aggregate of \$95.0 million in potential future milestone payments pursuant to the Janssen agreement related to the launch of telaprevir in the European Union, for nonrefundable payments totaling \$32.8 million. The purchase agreements contain representations, warranties, covenants and indemnification obligations of each party, including the obligation of the Company to make the milestone payments to the Purchaser when the underlying milestone events are achieved if the Janssen agreement has been terminated.

#### **Vertex Pharmaceuticals Incorporated**

#### **Notes to Condensed Consolidated Financial Statements (Continued)**

(unaudited)

#### L. September 2009 Financial Transactions (Continued)

The Company determined that this sale of a potential future revenue stream should be accounted for as a liability because the Company has significant continuing involvement in the generation of the potential milestone payments pursuant to its collaboration agreement with Janssen. As a result, the Company records a liability on its condensed consolidated balance sheets equal to the fair value of the purchase agreements. No revenues or deferred revenues have been recorded on account of the amounts that the Company received from the Purchaser pursuant to these purchase agreements. In addition, the Company determined that the purchase agreements are free-standing derivative instruments. The aggregate fair value of the free-standing derivatives created by the sale of the rights to future milestone payments to the Purchaser pursuant to the purchase agreements is based on a probability-weighted model of the discounted value that market participants would ascribe to these rights. The models used to estimate the fair value of the rights sold to the Purchaser pursuant to the purchase agreements require the Company to make estimates regarding, among other things, the assumptions market participants would make regarding the timing and probability of achieving the milestones and the appropriate discount rates. The fair value of the rights sold to the Purchaser pursuant to the purchase agreements will be evaluated each reporting period, with any changes in the fair value of the derivative instruments based on the probability of achieving the milestones, the timing of achieving the milestones or discount rates resulting in a corresponding gain or loss. Because the Company's estimate of the fair value of the rights to the future milestone payments includes the application of a discount rate to reflect the time-value-of-money, the Company expects to record costs related to this liability each quarter.

#### Costs and Liabilities Related to September 2009 Financial Transactions

In the second and third quarters of 2010, the Company received positive data from the Phase 3 clinical trials in the Company's registration program for telaprevir. Based on the positive data, the Company revised its estimates regarding the timing and probability of achieving the milestones under the Company's collaboration agreement with Janssen, which resulted in a significant increase in the fair value of the liability related to the sale of potential future milestone payments during the second and third quarters of 2010.

|  | <br>ree Month<br>Septembe |         |      |        |      |
|--|---------------------------|---------|------|--------|------|
|  | 2010                      | 2009    |      | 2010   | 2009 |
|  |                           | (in tho | usan |        |      |
| Expenses and Losses:   |                           |         |      |        |      |
| Interest expense related to 2012 Notes   | \$<br>3,827               | \$      | \$   | 11,112 | \$   |
| Change in fair value of embedded derivative related to   |                           |         |      |        |      |
| 2012 Notes   | (3,130)                   |         |      | 718    |      |
| Change in fair value of free-standing derivatives related to sale of potential future milestone payments | 9,041                     |         |      | 33,916 |      |
| Total September 2009 financial transaction expenses  | \$<br>9,738               | \$      | \$   | 45,746 | \$   |
|  | 26                        |         |      |        |      |

#### **Vertex Pharmaceuticals Incorporated**

#### **Notes to Condensed Consolidated Financial Statements (Continued)**

#### (unaudited)

#### L. September 2009 Financial Transactions (Continued)

|  | ember 30,<br>2010 | De | cember 31,<br>2009 |  |  |
|--|-------------------|----|--------------------|--|--|
|  | (in thousands)    |    |                    |  |  |
| Liabilities:   |                   |    |                    |  |  |
| 2012 Notes, excluding fair value of embedded derivative            | \$<br>121,335     | \$ | 111,313            |  |  |
| Embedded derivative related to 2012 Notes                          | 11,170            |    | 10,452             |  |  |
| Liability related to sale of potential future milestone payments   | 72,123            |    | 38,207             |  |  |
|  |                   |    |                    |  |  |
| Total liabilities related to September 2009 financial transactions | \$<br>204,628     | \$ | 159,972            |  |  |

#### M. Sale of HIV Protease Inhibitor Royalty Stream

In December 1993, the Company and GlaxoSmithKline plc entered into a collaboration agreement to research, develop and commercialize HIV protease inhibitors, including Agenerase (amprenavir) and Lexiva/Telzir (fosamprenavir calcium). Under the collaboration agreement, GlaxoSmithKline agreed to pay the Company royalties on net sales of drugs developed under the collaboration. GlaxoSmithKline has the right to terminate its arrangement with the Company without cause upon twelve months' notice. Termination of the collaboration agreement by GlaxoSmithKline will relieve it of its obligation to make further payments under the agreement and will end any license granted to GlaxoSmithKline by the Company under the agreement. In June 1996, the Company and GlaxoSmithKline obtained a worldwide, non-exclusive license under certain G.D. Searle & Co. ("Searle," now owned by Pharmacia/Pfizer) patents in the area of HIV protease inhibition. Searle is paid royalties based on net sales of Agenerase and Lexiva/Telzir.

On May 30, 2008, the Company entered into a purchase agreement (the "Purchase Agreement") with Fosamprenavir Royalty, L.P. ("Fosamprenavir Royalty") pursuant to which the Company sold, and Fosamprenavir Royalty purchased, the Company's right to receive royalty payments, net of royalty amounts to be earned and due to Searle, arising from sales of Lexiva/Telzir and Agenerase under the Company's 1993 agreement with GlaxoSmithKline, from April 1, 2008 to the end of the term of the collaboration agreement, for a one-time cash payment of \$160.0 million to the Company. In accordance with the Purchase Agreement, GlaxoSmithKline makes all royalty payments, net of the subroyalty amounts payable to Searle, directly to Fosamprenavir Royalty. The Purchase Agreement also contains other representations, warranties, covenants and indemnification obligations. The Company continues to be obligated for royalty amounts earned and that are due to Searle. The Company has instructed GlaxoSmithKline to pay such amounts directly to Searle as they become due.

Because the transaction was structured as a non-cancellable sale, the Company has no significant continuing involvement in the generation of the cash flows due to Fosamprenavir Royalty and there are no guaranteed rates of return to Fosamprenavir Royalty, the Company recorded the proceeds as deferred revenues. These deferred revenues are being recognized as royalty revenues over the life of the collaboration agreement because of the Company's continuing involvement in the royalty arrangement over the term of the Purchase Agreement. Such continuing involvement, which is required pursuant to covenants contained in the Purchase Agreement, includes overseeing GlaxoSmithKline's compliance with the collaboration agreement, monitoring and defending patent infringement, adverse claims or litigation involving the royalty stream, undertaking to cooperate with Fosamprenavir Royalty's efforts to find a new license partner if GlaxoSmithKline terminates the collaboration agreement, and

#### **Vertex Pharmaceuticals Incorporated**

#### **Notes to Condensed Consolidated Financial Statements (Continued)**

(unaudited)

#### M. Sale of HIV Protease Inhibitor Royalty Stream (Continued)

complying with the license agreement with Searle, including the obligation to make future royalty payments to Searle.

The Company recorded \$155.1 million, representing the proceeds of the transaction less the net royalty payable to Fosamprenavir Royalty for the period from April 1, 2008 through May 30, 2008, as deferred revenues to be recognized as royalty revenues over the life of the collaboration agreement based on the units-of-revenue method. The amount of deferred revenues to be recognized as royalty revenues in each period is calculated by multiplying the following: (1) the net royalty payments due to Fosamprenavir Royalty for the period by (2) the ratio of the remaining deferred revenue amount to the total estimated remaining net royalties that GlaxoSmithKline is expected to pay Fosamprenavir Royalty over the term of the collaboration agreement. As of September 30, 2010, the Company had \$117.9 million in deferred revenues related to the Purchase Agreement. In addition, the Company continues to recognize royalty revenues for the portion of the royalty earned that is due to Searle.

The Company recognizes royalty expenses in each period based on (i) deferred transaction expenses in the same manner and over the same period during which the related deferred revenues are recognized as royalty revenues plus (ii) the subroyalty paid by GlaxoSmithKline to Searle on net sales of Agenerase and Lexiva/Telzir for the period.

#### N. Guarantees

As permitted under Massachusetts law, the Company'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.

The Company customarily agrees in the ordinary course of its business to indemnification provisions in agreements with clinical trial investigators and sites in its drug development programs, in sponsored research agreements with academic and not-for-profit institutions, in various comparable agreements involving parties performing services for the Company, and in its real estate leases. The Company also customarily agrees to certain indemnification provisions in its drug discovery, development and commercialization collaboration agreements. With respect to the Company's clinical trials and sponsored research agreements, these indemnification provisions typically apply to any claim asserted against the investigator or the investigator's institution relating to personal injury or property damage, violations of law or certain breaches of the Company's contractual obligations arising out of the research or clinical testing of the Company's compounds or drug candidates. With respect to lease agreements, the indemnification provisions typically apply to claims asserted against the landlord relating to personal injury or property damage caused by the Company, to violations of law by the Company or to certain breaches of the Company's contractual obligations. The indemnification provisions appearing in the Company's collaboration agreements are similar, but in addition provide some limited indemnification obligation generally

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#### **Vertex Pharmaceuticals Incorporated**

#### **Notes to Condensed Consolidated Financial Statements (Continued)**

(unaudited)

#### N. Guarantees (Continued)

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 February 12, 2008, the Company entered into underwriting agreements with Merrill Lynch, Pierce, Fenner & Smith Incorporated; on September 18, 2008, the Company entered into an underwriting agreement with Goldman, Sachs & Co.; on February 18, 2009, the Company entered into an underwriting agreement with Merrill Lynch, Pierce, Fenner & Smith Incorporated; on December 2, 2009, the Company entered into an underwriting agreement with Goldman, Sachs & Co.; and on September 23, 2010, the Company entered into an underwriting agreement with Merrill Lynch, Pierce, Fenner & Smith Incorporated (collectively, the "Underwriting Agreements"), in each case as the representative of the several underwriters, if any, named in such agreements, relating to the public offering and sale of shares of the Company's common stock or convertible senior subordinated notes. The Underwriting Agreement relating to each offering requires the Company to indemnify the underwriters of that public offering against any loss they may suffer by reason of the Company's breach of any representation or warranty 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 Underwriting Agreements are of a type customary in agreements of this sort. The Company believes the estimated fair value of these indemnification arrangements is minimal.

#### O. 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 as of September 30, 2010 or December 31, 2009.

#### P. Recent Accounting Pronouncements

In April 2010, the Financial Accounting Standards Board ("FASB") provided updated guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research and development transactions. The update is effective on a prospective basis for fiscal years beginning on or after June 15, 2010, with early adoption permitted. The Company is currently evaluating the effect of this update to its accounting and reporting systems and processes; however, at this time the Company is unable to quantify the impact on its condensed consolidated financial statements of its adoption or determine the timing and method of its adoption.

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#### **Vertex Pharmaceuticals Incorporated**

#### **Notes to Condensed Consolidated Financial Statements (Continued)**

(unaudited)

#### P. Recent Accounting Pronouncements (Continued)

In September 2009, the FASB provided updated guidance (1) on whether multiple deliverables exist, how the deliverables in a revenue arrangement should be separated and how the consideration should be allocated; (2) requiring an entity to allocate revenue in an arrangement using estimated selling prices of deliverables if a vendor does not have vendor- specific objective evidence or third-party evidence of selling price; and (3) eliminating the use of the residual method and requiring an entity to allocate revenue using the relative selling price method. The update is effective for fiscal years beginning on or after June 15, 2010, with early adoption permitted. Adoption may either be on a prospective basis or by retrospective application. The Company is currently evaluating the effect of this update to its accounting and reporting systems and processes; however, at this time the Company is unable to quantify the impact on its condensed consolidated financial statements of its adoption or determine the timing and method of its adoption.

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#### 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 evaluated telaprevir, our lead drug candidate, in a registration program focused on treatment-naïve patients with hepatitis C virus, or HCV, infection and patients with HCV infection who have failed to achieve a sustained viral response, or SVR, with prior interferon-based treatment. We reported positive data from this registration program in the second and third quarters of 2010, and we intend to complete the submission of our new drug application, or NDA, for telaprevir in the United States in the fourth quarter of 2010. We expect to initiate sales of telaprevir in the United States in 2011. We are pursuing a number of other clinical development programs, including a registration program for VX-770, the lead drug candidate in our cystic fibrosis, or CF, program. We plan to continue investing in our research and development programs and to develop selected drug candidates that emerge from those programs, alone or with third-party collaborators.

#### **Business Focus**

Over the past several years, we have invested significant financial and management resources in the late-stage development of telaprevir and in strengthening our pipeline of drug candidates, through research and development activities and the 2009 acquisition of ViroChem Pharma Inc., or ViroChem. To fund these investments, we have raised significant capital through sales of common stock and convertible debt and other financial transactions. In order to execute our business plan and achieve profitability, we will need to obtain approval to market telaprevir on a timely basis and effectively commercialize telaprevir in the United States, where we have marketing rights to telaprevir.

We believe that over the next several years we will need to further investigate other potential therapies for the treatment of HCV infection in addition to telaprevir and to research, develop and commercialize additional drug candidates in other therapeutic areas with significant unmet needs. As a result, we are committed to advancing the other clinical drug candidates in our pipeline and investing in our preclinical research programs. We are conducting a Phase 2a clinical trial to evaluate telaprevir in combination with VX-222, an investigational HCV polymerase inhibitor that we obtained through our acquisition of ViroChem. The objective of our ongoing clinical trials of HCV drug candidates and our earlier-stage activities with respect to potential additional and combination treatments for HCV infection is to significantly improve the treatment options for patients with genotype 1 HCV infection.

The most advanced of our other drug candidates is VX-770, which we are evaluating in a fully-enrolled registration program that focuses on patients with CF who have the G551D mutation in the gene responsible for CF. We expect that we will receive final data from this registration program in the first half of 2011. In October 2010, we also initiated a Phase 2a clinical trial to evaluate VX-770 in combination with VX-809 in patients with the F508del mutation, the most common mutation in the gene responsible for CF. We are conducting a Phase 2a clinical trial of VX-509 in patients with moderate-to-severe rheumatoid arthritis and a fully-enrolled Phase 2a clinical trial of VX-765 in patients with treatment-resistant epilepsy. We expect data from the VX-765 clinical trial in the fourth quarter of 2010 and interim data from the VX-509 clinical trial in 2011.

Drug Discovery, Clinical Development and Regulatory Approval

Discovery and development of a new pharmaceutical product is a difficult and lengthy process that requires significant financial resources along with extensive technical and regulatory expertise and can 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, side-effects, proper dosage levels and a variety of other physical and

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chemical characteristics that are important in determining whether a drug candidate should be approved for marketing as a pharmaceutical product. The toxicity characteristics and profiles 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, most drug candidates that do advance into formal development never become commercial products and many drug candidates that complete Phase 3 clinical trials are not approved for commercial sale. 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 at any point during the discovery, development or approval process, including, for example, a lack of sufficient efficacy against the disease target, a 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 targeted or that adversely affect the competitive commercial profile of the drug candidate. Throughout the development process for a drug candidate, we must work collaboratively with regulatory authorities, including the United States Food and Drug Administration, or FDA, in order to identify the specific scientific issues that need to be addressed in the clinical trials to support continued development and approval of the drug candidate. If the data from our ongoing clinical trials or nonclinical studies regarding the safety or efficacy of a drug candidate are not favorable or regulatory authorities request additional clinical trials or changes to existing clinical trial protocols, we may be forced to delay or terminate the clinical development program for that drug candidate, which, particularly in the case of tela

If we complete a registration program for a drug candidate and believe the data supports approval of the drug candidate, we will submit an NDA to the FDA to market the drug candidate in the United States, and we or our collaborators will need to obtain the requisite approval from comparable authorities in foreign jurisdictions. Submitting an NDA and comparable foreign filings requires compiling, analyzing and synthesizing data from the clinical trials and nonclinical studies of the drug candidate and data regarding chemistry, manufacturing and controls, or CMC; developing proposed labeling; and providing plans for post-marketing studies, safety monitoring and risk evaluation and mitigation. To obtain approval, we must, among other things, demonstrate with evidence gathered in nonclinical and well-controlled clinical trials that the drug candidate is safe and effective for the disease it is intended to treat and that the manufacturing facilities, processes and controls for the drug candidate are adequate. After receiving an NDA or foreign regulatory submission, the FDA and/or other regulatory authorities may request supplemental analyses or data and/or ask us to complete additional clinical trials to support approval. In addition, the FDA and/or other regulatory authorities will conduct audits and inspections of our and our third-party contractors' practices, procedures and facilities. The FDA and foreign regulatory authorities will have substantial discretion in deciding whether or not each of our drug candidates should be granted approval based on the benefits and risks of a drug candidate in the treatment of a particular disease. Their review of our NDAs or foreign regulatory filings could delay, limit or prevent regulatory approval of the drug candidate in the United States and foreign jurisdictions.

Because our investments are subject to considerable risks, we closely monitor the results of our discovery research, clinical trials and nonclinical studies and frequently evaluate our drug development programs in light of new data and scientific, business and commercial insights, with the objective of balancing risk and potential. This process can result in relatively abrupt changes in focus and priority as new information becomes available and we gain additional understanding of our ongoing programs and potential new programs. Although we believe that our development activities and the clinical trial data we have obtained regarding telaprevir have reduced the risks associated with seeking regulatory approval, we cannot be sure that our development of telaprevir will lead to regulatory approval of telaprevir in the United States or that such approval, if obtained, will occur in 2011. With respect to

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our other drug candidates, including VX-770, we have more limited data from clinical trials and nonclinical studies and as a result it is difficult to predict which, if any, of these drug candidates ultimately will become pharmaceutical products. If regulatory delays are significant or regulatory approval is limited or denied altogether, our financial results and the commercial prospects for the drug candidates involved will be harmed.

Recent Developments in Clinical Programs

#### **Telaprevir Registration Program**

Our registration program for telaprevir consists of two Phase 3 clinical trials in treatment-naïve patients infected with genotype 1 HCV, ADVANCE and ILLUMINATE, and a Phase 3 clinical trial in patients infected with genotype 1 HCV who failed to achieve an SVR with prior interferon-based treatment, REALIZE. This clinical development program was designed to support registration by us of telaprevir in North America and by our collaborator, Janssen Pharmaceuticals, N.V., or Janssen, a Johnson & Johnson company, in the European Union and other international markets. An additional collaborator, Mitsubishi Tanabe Pharma Corporation, is responsible for the commercialization of telaprevir in Japan and specified other countries in the Far East.

As part of our rolling NDA submission, we have submitted our CMC package, nonclinical package and clinical data from ADVANCE to the FDA. We intend to complete the submission of the NDA for telaprevir in the fourth quarter of 2010. Janssen has indicated that it plans to submit its marketing authorization application, or MAA, for telaprevir to the European Medicines Agency, or EMA, in the fourth quarter of 2010. Our United States patent covering the composition-of-matter of telaprevir was granted in October 2010 and is scheduled to expire in 2025.

#### REALIZE

REALIZE was a pivotal three-arm double-blinded placebo-controlled clinical trial of telaprevir-based treatment regimens that enrolled 662 patients with genotype 1 HCV infection who failed to achieve an SVR after treatment with pegylated-interferon, or peg-IFN, and ribavirin, or RBV. Patients were randomized 2:2:1 to the two telaprevir-based treatment arms and the control arm, respectively. REALIZE included the following patient groups:

null responders those patients who experienced less than a 2 log reduction in HCV RNA levels at week 12 of prior therapy;

partial responders those patients who experienced at least a 2 log reduction in HCV RNA levels at week 12, but who failed to achieve undetectable HCV RNA levels by week 24 in their prior course of therapy; and

relapsers those patients who experienced undetectable HCV RNA levels at the completion of at least 42 weeks of prior treatment, but who relapsed after treatment ended.

REALIZE is the only Phase 3 clinical trial of an HCV protease inhibitor to date to enroll null responders. REALIZE's primary endpoint was SVR, defined as the percentage of patients who had undetectable HCV RNA levels both at the end of treatment and 24 weeks after the end of treatment, on an intent-to-treat basis in each of the two telaprevir-based treatment arms compared to the control arm, as well as across the three subgroups of patients in the trial arms. One of the two telaprevir-based treatment arms evaluated a delayed-start approach in which patients received four weeks of pre-treatment with peg-IFN and RBV before receiving telaprevir. The secondary endpoint of REALIZE was the safety of telaprevir when dosed in combination with peg-IFN and RBV.

The following table sets forth the SVR rates on an intent-to-treat basis for patients in the control arm and the combined telaprevir-based treatment arms. In addition, the table includes a supplemental

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analysis of the SVR rates on an intent-to-treat basis of the pooled relapsers and partial responders in each of the control arm and in the two telaprevir-based treatment arms combined.

|                                 | Relapsers            | Partial Responders | Null Responders | Overall   |  |  |  |  |  |  |  |
|---------------------------------|----------------------|--------------------|-----------------|-----------|--|--|--|--|--|--|--|
| Telaprevir-based treatment arms | 86%                  | 57%                | 31%             | 65%       |  |  |  |  |  |  |  |
|                                 | (245/286)            | (55/97)            | (46/147)        | (346/530) |  |  |  |  |  |  |  |
|                                 |                      |                    |                 |           |  |  |  |  |  |  |  |
|                                 | Pooled Analysis: 78% |                    |                 |           |  |  |  |  |  |  |  |
| (300/383)                       |                      |                    |                 |           |  |  |  |  |  |  |  |
|                                 |                      |                    |                 |           |  |  |  |  |  |  |  |
| Control arm                     | 24%                  | 15%                | 5%              | 17%       |  |  |  |  |  |  |  |
|                                 | (16/68)              | (4/27)             | (2/37)          | (22/132)  |  |  |  |  |  |  |  |
|                                 |                      |                    |                 |           |  |  |  |  |  |  |  |
|                                 | Pooled               | Analysis: 21%      |                 |           |  |  |  |  |  |  |  |
|                                 |                      | (20/95)            |                 |           |  |  |  |  |  |  |  |

The table below sets forth the SVR rates on an intent-to-treat basis in each of the arms across the three subgroups of patients.

|   |           | Partial    | Null       |         |
|---|-----------|------------|------------|---------|
|   | Relapsers | Responders | Responders | Overall |
| Telaprevir-based treatment arm (simultaneous start):                            |           |            |            |         |
| telaprevir in combination with peg-IFN and RBV for 12 weeks, followed by        |           |            |            |         |
| peg-IFN combined with RBV for 36 weeks  | 83%       | 59%        | 29%        | 64%     |
| Telaprevir-based treatment arm (delayed start):                                 |           |            |            |         |
| peg-IFN and RBV for 4 weeks, followed by telaprevir in combination with peg-IFN |           |            |            |         |
| and RBV for 12 weeks, followed by peg-IFN combined with RBV for 32 weeks        | 88%       | 54%        | 33%        | 66%     |
| Control arm:  |           |            |            |         |
| peg-IFN combined with RBV for 48 weeks  | 24%       | 15%        | 5%         | 17%     |

### ADVANCE

ADVANCE was a pivotal three-arm double-blinded placebo-controlled clinical trial that enrolled 1,095 treatment-naïve patients with genotype 1 HCV infection. ADVANCE had two telaprevir-based treatment arms, one in which patients received 12 weeks of telaprevir-based triple combination therapy and one in which patients received 8 weeks of telaprevir-based triple combination therapy, in each case taking peg-IFN and RBV for a period of time after completing telaprevir dosing. Patients in both of the telaprevir-based treatment arms who met criteria for extended rapid viral response, or eRVR, completed all treatment after 24 weeks, while patients who responded to treatment but did not meet the eRVR criteria continued receiving peg-IFN and RBV for a total of 48 weeks of therapy. To satisfy our eRVR criteria, a patient must have undetectable HCV RNA levels at the end of week 4 and week 12 after the start of treatment.

The primary endpoint of ADVANCE was SVR in the telaprevir-based treatment arms compared to the control arm. The secondary endpoint was the safety of telaprevir when dosed in combination with

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peg-IFN and RBV. The SVR rates on an intent-to-treat basis for patients in ADVANCE are set forth in the table below.

|  | SVR |
|--|-----|
| 12-week telaprevir-based treatment arm:  |     |
| telaprevir in combination with peg-IFN and RBV for 12 weeks, followed by peg-IFN combined with RBV for 12 weeks or         |     |
| 36 weeks   | 75% |
| 8-week telaprevir-based treatment arm:   |     |
| telaprevir in combination with peg-IFN and RBV for 8 weeks, followed by peg-IFN combined with RBV for 16 weeks or 40 weeks | 69% |
| 48-week control arm:   |     |
| 48 weeks of therapy with peg-IFN and RBV   | 44% |

#### **ILLUMINATE**

ILLUMINATE was a supplemental Phase 3 clinical trial that included evaluation of 24-week and 48-week total treatment durations in treatment-naïve patients infected with genotype 1 HCV who achieved an eRVR in response to telaprevir-based treatment regimens. This clinical trial was a randomized, open-label trial that enrolled 540 patients. ILLUMINATE was designed to supplement SVR data obtained from ADVANCE to evaluate the benefits and risks, for patients who achieve an eRVR, of extending total treatment duration from 24 to 48 weeks, through a non-inferiority evaluation of the 24-week and 48-week regimens. The SVR rates from the trial met the predefined non-inferiority criteria established to compare the 24-week regimen and the 48-week regimen and thus indicated that there was no additional benefit to extending treatment to 48 weeks in patients who achieve an eRVR. The following table provides SVR rates for patients who achieved an eRVR at week 4 and week 12, and remained on treatment through week 20.

|   | SVR Rate<br>(For Patients Who<br>Achieved eRVR) | Patients with<br>SVR/Total Patients<br>(Who Achieved eRVR) |
|---|---|--|
| 24-week telaprevir-based treatment regimen:   |   |  |
| telaprevir in combination with peg-IFN and RBV for 12 weeks, followed by peg-IFN                                |   |  |
| combined with RBV for 12 weeks  | 92%   | 149/162  |
| 48-week telaprevir-based treatment regimen:   |   |  |
| telaprevir in combination with peg-IFN and RBV for 12 weeks, followed by peg-IFN combined with RBV for 36 weeks | 88%   | 140/160  |

The overall SVR for the patients enrolled in ILLUMINATE on an intent-to-treat basis was 72%. For patients who received the 24-week telaprevir-based treatment regimen after achieving an eRVR, remained on treatment through week 20 and had undetectable HCV levels at the end of treatment, the relapse rate was 5.7% (9/159). The relapse rate for patients who achieved an eRVR and received the 48-week telaprevir-based treatment regimen was 1.9% (3/154).

# Safety and Tolerability

The most common adverse events reported in the telaprevir-based treatment arms were fatigue, rash, pruritus, nausea, headache and anemia, of which anemia, rash, pruritus and nausea occurred more frequently in the telaprevir-based treatment arms than in the control arms. The majority of these adverse events were graded mild to moderate. In all of our Phase 3 clinical trials, the use of erythropoiesis-stimulating agents was not allowed.

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Discontinuation of all study drugs in REALIZE, ADVANCE and ILLUMINATE during the telaprevir-based dosing periods were as follows:

| Te | otal | A      |      |
|----|------|--------|------|
|    | J    | Anemia | Rash |
|    | 4%   | 0.6%   | 0.4% |
|    | 3%   | 0.0%   | 0.0% |

Discontinuation of All Study

|  | - 0 |      |      |
|--|-----|------|------|
| REALIZE  |     |      |      |
| Telaprevir-based treatment arms:                     | 4%  | 0.6% | 0.4% |
| Control arm:   | 3%  | 0.0% | 0.0% |
| ADVANCE  |     |      |      |
| 12-week telaprevir-based treatment arm:              | 7%  | 0.8% | 1.4% |
| 8-week telaprevir-based treatment arm:               | 8%  | 3.3% | 0.5% |
| Control arm:   | 4%  | 0.6% | 0.0% |
| ILLUMINATE   |     |      |      |
| Telaprevir-based treatment regimen (no control arm): | 7%  | 1.1% | 0.6% |
| -  |     |      |      |

### Telaprevir Twice-daily Dosing and HIV Co-infection Clinical Trials

In October 2010, Tibotec initiated a Phase 3b clinical trial to evaluate twice-daily dosing of telaprevir compared to three-times-daily dosing of telaprevir. We expect Tibotec will begin screening patients for this clinical trial in November 2010. In October 2010, we completed enrollment of a Phase 2 clinical trial in patients co-infected with HCV and the human immunodeficiency virus, or HIV. The primary endpoint of this clinical trial is to evaluate the safety and tolerability of telaprevir-based therapy in patients co-infected with HCV and HIV. The secondary endpoint is to evaluate SVR rates.

#### VX-222

We are conducting a four-arm Phase 2a clinical trial designed to evaluate response-guided telaprevir/VX-222-based combination treatment regimens in patients with genotype 1 HCV. This clinical trial, which began dosing patients in August 2010, originally included two treatment arms of patients receiving a four-drug treatment regimen consisting of telaprevir, VX-222, peg-IFN and RBV, as well as two treatment arms of patients receiving a two-drug treatment regimen consisting of telaprevir and VX-222, in one of a lower dose (100 mg) or a higher dose (400 mg) of VX-222. In October 2010, we modified the clinical trial to discontinue the two-drug treatment arm of patients receiving the lower dose (100 mg) of VX-222, because patients in this treatment arm met a pre-defined stopping rule related to viral breakthrough during the first four weeks of dosing. The remaining three treatment arms, including the two-drug treatment arm of patients receiving the higher (400 mg) dose of VX-222, are continuing without modification, and no viral breakthrough has been reported in these treatment arms. We have completed patient recruitment for this clinical trial, and we expect to obtain on-treatment clinical data in the first half of 2011, and SVR data in the second half of 2011.

In addition to the clinical trial evaluating VX-222 in combination with telaprevir, we are conducting a Phase 2a clinical trial to evaluate multiple doses of VX-222 in combination with only peg-IFN and RBV. This Phase 2a clinical trial is designed to evaluate the safety, tolerability and antiviral activity of two dose levels of VX-222 (400 mg and 750 mg) in a total of 50 patients with genotype 1 HCV infection. Patients in the clinical trial are receiving VX-222 in combination with peg-IFN and RBV for 12 weeks, followed by peg-IFN and RBV for 36 weeks. We began enrolling patients in this clinical trial in August 2010.

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#### VX-770

We are conducting a registration program for VX-770 that is focused on patients with CF who have the G551D mutation in the gene responsible for CF. The three clinical trials in this registration program are the Phase 3 STRIVE clinical trial in patients 12 years of age and older with the G551D mutation, the Phase 3 ENVISION clinical trial in patients between 6 to 11 years of age with the G551D mutation and the Phase 2 DISCOVER clinical trial in patients 12 years of age and older with only the F508del mutation. We completed enrollment in STRIVE in the first quarter of 2010 and in ENVISION in the second quarter of 2010. In STRIVE and ENVISION, patients in VX-770 treatment arms will receive 48-weeks of treatment with VX-770. In DISCOVER, the 16-week dosing period is complete. We expect that we will receive final data from the registration program in the first half of 2011, and if we believe the data from the registration program support approval, we could submit an NDA for VX-770 to the FDA in the second half of 2011.

#### VX-770 and VX-809 Combination Clinical Trial

In October 2010, we initiated a Phase 2a clinical trial that will evaluate multiple combinations of VX-770 and VX-809. The trial is designed to evaluate the safety and tolerability of VX-809 dosed alone for 14 days followed by dosing of VX-809 combined with VX-770 for seven days. The trial also will assess the effect of VX-809 on the function of the cystic fibrosis transmembrane conductance regulator, or CFTR, both as a single compound and combined with VX-770. The three-part trial is designed to enroll up to a total of 160 patients with two copies of the F508del CFTR mutation, the most common mutation in the CFTR gene.

#### Commercialization

We plan to market telaprevir in North America, if and when it is approved for sale. Over the past several years, we have expanded our commercial organization in the United States with a focus on building our understanding of the HCV market, developing our commercial strategy for the potential launch of telaprevir, executing plans to establish the infrastructure to support commercial sales, incorporating appropriate compliance policies and procedures, establishing patient-focused programs, and creating a sales force and hiring employees for our managed markets organization to promote telaprevir, if approved, to health care providers and payors. During the period prior to the potential launch of telaprevir, we will need to complete the build-out of our commercial organization in the United States, which will include hiring additional personnel. We also are planning to market telaprevir and VX-770 in Canada and VX-770 in the European Union, if we are successful in obtaining approval in these territories, and have begun the process of expanding our commercial organization into these territories. Successful development and commercialization of any of our other drug candidates would require further expansion of our commercial capabilities in North America, Canada and the European Union.

## Manufacturing

We will require a supply of telaprevir for sale in North America and a supply of VX-770 for sale worldwide if we are successful in obtaining marketing approval for these drug candidates. We rely on an international network of third parties to manufacture and distribute our drug candidates for clinical trials, and we expect that we will continue to rely on third parties for the foreseeable future to meet our commercial supply needs for any of our drug candidates that are approved for sale. Third-party contract manufacturers, including some in Asia, supply us with raw materials, and contract manufacturers in the European Union and the United States convert these raw materials into drug substance, and convert the drug substance into final dosage form. Establishing and managing this global supply chain requires a significant financial commitment and the creation and maintenance of

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numerous third-party relationships. Although we attempt to effectively manage the business relationships with companies in our supply chain, we do not have complete control over their activities.

#### Financing Strategy

We have incurred losses from our inception and expect to continue to incur losses at least until we obtain approval for and successfully commercialize a product. Therefore, we have been dependent in large part on our ability to raise significant funding to finance our research and development operations, to create a commercial infrastructure and to meet our overhead costs and long-term contractual commitments and obligations. To date, we have secured funds principally through capital market and other financing transactions, strategic collaborative agreements, investment income and the issuance of common stock under our employee benefit plans. In September 2010, we secured an additional \$391.6 million through the issuance of \$400.0 million in aggregate principal amount of our 3.35% convertible senior subordinated notes due 2015, or 2015 Notes. We have from time to time transferred to third parties future financial rights under certain of our collaborations in exchange for one-time cash payments.

We expect that we will incur substantial expenses in order to seek approval for and commercialize telaprevir while at the same time continuing to pursue diversified research and development efforts for our other drug candidates and build out our other capabilities. We may seek to borrow working capital if such financing is available to us. Although we have no plans to do so in the near term, we may raise additional capital from public offerings or private placements of our securities, securing new collaborative agreements or through other methods of financing. We cannot be sure that financing opportunities will be available on acceptable terms, if at all. If adequate funds are not available on acceptable terms, we may be required to significantly curtail or discontinue one or more of our research or development programs, including clinical trials, incur significant cash exit costs, or attempt to obtain funds through arrangements with collaborators or others that may require us to relinquish rights to certain of our drug candidates.

#### **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. 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. During the nine months ended September 30, 2010, there were no material changes to our critical accounting policies as reported in our Annual Report on Form 10-K for the year ended December 31, 2009.

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Results of Operations Three and Nine Months Ended September 30, 2010 Compared with Three and Nine Months Ended September 30, 2009

|                      | Three Mor<br>Septem |            | Increase/<br>(Decrease) | Increase/<br>(Decrease) | - 1        | ths Ended<br>aber 30, | Increase/<br>(Decrease) | Increase/<br>(Decrease) |
|----------------------|---------------------|------------|-------------------------|-------------------------|------------|-----------------------|-------------------------|-------------------------|
|                      | 2010                | 2009       | \$                      | %                       | 2010       | 2009                  | \$                      | %                       |
|                      |                     | (in thou   | sands)                  |                         |            | (in thou              | ısands)                 |                         |
| Revenues             | \$ 23,795           | \$ 24,957  | \$ (1,162)              | (5)%                    | \$ 77,846  | \$ 68,000             | \$ 9,846                | 14%                     |
| Operating costs and  |                     |            |                         |                         |            |                       |                         |                         |
| expenses             | 223,383             | 173,190    | 50,193                  | 29%                     | 607,289    | 535,293               | 71,996                  | 13%                     |
| Net interest expense | 3,458               | 1,332      | 2,126                   | 160%                    | 10,157     | 3,947                 | 6,210                   | 157%                    |
| Other loss           | 5,911               |            | 5,911                   | n/a                     | 34,634     | 12,294                | 22,340                  | 182%                    |
| Net loss             | \$ 208,957          | \$ 149,565 | \$ 59,392               | 40%                     | \$ 574,234 | \$ 483,534            | \$ 90,700               | 19%                     |

#### Net Loss

Our net loss in the third quarter of 2010 increased by \$59.4 million, or 40%, as compared to our net loss in the third quarter of 2009, and our net loss in the nine months ended September 30, 2010 increased by \$90.7 million, or 19%, as compared to our net loss in the nine months ended September 30, 2009. The increases in our net loss in the three and nine months ended September 30, 2010 as compared to the comparable periods in 2009 were primarily the result of significant increases in our operating expenses, and increased non-cash losses that we incurred in the 2010 periods related to increases in the fair value of outstanding derivative instruments. The increases in our operating expenses during the 2010 periods as compared to the 2009 periods related primarily to increased expenses for our commercial organization and increased investment in commercial supplies of telaprevir.

#### Net Loss per Share

Our net loss for the third quarter of 2010 was \$1.04 per basic and diluted common share compared to a net loss of \$0.84 per basic and diluted common share for the third quarter of 2009. Our increased net loss per common share in the third quarter of 2010 was the result of an increased net loss in the third quarter of 2010 compared to the third quarter of 2009, partially offset by an increase in the basic and diluted weighted-average number of common shares outstanding from 178.7 million to 200.9 million. Our net loss for the nine months ended September 30, 2010 was \$2.87 per basic and diluted common share compared to a net loss of \$2.86 per basic and diluted common share for nine months ended September 30, 2009. This net loss per common share for the nine months ended September 30, 2010 was similar to our net loss per common share in the nine months ended September 30, 2009 because our increased net loss was largely offset by an increase in the basic and diluted weighted-average number of common shares outstanding from 169.1 million to 200.1 million. The increase in the number of common shares outstanding in 2010 compared to 2009 resulted primarily from the equity offerings we completed in February 2009 and December 2009, the ViroChem acquisition in March 2009 and the exchanges and conversions of our 4.75% convertible senior subordinated notes due 2013, or 2013 Notes, into common stock during 2009 and the first quarter of 2010.

#### Stock-based Compensation and Certain Other Expenses

The comparison of our costs and expenses during the three and nine months ended September 30, 2010 and 2009 reflects changes in our levels of stock-based compensation expense and certain other expenses during the periods. Our stock-based compensation expense increased in the third quarter of 2010 as compared to the third quarter of 2009 due to the expansion of our workforce and increased expenses related to equity awards that contain performance-based vesting acceleration. The small decrease in our stock-based compensation expense for the nine months ended September 30, 2010 as

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compared to the nine months ended September 30, 2009 was the result of one-time expenses that were incurred in the first and second quarters of 2009 related to our CEO transition, largely offset in 2010 by the expansion of our workforce and the expenses related to equity awards that contain performance-based vesting acceleration. In the three and nine months ended September 30, 2010, we incurred \$9.7 million and \$45.7 million, respectively, in non-cash expenses related to financial transactions that we completed in September 2009. Most of these non-cash expenses related to changes in the fair value of derivative instruments associated with the September 2009 financial transactions due to updated estimates regarding the timing and probability of achieving milestones under our Janssen collaboration agreement. These estimates were adjusted to incorporate the increased likelihood of achieving the milestones upon receipt of positive data from the Phase 3 clinical trials in our registration program for telaprevir. We incurred acquisition-related expenses in the first quarter of 2009 and a loss on the exchange of convertible notes in the second quarter of 2009, for which there were no corresponding expenses in 2010.

Our costs and expenses in the three and nine months ended September 30, 2010 and 2009 included the following:

|   |           | nths Ended<br>aber 30, |           | ths Ended<br>iber 30, |
|---|-----------|------------------------|-----------|-----------------------|
|   | 2010      | 2009                   | 2010      | 2009                  |
|   |           | (in thou               | ısands)   |                       |
| Stock-based compensation expense              | \$ 23,768 | \$ 20,134              | \$ 67,550 | \$ 68,996             |
| Restructuring expense                         | 866       | 774                    | 3,758     | 4,283                 |
| Acquisition-related expenses (ViroChem)       |           |                        |           | 7,793                 |
| September 2009 financial transaction expenses | 9,738     |                        | 45,746    |                       |
| Loss on exchange of convertible notes         |           |                        |           | 12,294                |

#### Revenues

|     |                               | Three I<br>End<br>Septem<br>2010 | ded  | r 30,<br>2009 | (D  | ncrease/<br>decrease) | Increase/<br>(Decrease)<br>% |    | Nine M<br>End<br>Septem<br>2010 | ded  | l<br>r 30,<br>2009 | (D  | ecrease/ | Increase/<br>(Decrease)<br>% |
|-----|-------------------------------|----------------------------------|------|---------------|-----|-----------------------|------------------------------|----|---------------------------------|------|--------------------|-----|----------|------------------------------|
|     |                               | (                                | in t | housand       | ls) |                       |                              |    | (1                              | in t | housana            | ls) |          |                              |
| rev | yalty<br>enues<br>llaborative | \$<br>8,173                      | \$   | 7,834         | \$  | 339                   | 4%                           | \$ | 21,842                          | \$   | 19,891             | \$  | 1,951    | 10%                          |
|     | enues                         | 15,622                           |      | 17,123        |     | (1,501)               | (9)%                         | ,  | 56,004                          |      | 48,109             |     | 7,895    | 16%                          |
| T   | otal revenues                 | \$<br>23,795                     | \$   | 24,957        | \$  | (1,162)               | (5)%                         | \$ | 77,846                          | \$   | 68,000             | \$  | 9,846    | 14%                          |

Our total revenues in recent periods have consisted primarily of collaborative revenues, which have fluctuated significantly on a quarterly basis. This variability is due to, among other things, the July 2009 amendment of our collaboration agreement with Mitsubishi Tanabe, which provided for an up-front payment that is being recognized over the expected period of performance; the variable level of reimbursement we have received for our development programs; increased revenues from services we provide to our collaborators through our third-party manufacturing network and the timing of recognition of significant milestone payments. During the fourth quarter of 2010, we expect to continue to recognize deferred revenues and additional revenues from our collaborative relationships. We do not expect to have any product revenues from the sale of telaprevir in 2010. If we are able to successfully commercialize telaprevir in accordance with our current plans, we expect to receive product revenues from the sales of telaprevir beginning in 2011.

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Collaborative Revenues

The table presented below is a summary of revenues from our collaborative arrangements for the three and nine months ended September 30, 2010 and 2009:

|                              | 1         | Three Months Ended<br>September 30, |    |         |        | Nine Months Ended<br>September 30, |    |        |  |
|------------------------------|-----------|-------------------------------------|----|---------|--------|------------------------------------|----|--------|--|
|                              | 2010 2009 |                                     |    |         | 2010 2 |                                    |    | 2009   |  |
|                              |           |                                     |    | (in tho | ısan   | ds)                                |    |        |  |
| Janssen                      | \$        | 4,566                               | \$ | 10,232  | \$     | 22,912                             | \$ | 40,157 |  |
| Mitsubishi Tanabe            |           | 11,056                              |    | 6,891   |        | 32,650                             |    | 7,734  |  |
| Other                        |           |                                     |    |         |        | 442                                |    | 218    |  |
|                              |           |                                     |    |         |        |                                    |    |        |  |
| Total collaborative revenues | \$        | 15 622                              | \$ | 17 123  | \$     | 56 004                             | \$ | 48 109 |  |

Our revenues from the Janssen collaboration in each period consist of:

net reimbursements from Janssen for costs of developing telaprevir;

specified manufacturing services, if any, we provided to Janssen in the period; and

an amortized portion of the \$165.0 million up-front payment received from Janssen in 2006.

We record telaprevir clinical development expenses to be reimbursed by Janssen, after we offset amounts to be reimbursed by us to Janssen for its telaprevir clinical development expenses, as revenues.

Our revenues from the Janssen collaboration decreased by \$5.7 million, or 55%, in the third quarter of 2010 compared to the third quarter of 2009 and decreased by \$17.2 million, or 43%, in the nine months ended September 30, 2010 compared to the same period in 2009. These decreases were primarily the result of decreased net reimbursable expenses as we completed the Phase 3 clinical trials in our registration program for telaprevir and decreased revenues from the up-front payment, partially offset by increased reimbursement for manufacturing services. We adjusted our estimates regarding the period of performance under the Janssen agreement in the first quarter of 2010 as a result of changes in the global development plan for telaprevir, which contemplates the conduct of certain development activities in the post-approval period if telaprevir is approved for marketing. This adjustment, together with a similar adjustment that we made in the third quarter of 2009, resulted in our recognizing \$3.1 million and \$9.3 million, respectively, in collaborative revenues related to the up-front payment in the three and nine months ended September 30, 2010 as compared to \$4.5 million and \$15.7 million, respectively, in the three and nine months ended September 30, 2009. We did not achieve any development milestones under the Janssen agreement in 2009 or the nine months ended September 30, 2010. In the third quarter of 2009, we entered into two financial transactions related to \$250.0 million in potential future milestone payments under the Janssen agreement related to the regulatory filing with and approval of telaprevir by the EMA, and the launch of telaprevir in the European Union. We anticipate these milestone payments will be earned prior to April 2012. We expect that, when and if earned, these milestone payments will result in collaborative revenues of \$250.0 million. We are obligated to apply the proceeds from the first \$155.0 million of these milestone payments toward redemption of the secured notes due 2012, or 2012 Notes, we issued in the transaction. The remaining \$95.0 million are to be paid by Janssen directly to the purchaser of \$95.0 million of these milestone payments.

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In the three and nine months ended September 30, 2010, the majority of our collaborative revenues related to our collaboration with Mitsubishi Tanabe. In the third quarter of 2009, we entered into an amendment to our license, development and commercialization agreement with Mitsubishi Tanabe that resulted in a \$105.0 million payment when the amendment was executed. We classified this payment as deferred revenues and are recognizing it over our expected period of performance. In the three and nine months ended September 30, 2010, we recognized \$9.6 million and \$28.7 million, respectively, of revenues from Mitsubishi Tanabe related to the \$105.0 million payment. In the three and nine months ended September 30, 2009, we recognized \$6.4 million of revenues from Mitsubishi Tanabe related to the \$105.0 million payment. In addition, in the three and nine months ended September 30, 2010, we recognized \$1.5 million and \$4.0 million, respectively, of revenues related to manufacturing services provided to Mitsubishi Tanabe through our third-party manufacturing network. As of September 30, 2010, we also had \$27.0 million in deferred revenues related to manufacturing services that Mitsubishi Tanabe has paid for, but which have not yet been completed. We believe it is likely that we will recognize the deferred revenues related to the manufacturing services that Mitsubishi Tanabe has paid for in the fourth quarter of 2010.

#### Royalty Revenues

Our royalty revenues relate to sales of the HIV protease inhibitors Lexiva/Telzir and Agenerase by GlaxoSmithKline. In 2008, we sold our right to receive future royalties from GlaxoSmithKline with respect to these HIV protease inhibitors, excluding the portion allocated to pay a subroyalty to a third party, in return for a one-time cash payment of \$160.0 million. We are recognizing revenues from this sale transaction on a deferred basis over the term of our agreement with GlaxoSmithKline, under the units-of-revenue method.

Our royalty revenues increased by \$0.3 million, or 4%, in the third quarter of 2010 compared to the third quarter of 2009. Our royalty revenues increased by \$2.0 million, or 10%, in the nine months ended September 30, 2010 compared to the same period in 2009. In the fourth quarter of 2010, we expect that we will recognize as royalty revenues a portion of the remaining deferred revenues from the sale of our HIV royalty stream plus the full amount of the third-party subroyalty.

#### **Costs and Expenses**

|                                   | Three Months Ended<br>September 30, |              | Increase/<br>(Decrease) | Increase/<br>(Decrease) |            | ths Ended<br>iber 30, | Increase/<br>(Decrease) | Increase/<br>(Decrease) |
|-----------------------------------|-------------------------------------|--------------|-------------------------|-------------------------|------------|-----------------------|-------------------------|-------------------------|
|                                   | 2010                                | 2009         | \$                      | %                       | 2010       | 2009                  | \$                      | %                       |
|                                   | (                                   | in thousands | s)                      |                         | (          | in thousand           | s)                      |                         |
| Research and development          |                                     |              |                         |                         |            |                       |                         |                         |
| expenses                          | \$ 170,434                          | \$ 132,132   | \$ 38,302               | 29%                     | \$ 468,528 | \$ 415,044            | \$ 53,484               | 13%                     |
| Sales, general and administrative |                                     |              |                         |                         |            |                       |                         |                         |
| expenses                          | 48,855                              | 36,572       | 12,283                  | 34%                     | 125,322    | 97,618                | 27,704                  | 28%                     |
| Royalty expenses                  | 3,228                               | 3,712        | (484)                   | (13)%                   | 9,681      | 10,555                | (874)                   | (8)%                    |
| Restructuring                     | 066                                 | 77.4         | 02                      | 100                     | 2.750      | 4.202                 | (505)                   | (10)0                   |
| expense                           | 866                                 | 774          | 92                      | 12%                     | 3,758      | 4,283                 | (525)                   | (12)%                   |
| Acquisition-related expenses      |                                     |              |                         | n/a                     |            | 7,793                 | (7,793)                 | (100)%                  |
| Total costs and expenses          | \$ 223,383                          | \$ 173,190   | \$ 50,193               | 29%                     | \$ 607,289 | \$ 535,293            | \$ 71,996               | 13%                     |

Our operating costs and expenses primarily relate to our research and development expenses and our sales, general and administrative expenses. Our research and development expenses fluctuate on a quarterly basis due to the timing and scope of activities related to development of clinical drug candidates and our commercial supply investment for development-stage assets. Our sales, general and administrative expenses generally have been increasing as we increase our headcount and expand our capabilities in preparation for the potential commercial launch of telaprevir.

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Research and Development Expenses

|   | Three Months Ended<br>September 30, | Increase/ Incr<br>(Decrease) (Decr | rease/<br>rease) Nine Montl<br>Septemb |             | Increase/<br>(Decrease) ( | Increase/<br>Decrease) |
|---|-------------------------------------|------------------------------------|--|-------------|---------------------------|------------------------|
|   | 2010 2009                           | \$                                 | % 2010                                 | 2009        | \$                        | %                      |
|   | (in thousand                        | s)                                 | (iı                                    | n thousands | )                         |                        |
| Research expenses                       | \$ 48,416 \$ 42,663                 | \$ 5,753                           | 13% \$ 140,146                         | \$ 129,418  | \$ 10,728                 | 8%                     |
| Development expenses                    | 122,018 89,469                      | 32,549                             | 36% 328,382                            | 285,626     | 42,756                    | 15%                    |
| Total research and development expenses | \$ 170,434 \$ 132,132               | \$ 38,302                          | 29% \$ 468,528                         | \$ 415,044  | \$ 53,484                 | 13%                    |

Our research and development expenses include internal and external costs incurred for our drug candidates, including telaprevir and VX-770. We do not assign our internal costs, such as salary and benefits, stock-based compensation expense, laboratory supplies and infrastructure costs, to individual drug candidates, because the employees within our research and development groups typically are deployed across multiple research and development programs. These internal costs are significantly greater than our external costs, such as the costs of services provided to us by clinical research organizations and other outsourced research, which we do allocate by individual drug development program. All research and development costs for our drug candidates are expensed as incurred.

To date, we have incurred in excess of \$3.8 billion in research and development expenses associated with drug discovery and development. The successful development of our drug candidates is highly uncertain and subject to a number of risks. In addition, the duration of clinical trials may vary substantially according to the type, complexity and novelty of the drug candidate and the disease indication being targeted. The FDA and comparable agencies in foreign countries impose substantial requirements on the introduction of therapeutic pharmaceutical products, typically requiring lengthy and detailed laboratory and clinical testing procedures, sampling activities and other costly and time-consuming procedures. Data obtained from nonclinical and clinical activities at any step in the testing process may be adverse and lead to discontinuation or redirection of development 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, 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.

Over the past several years, telaprevir has represented the largest portion of the development costs for our clinical drug candidates. We have completed the registration program for telaprevir, but expect to continue to incur telaprevir development costs in connection with seeking regulatory approval for telaprevir and conducting additional clinical trials of telaprevir. If we are able to successfully obtain approval to market telaprevir in accordance with current regulatory timelines, we anticipate that we will begin generating revenues and cash flows from the sales of telaprevir in 2011. If our registration program for VX-770 is successful and completed on currently projected timelines, we could submit an NDA for VX-770 in the second half of 2011. Our other drug candidates are less advanced and as a result any estimates regarding development and regulatory timelines for these drug candidates are highly subjective and subject to change. We cannot make a meaningful estimate when, if ever, these drug candidates, including the drug candidates we acquired from ViroChem, will generate revenues and cash flows.

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### **Research Expenses**

|                                      | En        | Months<br>ded<br>aber 30, |    | crease/<br>crease) | Increase/ (Decrease) | Nine Mon<br>Septem | ths Ended | 1     | (ncrease/<br>Decrease) | Increase/ (Decrease) |
|--------------------------------------|-----------|---------------------------|----|--------------------|----------------------|--------------------|-----------|-------|------------------------|----------------------|
|                                      | 2010      | 2009                      |    | \$                 | %                    | 2010               | 2009      |       | \$                     | %                    |
|                                      | (         | in thousand               |    |                    | (in thousands)       |                    |           |       |                        |                      |
| Research Expenses:                   |           |                           |    |                    |                      |                    |           |       |                        |                      |
| Salary and benefits                  | \$ 17,422 | \$ 16,631                 | \$ | 791                | 5% \$                | 50,036             | \$ 46,75  | 51 \$ | 3,285                  | 7%                   |
| Stock-based compensation             |           |                           |    |                    |                      |                    |           |       |                        |                      |
| expense                              | 6,063     | 5,152                     |    | 911                | 18%                  | 17,988             | 18,75     | 57    | (769)                  | (4)%                 |
| Laboratory supplies and other direct |           |                           |    |                    |                      |                    |           |       |                        |                      |
| expenses                             | 6,383     | 6,266                     |    | 117                | 2%                   | 21,543             | 20,54     | 19    | 994                    | 5%                   |
| Contractual services                 | 3,300     | 1,498                     |    | 1,802              | 120%                 | 7,559              | 3,84      | 14    | 3,715                  | 97%                  |
| Infrastructure costs                 | 15,248    | 13,116                    |    | 2,132              | 16%                  | 43,020             | 39,51     | 7     | 3,503                  | 9%                   |
| T . 1                                |           |                           |    |                    |                      |                    |           |       |                        |                      |
| Total research expenses              | \$ 48,416 | \$ 42,663                 | \$ | 5,753              | 13% \$               | 140,146            | \$ 129,41 | 8 \$  | 10,728                 | 8%                   |

Our research expenses primarily are related to expenses for our workforce and generally are not dependent on the timing of clinical development activities. Our increased expenses in the three and nine months ended September 30, 2010 as compared to the three and nine months ended September 30, 2009 were primarily the result of increases in our salary and benefits expenses, contractual services expenses and infrastructure costs. We expect to continue to invest in our research programs in an effort to identify additional drug candidates for development.

#### **Development Expenses**

|                                      | Three M<br>End<br>Septem | led        | Increase/<br>(Decrease) | Increase/<br>(Decrease) |            | ths Ended<br>aber 30, | Increase/<br>(Decrease) | Increase/<br>(Decrease) |
|--------------------------------------|--------------------------|------------|-------------------------|-------------------------|------------|-----------------------|-------------------------|-------------------------|
|                                      | 2010                     | 2009       | \$                      | %                       | 2010       | 2009                  | \$                      | %                       |
|                                      | (i                       | n thousand | ls)                     |                         | (          | in thousand           | s)                      |                         |
| Development Expenses:                |                          |            |                         |                         |            |                       |                         |                         |
| Salary and benefits                  | \$ 29,908                | \$ 26,963  | \$ 2,945                | 11%                     | \$ 80,103  | \$ 73,399             | \$ 6,704                | 9%                      |
| Stock-based                          |                          |            |                         |                         |            |                       |                         |                         |
| compensation expense                 | 10,916                   | 7,896      | 3,020                   | 38%                     | 31,046     | 32,185                | (1,139)                 | (4)%                    |
| Laboratory supplies and other direct |                          |            |                         |                         |            |                       |                         |                         |
| expenses                             | 9,901                    | 6,996      | 2,905                   | 42%                     | 24,348     | 20,819                | 3,529                   | 17%                     |
| Contractual services                 | 30,042                   | 25,410     | 4,632                   | 18%                     | 76,940     | 88,281                | (11,341)                | (13)%                   |
| Commercial supply                    |                          |            |                         |                         |            |                       |                         |                         |
| investment                           | 18,970                   | 4,295      | 14,675                  | 342%                    | 53,994     | 14,712                | 39,282                  | 267%                    |
| Infrastructure costs                 | 22,281                   | 17,909     | 4,372                   | 24%                     | 61,951     | 56,230                | 5,721                   | 10%                     |
| Total development expenses           | \$ 122,018               | \$ 89,469  | \$ 32,549               | 36%                     | \$ 328,382 | \$ 285,626            | \$ 42,756               | 15%                     |

The increase in our development expenses during the three months ended September 30, 2010 as compared to the three months ended September 30, 2009 relates to a large increase in our commercial supply investment and to significant increases across the other categories of our development expenses. The increase in our development expenses during the nine months ended September 30, 2010 as compared to the nine months ended September 30, 2009 relates primarily to a large increase in our commercial supply investment. We expect we will continue to increase our investment in commercial supplies of telaprevir, and that our related expenses will continue to increase, until we can begin to capitalize these investments.

Our development expenses excluding our commercial supply investment increased by \$17.9 million, or 21%, for the third quarter of 2010 compared to the third quarter of 2009. This increase was the result of significant increases in each major category of our development expenses. Our development expenses excluding our commercial supply investment increased by \$3.5 million, or 1%, for the nine months ended September 30, 2010 as compared to the nine months ended September 30, 2009, as increases in our salary and benefits expenses and infrastructure costs were largely offset by a significant decrease in our contractual services expenses.

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Sales, General and Administrative Expenses

|  | Three Months<br>Ended<br>September 30, |           | Increase/ Increase/<br>(Decrease) (Decrease) |     | Nine Mon<br>Septem | ths Ended<br>aber 30, | Increase/ Increase/<br>(Decrease) (Decrease) |         |
|--|--|-----------|--|-----|--------------------|-----------------------|--|---------|
|  | 2010                                   | 2009      | \$   | %   | 2010               | 2009                  | \$   | %       |
|  | (in thousands)                         |           |  |     |                    |                       |  |         |
| Sales, general and administrative expenses | \$ 48,855                              | \$ 36,572 | 2 \$ 12,283                                  | 34% | \$ 125,322         | \$ 97,618             | \$ 27,                                       | 704 28% |

The increases in sales, general and administrative expenses in the 2010 periods as compared to the 2009 periods are the result of increased headcount and external costs in 2010 as we prepare for the potential commercial launch of telaprevir. We expect the trend of increases in sales, general and administrative expenses to continue. In the three months ended September 30, 2010 and 2009, our sales, general and administrative expenses included \$6.8 million and \$7.1 million, respectively, of stock-based compensation expense. In the nine months ended September 30, 2010 and 2009, our sales, general and administrative expenses included \$18.5 million and \$18.1 million, respectively, of stock-based compensation expense.

Royalty Expenses

Royalty expenses decreased in the three and nine months ended September 30, 2010 as compared to the three and nine months ended September 30, 2009. Royalty expenses primarily relate to a subroyalty payable to a third party on net sales of Lexiva/Telzir. The subroyalty results in both a royalty expense and offsetting royalty revenues. We expect to continue to recognize this subroyalty as an expense in future periods.

#### Restructuring Expense

We recorded restructuring expense of \$0.9 million for the three months ended September 30, 2010 consistent with the \$0.8 million of restructuring expenses we recorded for the three months ended September 30, 2009. We recorded restructuring expense of \$3.8 million for the nine months ended September 30, 2010 compared to \$4.3 million for the nine months ended September 30, 2009. The restructuring expense in all periods included imputed interest cost related to the restructuring liability associated with our Kendall Square lease. The decrease in restructuring expense for the nine months ended September 30, 2010 compared to the nine months ended September 30, 2009 was primarily the result of a revision, in the first quarter of 2009, of certain key estimates and assumptions about facility operating costs for the remaining period of the lease commitment for the Kendall facility. The lease restructuring liability was \$33.2 million as of September 30, 2010.

We review our estimates and assumptions with respect to the Kendall Square lease at least on a quarterly basis and will make whatever modifications we believe are 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 the liability, and the effect of any such adjustments could be material.

#### Acquisition-related Expenses

We incurred \$7.8 million of expenses in the nine months ended September 30, 2009 in connection with our acquisition of ViroChem, including \$5.7 million in transaction expenses and \$2.1 million related to a restructuring of ViroChem's operations that we undertook in March 2009 in order to focus ViroChem's activities on its HCV assets. We did not have corresponding acquisition-related expenses in the nine months ended September 30, 2010.

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### **Non-operating Items**

Interest Income

Interest income decreased by \$0.1 million, or 17%, to \$0.5 million for the third quarter of 2010 from \$0.6 million for the third quarter 2009. Interest income decreased by \$3.3 million, or 69%, to \$1.4 million for the nine months ended September 30, 2010 from \$4.7 million for the same period of 2009. The decrease in the nine months ended September 30, 2010 compared to the nine months ended September 30, 2009 was the result of lower portfolio yields in 2010 periods as compared to 2009. Our cash, cash equivalents and marketable securities yielded approximately 0% on an annual basis in the third quarter of 2010 and 2009.

#### Interest Expense

Interest expense increased by 105% to \$4.0 million in the third quarter of 2010 from \$1.9 million in the third quarter of 2009 and by \$3.0 million, or 34%, to \$11.6 million in the nine months ended September 30, 2010 from \$8.6 million in the same period in 2009. These increases were the result of interest expense related to the 2012 Notes that we issued in September 2009, partially offset by a decrease in interest expense related to our 2013 Notes. Our 2015 Notes did not begin to accrue interest until September 28, 2010. During the fourth quarter of 2010, we expect that we will have approximately \$3.4 million in interest expense related to the 2015 Notes and that we will continue to incur imputed interest expense related to our 2012 Notes.

#### Change in Fair Value of Derivative Instruments

In the three and nine months ended September 30, 2010, we recorded losses of \$5.9 million and \$34.6 million, respectively, in connection with the embedded and free-standing derivatives associated with our September 2009 financial transactions. These losses were principally related to adjustments we made in the second quarter and third quarter of 2010 to estimates regarding the timing and probability of achieving the milestones under the Janssen agreement based on the positive data from our registration program for telaprevir that we received in the second and third quarters of 2010. These losses also included time-value-of-money adjustments to the estimated fair value of the free-standing derivative. If we earn the \$250.0 million in milestone payments under the Janssen agreement, we expect that we will incur \$45.4 million in additional non-cash expenses related to the September 2009 financial transactions. We expect the majority of these additional expenses to be reflected as changes in the fair value of derivative instruments and a portion of these additional expenses to be reflected as interest expense.

# Loss on Exchange of Convertible Subordinated Notes

In the nine months ended September 30, 2009, we incurred a non-cash charge of \$12.3 million in connection with the exchange of \$143.5 million in aggregate principal amount of the 2013 Notes in the second quarter for 6.6 million newly-issued shares of our common stock. The charge related to the approximately 400,000 shares of common stock that we issued in excess of the number of shares of common stock into which such 2013 Notes were convertible prior to the exchange. We did not have comparable charges in the nine months ended September 30, 2010.

#### **Liquidity and Capital Resources**

We have incurred operating losses since our inception and 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, strategic sales of assets or businesses, financial transactions, investment income and proceeds from the issuance of common stock under our employee benefit plans. We expect that we

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will incur substantial expenses in order to seek approval for and commercialize telaprevir while at the same time continuing to pursue diversified research and development efforts for our other drug candidates. For these purposes, we may raise additional capital in order to maintain adequate working capital and cash reserves.

At September 30, 2010, we had cash, cash equivalents and marketable securities of \$1.2 billion, which was a decrease of \$81.9 million from \$1.3 billion at December 31, 2009. The decrease was primarily the result of cash expenditures we made in the first nine months of 2010 related to, among other things, research and development expenses and sales, general and administrative expenses, partially offset by the \$391.6 million in net proceeds we received from our September 2010 issuance of the 2015 Notes. Capital expenditures for property and equipment during the nine months ended September 30, 2010 were \$23.6 million.

We had \$155.0 million in aggregate principal amount of 2012 Notes outstanding on September 30, 2010. The 2012 Notes mature on October 31, 2012, subject to earlier mandatory redemption as specified milestone events under our collaboration with Janssen are achieved prior to October 31, 2012. In addition, in September 2009, we sold our rights to receive an additional \$95.0 million of potential future milestone payments that we expect to receive from Janssen for the launch of telaprevir in the European Union. As a result of these transactions, the \$250.0 million of potential milestone payments from Janssen related to the filing, approval and launch of telaprevir in the European Union, if and when earned, will not provide us with liquidity in the future except to the extent that they fund redemption of \$155.0 million in principal amount of our 2012 Notes.

At September 30, 2010, we had outstanding \$400.0 million in aggregate principal amount of our 2015 Notes. The 2015 Notes bear interest at the rate of 3.35% per annum, and we are required to make semi-annual interest payments on the outstanding principal balance of the 2015 Notes on April 1 and October 1 of each year, beginning on April 1, 2011. The 2015 Notes will mature on October 1, 2015. The 2015 Notes are convertible, at the option of the holder, into our common stock at a price equal to approximately \$48.83 per share, subject to adjustment.

Our accrued restructuring expense of \$33.2 million at September 30, 2010 relates to the portion of the facility that we lease in Kendall Square that we do not intend to occupy and includes other related lease obligations, recorded at net present value. In the nine months ended September 30, 2010, we made cash payments of \$11.2 million against the accrued expense and received \$6.6 million in sublease rental payments. During the fourth quarter of 2010, we expect to make additional cash payments of \$3.7 million against the accrued expense and to receive \$2.0 million in sublease rental payments.

We expect to continue to make significant investments in our development pipeline, particularly in our effort to prepare for potential registration, regulatory approval and commercial launch of telaprevir and VX-770, and in clinical trials for VX-770 and our other drug candidates, including telaprevir, VX-222, VX-809, VX-509 and VX-765. We also expect to continue to make a substantial investment in drug discovery research. As a result, we expect to incur future losses on a quarterly and annual basis at least until we obtain marketing approval and successfully commercialize a product. 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.

We believe that our current cash, cash equivalents and marketable securities will be sufficient to fund our operations for at least the next twelve months. We may seek to borrow working capital if such financing is available to us. Although we do not have any plans to do so in the near term, we may raise additional capital through public offerings or private placements of our securities, securing new collaborative agreements or other methods of financing. Any such capital transactions may or may not be similar to transactions in which we have engaged in the past. We will continue to manage our capital

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structure and to 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. If adequate funds are not available, we may be required to curtail significantly or discontinue one or more of our research, drug discovery or development programs or attempt to obtain funds through arrangements that may require us to relinquish rights to certain of our technologies or drug candidates.

#### **Contractual Commitments and Obligations**

Our commitments and obligations were reported in our Annual Report on Form 10-K for the year ended December 31, 2009, which was filed with the Securities and Exchange Commission, or SEC, on February 19, 2010. There have been no material changes from the contractual commitments and obligations previously disclosed in that Annual Report on Form 10-K, except that:

The holders of our remaining 2013 Notes converted those 2013 Notes into 1.4 million shares of our common stock in the first quarter of 2010.

On September 28, 2010, we issued \$400.0 million in aggregate principal amount of 2015 Notes, which mature on October 1, 2015. In addition to repaying the principal amount of the 2015 Notes on the maturity date, we are obligated to make semi-annual interest payments to the holders of the 2015 Notes of approximately \$6.7 million on April 1 and October 1, beginning on April 1, 2011.

#### **Recent Accounting Pronouncements**

Refer to Note P, "Recent Accounting Pronouncements," in the accompanying notes to the condensed consolidated financial statements for a discussion of recent accounting pronouncements.

#### 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 United States government and its agencies, investment grade corporate bonds and notes and money market instruments. These investments are denominated in United States 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 Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this Quarterly Report on Form 10-Q, have concluded that, based on such evaluation, as of September 30, 2010 our disclosure controls and procedures were effective and designed to provide reasonable assurance that the

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information required to be disclosed is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

### **Changes in Internal Controls Over Financial Reporting**

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended) occurred during the third quarter of 2010 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 Annual Report on Form 10-K for the year ended December 31, 2009, which was filed with the SEC on February 19, 2010. There have been no material changes to the risk factors previously disclosed in that Annual Report on Form 10-K, but in connection with receipt of data from our Phase 3 clinical trials in our registration program for telaprevir we are updating our risk factor regarding our dependence on telaprevir to focus on (i) the risks associated with obtaining approval for telaprevir and (ii) the risks associated with commercializing telaprevir. The updated risk factors are as follows:

We depend heavily on the success of our lead drug candidate, telaprevir, which has not yet been approved by the FDA. If we experience material delays in obtaining or are unable to obtain marketing approval for telaprevir our business will be materially harmed.

We believe that a significant portion of the value attributed to our company by investors relates to the commercial potential of telaprevir, which has not yet been approved by the FDA. While we and Janssen have completed the Phase 3 clinical trials in the registration program for telaprevir, we need to obtain approval from the FDA to market telaprevir in the United States. Submitting an NDA for approval of a drug candidate, such as telaprevir, is a complex and resource-intensive process. In addition, the FDA will have substantial discretion in deciding whether or not telaprevir should be granted approval based on the benefits and risks of telaprevir-based therapies in the treatment of genotype 1 HCV infection.

Obtaining approval to market telaprevir in a timely manner will depend on many factors, including the following:

successful completion and submission of our NDA, which will require, among other things, compiling, analyzing and synthesizing data from the clinical trials of telaprevir; developing proposed labeling; and providing plans for post-marketing studies, safety monitoring and risk evaluation and mitigation;

whether or not the FDA determines that the evidence gathered in well-controlled clinical trials, other clinical trials and nonclinical studies of telaprevir demonstrates that telaprevir is safe and effective as a treatment for genotype 1 HCV infection;

whether or not the FDA is satisfied that the manufacturing facilities, processes and controls for telaprevir are adequate, that labeling is satisfactory and plans for post-marketing studies, safety monitoring and risk evaluation and mitigation are sufficient; and

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the timing and nature of the FDA's comments and questions regarding the NDA for telaprevir, the scheduling and recommendations of any advisory committee meeting to consider telaprevir, the time required to respond to the FDA's comments and questions and to obtain the final labeling for telaprevir and any delays that may be associated with the NDA review process.

If we experience material delays or are unable to obtain marketing approval for telaprevir in the United States, our business will be materially harmed.

In addition, Janssen will need to seek approval from the EMA to market telaprevir in the European Union. The regulatory process in the European Union is similar to the process in the United States, but typically takes longer to complete. If Janssen experiences material delays or is unable to obtain marketing approval for telaprevir in its territories, our business may be materially harmed.

### In order to execute our business plan and achieve profitability, we need to effectively commercialize telaprevir.

We can not be sure that telaprevir will be commercially successful in the pharmaceutical market even if we and Janssen gain marketing approval for telaprevir in a timely manner. In addition to the other challenges related to a company launching its first commercial drug, we may face competition from Merck & Co., Inc., which is developing boceprevir, a potentially competitive HCV protease inhibitor. In August 2010, Merck announced that the primary endpoints in the Phase 3 clinical trials of boceprevir had been achieved and that Merck expected to complete the regulatory submissions for boceprevir in the United States and European Union in 2010.

We expect that the initial commercial success of telaprevir will depend on many factors, including the following:

the efficacy, cost, breadth of approved use, side-effect profile and cost of co-therapies of telaprevir-based treatment regimens relative to competitive treatment regimens, including boceprevir if it is approved;

the relative timing of marketing approvals from the FDA and comparable foreign regulatory authorities for telaprevir and boceprevir;

the effectiveness of our commercial strategy for the launch and marketing of telaprevir;

the number of patients with genotype 1 HCV infection, including treatment-naïve patients and patients who did not achieve an SVR with prior treatment, who seek treatment;

maintaining and successfully monitoring commercial manufacturing arrangements for telaprevir with third-party manufacturers to ensure they meet our standards and those of regulatory authorities, including the FDA, which extensively regulate and monitor pharmaceutical manufacturing facilities;

our ability to increase awareness of the benefits of early treatment of HCV infection and to increase the rates of diagnosis and subsequent treatment of currently undiagnosed patients with genotype 1 HCV infection;

the acceptance of telaprevir by patients, the medical community and third-party payors; and

the effect of new health care legislation currently being implemented in the United States.

If we do not effectively commercialize telaprevir, we will not be able to execute our business plan and may not be able to achieve profitability. If our revenues, market share and/or other indicators of market acceptance of telaprevir do not meet the expectations of investors or public market analysts, the market price of our common stock would likely decline.

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#### 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 and submissions for telaprevir, VX-770, VX-222, VX-809, VX-509, VX-765, including our intention to complete the NDA submission for telaprevir in the United States in the fourth quarter of 2010, Janssen's plans to submit its MAA for telaprevir to the EMA in the fourth quarter of 2010, and the possibility that we could submit an NDA to the FDA for VX-770 in the second half of 2011;

our belief that if we are able to successfully commercialize telaprevir in accordance with current development timelines, we will begin generating revenues and cash flows from sales of telaprevir in 2011;

our ability to successfully market telaprevir and VX-770 or any of our other drug candidates if we are able to obtain regulatory approval;

our expectations regarding the timing and structure of clinical trials of our other drug candidates, including telaprevir, VX-770, VX-222, VX-509 and VX-765 and combinations of telaprevir with VX-222 and VX-770 with VX-809, and the timing of our receipt of data from our VX-770 registration program and data from our VX-765 and VX-509 clinical trials;

expectations regarding the amount of, timing of and trends with respect to our revenues, costs and expenses and other gains and losses, including those related to the intangible assets associated with the ViroChem acquisition and to the liabilities we recorded in connection with the September 2009 financial transactions;

the data that will be generated by ongoing and planned clinical trials and the ability to use that data to support regulatory filings, including potential applications for marketing approval for telaprevir and VX-770;

our beliefs regarding the support provided by clinical trials and preclinical and nonclinical studies of our drug candidates for further investigation, clinical trials or potential use as a treatment;

the focus of our drug development efforts and our financial and management resources and our plan to continue investing in our research and development programs and to develop selected drug candidates that emerge from those programs, alone or with third-party collaborators;

the establishment, development and maintenance of collaborative relationships;

potential business development activities;

our ability to use our research programs to identify and develop new drug candidates to address serious diseases and significant unmet medical needs;

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

our liquidity and our expectations regarding the possibility of raising additional capital.

Without limiting the foregoing, the words "believes," "anticipates," "plans," "intends," "expects" and similar expressions are intended to identify forward-looking statements. Any or all of our forward-

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looking statements in this Quarterly Report on Form 10-Q 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 on Form 10-Q will be important in determining future results. Consequently, no forward-looking statement can be guaranteed. Actual future results may vary materially from expected results. We also provide a cautionary discussion of risks and uncertainties under "Risk Factors" in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2009, which was filed with the SEC on February 19, 2010, and updated and supplemented by "Part II Item 1A Risk Factors" of Quarterly Reports on Form 10-Q. These are factors that we think could cause our actual results to differ materially from expected results. Other factors besides those listed could also adversely affect us. 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, 2010:

|                                      |                                  |             |                   |                   | Maximum         |
|--------------------------------------|----------------------------------|-------------|-------------------|-------------------|-----------------|
|                                      |                                  |             |                   |                   | Number of       |
|                                      |                                  |             |                   |                   | Shares That May |
|                                      |                                  |             |                   | Total Number of   | Yet             |
|                                      |                                  |             |                   | Shares            | be Purchased    |
|                                      |                                  |             |                   | Purchased as Part | Under           |
|                                      | Total                            |             |                   | of                | Publicly        |
|                                      | Number                           | Average     | Price             | Publicly          | Announced       |
|                                      | 1 (dilloct                       | 11,01,05    |                   |                   |                 |
|                                      | of Shares                        | Paid        |                   | Announced         | Plans or        |
| Period                               |                                  | 8           | per               | •                 |                 |
| Period July 1, 2010 to July 31, 2010 | of Shares                        | Paid<br>Sha | per               | Announced         | Plans or        |
|                                      | of Shares<br>Purchased           | Paid<br>Sha | per<br>re         | Announced         | Plans or        |
| July 1, 2010 to July 31, 2010        | of Shares<br>Purchased<br>11,314 | Paid<br>Sha | per<br>re<br>0.01 | Announced         | Plans or        |

The repurchases were made under the terms of our 2006 Stock and Option Plan. Under this plan, we award shares of restricted stock to our employees and consultants that 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 2006 Stock and Option Plan and are available for future awards under the terms of that plan.

#### Item 6. Exhibits

#### Exhibit No. Description

- 4.1 Subordinated Indenture, dated as of September 28, 2010, by and between Vertex Pharmaceuticals Incorporated and U.S. Bank National Association, as trustee.\*
- 4.2 First Supplemental Indenture, dated as of September 28, 2010, by and between Vertex Pharmaceuticals Incorporated and U.S. Bank National Association, as trustee.\*
- 4.3 Form of 3.35% Convertible Senior Subordinated Note due 2015.\*
- 31.1 Certification of the Chief Executive Officer under Section 302 of the Sarbanes-Oxley Act of 2002.

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| Exhibit No. | Description   |
|-------------|---|
| 31.2        | Certification of the Chief Financial Officer under Section 302 of the Sarbanes-Oxley Act of 2002. |
| 32.1        | Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.                          |
| 101.INS     | XBRL Instance**   |
| 101.SCH     | XBRL Taxonomy Extension Schema**  |
| 101.CAL     | XBRL Taxonomy Extension Calculation**   |
| 101.LAB     | XBRL Taxonomy Extension Labels**  |
| 101.PRE     | XBRL Taxonomy Extension Presentation**  |
| 101.DEF     | XBRL Taxonomy Extension Definition**  |

Incorporated by reference to Exhibits 4.1, 4.2 and 4.3, respectively, included in Vertex's Current Report on Form 8-K, filed on September 29, 2010 (File No. 000-19319).

\*\*

Pursuant to applicable securities laws and regulations, we will be deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and will not be subject to liability under any anti-fraud provisions of the federal securities laws with respect to such interactive data files as long as we have made a good faith attempt to comply with the submission requirements and promptly amend the interactive data files after becoming aware that the interactive data files fail to comply with the submission requirements. Users of this data are advised that, pursuant to Rule 406T of Regulation S-T, these interactive data files are deemed not filed and otherwise are not subject to liability, except as provided by applicable securities laws and regulations.

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### **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.

October 28, 2010

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)