

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

- QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934  
FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2006  
OR  
 TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934

FOR THE TRANSITION PERIOD FROM TO  
COMMISSION FILE NUMBER 000-19319

VERTEX PHARMACEUTICALS INCORPORATED

(Exact name of registrant as specified in its charter)

MASSACHUSETTS  
(State or other jurisdiction of  
incorporation or organization)

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

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

02139-4242  
(zip code)

(617) 444-6100

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES  NO

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

Large Accelerated Filer

Accelerated Filer

Non-Accelerated Filer

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

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

111,801,481  
Outstanding at August 7, 2006

Vertex Pharmaceuticals Incorporated

Form 10-Q

For the Quarter Ended June 30, 2006

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## Part I. Financial Information

### Item 1. Condensed Consolidated Financial Statements

**Vertex Pharmaceuticals Incorporated**  
**Condensed Consolidated Balance Sheets**  
**(Unaudited)**  
**(In thousands, except share data)**

	June 30, 2006	December 31, 2005
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 41,430	\$ 78,045
Marketable securities, available for sale	220,911	283,112
Accounts receivable	183,668	20,595
Prepaid expenses	6,580	3,303
Total current assets	<u>452,589</u>	<u>385,055</u>
Marketable securities, available for sale	53,523	46,353
Restricted cash	41,482	41,482
Property and equipment, net	59,971	54,533
Investments	14,849	18,863
Other assets	3,064	2,712
Total assets	<u>\$ 625,478</u>	<u>\$ 548,998</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 8,277	\$ 6,210
Accrued expenses and other current liabilities	46,480	42,061
Accrued interest	3,185	3,184
Deferred revenue	42,931	31,449
Accrued restructuring expense	7,862	14,351
Other obligations	—	2,988
Total current liabilities	<u>108,735</u>	<u>100,243</u>
Accrued restructuring expense, excluding current portion	28,416	28,631
Collaborator development loan	19,997	19,997
Deferred revenue, excluding current portion	133,239	851
Convertible subordinated notes (due September 2007)	42,102	42,102
Convertible senior subordinated notes (due February 2011)	117,993	117,998
Total liabilities	<u>450,482</u>	<u>309,822</u>
Commitments and contingencies:		
Stockholders' equity:		
Preferred stock, \$0.01 par value; 1,000,000 shares authorized; none issued and outstanding at June 30, 2006 and December 31, 2005, respectively	—	—
Common stock, \$0.01 par value; 200,000,000 shares authorized; 110,600,314 and 108,153,149 shares issued and outstanding at June 30, 2006 and December 31, 2005, respectively	1,089	1,081
Additional paid-in capital	1,282,984	1,243,960
Deferred compensation, net	—	(13,408)
Accumulated other comprehensive income (loss)	8,252	(2,873)
Accumulated deficit	<u>(1,117,329)</u>	<u>(989,584)</u>
Total stockholders' equity	<u>174,996</u>	<u>239,176</u>
Total liabilities and stockholders' equity	<u>\$ 625,478</u>	<u>\$ 548,998</u>

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2006	2005	2006	2005
<b>Revenues:</b>				
Royalties	\$ 9,005	\$ 7,467	\$ 18,184	\$ 13,620
Collaborative and other research and development revenues	20,721	24,854	50,629	47,307
Total revenues	29,726	32,321	68,813	60,927
<b>Costs and expenses:</b>				
Royalty payments	2,885	2,489	5,880	4,519
Research and development(1)	91,250	59,357	166,452	116,792
Sales, general and administrative(1)	14,370	10,814	27,249	20,441
Restructuring expense/(credit)	443	(1,743)	1,210	171
Total costs and expenses	108,948	70,917	200,791	141,923
Loss from operations	(79,222)	(38,596)	(131,978)	(80,996)
Interest income	3,921	2,247	7,901	4,566
Interest expense	(2,357)	(4,639)	(4,714)	(9,278)
Loss from continuing operations before cumulative effect of a change in accounting principle	(77,658)	(40,988)	(128,791)	(85,708)
Cumulative effect of a change in accounting principle—FAS 123(R)*	—	—	1,046	—
Net loss	(77,658)	\$ (40,988)	(127,745)	\$ (85,708)
Basic and diluted net loss from continuing operations per common share	\$ (0.72)	\$ (0.50)	\$ (1.19)	\$ (1.06)
Basic and diluted cumulative effect of a change in accounting principle per common share	—	—	0.01	—
Basic and diluted net loss per common share	\$ (0.72)	\$ (0.50)	\$ (1.18)	\$ (1.06)
Basic and diluted weighted average number of common shares outstanding	108,523	82,274	107,985	80,859

(1) Includes the following stock-based compensation expense:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2006	2005	2006	2005
Research and development	\$ 9,755	\$ 927	\$ 16,161	\$ 1,764
Sales, general and administrative	1,892	202	3,611	396
Total	\$ 11,647	\$ 1,129	\$ 19,772	\$ 2,160

\* The Company adopted Financial Accounting Standards Board Statement No. 123 (R), "Share-Based Payments", using a modified prospective method. See Note 3 to the Condensed Consolidated Financial Statements, "Stock-based Compensation", for further detail.

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)**

	Six Months Ended June 30,	
	2006	2005
<b>Cash flows from operating activities:</b>		
Net loss	\$ (127,745)	\$ (85,708)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Depreciation and amortization	13,059	13,371
Non-cash stock-based compensation expense under FAS 123(R)	19,772	—
Other non-cash based compensation expense	1,793	3,651
Cumulative effect of a change in accounting principle	(1,046)	—
Realized loss on marketable securities	—	53
Loss on disposal of property and equipment	2	272
<b>Changes in operating assets and liabilities:</b>		
Accounts receivable	1,927	(2,050)
Prepaid expenses	(3,277)	(2,262)

Accounts payable	2,067	2,769
Accrued expenses and other liabilities	1,591	(6,571)
Accrued restructuring expense	(6,704)	(12,030)
Accrued interest	1	406
Deferred revenue	(21,130)	(20,641)
Net cash used in operating activities	(119,690)	(108,740)
Cash flows from investing activities:		
Purchase of marketable securities	(93,370)	(48,685)
Sales and maturities of marketable securities	163,292	133,897
Expenditures for property and equipment	(18,232)	(7,383)
Restricted cash	—	840
Investments and other assets	(572)	48
Net cash provided by investing activities	51,118	78,717
Cash flows from financing activities:		
Issuances of common stock from employee benefit plans, net	31,927	4,715
Issuances of common stock from stock offering, net	—	165,331
Debt exchange costs	(218)	—
Net cash provided by financing activities	31,709	170,046
Effect of changes in exchange rates on cash	248	(334)
Net increase (decrease) in cash and cash equivalents	(36,615)	139,689
Cash and cash equivalents—beginning of period	78,045	55,006
Cash and cash equivalents—end of period	41,430	\$ 194,695
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ 4,445	\$ 8,341

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

**Vertex Pharmaceuticals Incorporated**  
**Notes to Condensed Consolidated Financial Statements**

**1. Basis of Presentation**

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

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

Certain information and footnote disclosures normally included in the Company’s annual financial statements have been condensed or omitted. The interim financial statements, in the opinion of management, reflect all normal recurring adjustments (including accruals) necessary for a fair presentation of the financial position and results of operations for the interim periods ended June 30, 2006 and 2005.

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, 2006. These interim financial statements should be read in conjunction with the audited financial statements for the year ended December 31, 2005, which are contained in the Company’s 2005 Annual Report on Form 10-K that was filed with the Securities and Exchange Commission on March 16, 2006.

**2. Accounting Policies**

*Basic and Diluted Net Loss per Common Share*

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

	At June 30,	
	2006	2005
Stock options	14,617	16,133
Weighted-average exercise price, per share	\$ 25.30	\$ 22.02
Convertible notes	8,354	16,454
Weighted-average conversion price, per share	\$ 19.16	\$ 19.15
Unvested restricted shares	1,739	1,598

*Stock-based Compensation Expense*

The Company adopted Financial Accounting Standards Board Statement No. 123(R), “Share-Based Payments” (“FAS 123(R)”), as of January 1, 2006. FAS 123(R) revises FAS Statement No. 123, “Accounting for Stock-Based Compensation” (“FAS 123”), supersedes APB Opinion No. 25, “Accounting for Stock Issued to Employees” (“APB 25”), and amends FAS Statement No. 95, “Statement of Cash Flows.” FAS 123(R) requires companies to expense the fair value of employee stock options and other

forms of stock-based employee compensation over the employees' service periods. Compensation cost is measured at the fair value of the award at the grant date and is adjusted to reflect actual forfeitures and the outcomes of certain conditions. See Note 3, below, for additional information regarding the Company's stock-based compensation.

#### Research and Development

All research and development costs, including amounts funded by research collaborators, are expensed as incurred. Research and development expenses are comprised of costs incurred in performing research and development activities, including salaries and benefits; laboratory supplies; contract services, including clinical trial costs; and infrastructure costs, including facilities costs and depreciation. The Company's collaborators have funded portions of the Company's research and development programs related to specific drug candidates and research targets, including, in 2006, VX-950 (telaprevir), VX-702, VX-770, kinases, and certain cystic fibrosis research targets, and, in 2005, VX-950 (telaprevir), VX-702, kinases, and certain cystic fibrosis research targets.

The following table details the research and development expenses for collaborator-sponsored and Company-sponsored programs for the three months ended June 30, 2006 and 2005 (in thousands):

	For the Three Months Ended June 30, 2006			For the Three Months Ended June 30, 2005		
	Research	Development	Total	Research	Development	Total
Collaborator-sponsored Programs	\$ 9,612	\$ 41,652	\$ 51,264	\$ 16,976	\$ 14,814	\$ 31,790
Company-sponsored Programs	26,809	13,177	39,986	12,836	14,731	27,567
<b>Total</b>	<b>\$ 36,421</b>	<b>\$ 54,829</b>	<b>\$ 91,250</b>	<b>\$ 29,812</b>	<b>\$ 29,545</b>	<b>\$ 59,357</b>

The total research and development expense for the three months ended June 30, 2006 and 2005 includes \$9.8 million and \$0.9 million, respectively, of stock-based compensation expense. The following table details the research and development expenses for collaborator-sponsored and Company-sponsored programs for the six months ended June 30, 2006 and 2005 (in thousands):

	For the Six Months Ended June 30, 2006			For the Six Months Ended June 30, 2005		
	Research	Development	Total	Research	Development	Total
Collaborator-sponsored Programs	\$ 29,153	\$ 70,830	\$ 99,983	\$ 33,428	\$ 26,431	\$ 59,859
Company-sponsored Programs	43,540	22,929	66,469	26,386	30,547	56,933
<b>Total</b>	<b>\$ 72,693</b>	<b>\$ 93,759</b>	<b>\$ 166,452</b>	<b>\$ 59,814</b>	<b>\$ 56,978</b>	<b>\$ 116,792</b>

The total research and development expense for the six months ended June 30, 2006 and 2005 includes \$16.2 million and \$1.8 million, respectively, of stock-based compensation expense.

#### Restructuring Expense

The Company records costs and liabilities associated with exit and disposal activities, as defined in Statement of Financial Accounting Standards No. 146, "Accounting for Costs Associated with Exit or Disposal Activities" ("FAS 146"), at fair value in the period the liability is incurred. In periods subsequent to initial measurement, changes to the liability are measured using the credit-adjusted risk-free discount rate applied in the initial period.

#### Revenue Recognition

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

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

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

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

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

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

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

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

Payments received after performance obligations are met completely are recognized when earned.

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

### 3. Stock-based Compensation

At June 30, 2006, the Company had four stock-based employee compensation plans: the 1991 Stock Option Plan (the "1991 Plan"), the 1994 Stock and Option Plan (the "1994 Plan"), the 1996 Stock and Option Plan (the "1996 Plan") and the 2006 Stock and Option Plan (the "2006 Plan", and together with the 1991 Plan, the 1994 Plan, and the 1996 Plan, collectively, the "Stock and Option Plans"), and one Employee Stock Purchase Plan (the "ESPP"). Pursuant to the Stock and Option Plans, the Company may issue restricted stock and options to its directors, employees and consultants for services. Each option granted under the Stock and Option Plans has an exercise price equal to the market value of the underlying common stock on the date of grant. The price per share of restricted stock granted to employees is equal to \$0.01, the par value of the Company's common stock. Vesting of options and restricted stock is ratable over specified periods, generally four or five years, and is determined by the Management Development and Compensation Committee of the Company's Board of Directors. All options awarded under the Stock and Option Plans expire not more than ten years from the grant date. Pursuant to the ESPP, participating employees may periodically purchase shares of the Company's common stock at a discount to the fair value of the stock on specified measurement dates, using funds withheld from their compensation over specified offering terms.

The Company reserved an aggregate of 8,000,000 shares under the 1991 Plan and 1994 Plan. The Company reserved 22,000,000 shares under the 1996 Plan and 7,302,380 shares under the 2006 Plan. At June 30, 2006, the Company had approximately 7,105,000 shares of common stock available for grants under the 2006 Plan, and no shares were available for grants under the 1991 Plan, the 1994 Plan or the 1996 Plan. As of June 30, 2006, approximately 621,000 shares remained available for future purchases under the ESPP.

On January 1, 2006, Vertex adopted Statement of Financial Accounting Standards No. 123(R), "Share-Based Payments" ("FAS 123(R)"), using the modified prospective method, pursuant to which the Company applies the provisions of FAS 123(R) to its consolidated financial statements on a going-forward basis. The modified prospective transition method requires the application of the accounting standard as of January 1, 2006, the first day of Vertex's fiscal year 2006. Prior periods have not been restated. FAS 123(R) requires companies to recognize share-based payments to employees as compensation expense using the "fair value" method. Under the fair value recognition provisions of FAS 123(R), stock-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as expense over the service period, which generally is the vesting period of the award. The fair value of stock options and shares purchased pursuant to the ESPP is calculated using the Black-Scholes valuation model. The fair value of restricted stock is based on intrinsic value. The expense recognized over the service period includes an estimate of awards that will be forfeited. Prior to adoption of FAS 123(R), Vertex recorded the impact of forfeitures as they occurred. In connection with the adoption of FAS 123(R) during the first half of fiscal year 2006, Vertex recorded a \$1.0 million benefit from the cumulative effect of changing from recording forfeitures related to restricted stock awards as they occurred to estimating forfeitures during the service period.

Stock-based compensation expense recognized during the first half of 2006 includes: (a) ESPP awards with offering periods commencing May 15, 2005 and November 15, 2005, based on the grant-date fair value estimated in accordance with the provisions of FAS 123, (b) stock options and restricted awards granted prior to, but not yet vested as of December 31, 2005, based on the grant-date fair value estimated in accordance with the provisions of FAS 123, and (c) stock options and restricted stock awards granted after

December 31, 2005, based on the grant-date fair value and ESPP awards with the offering period commencing May 15, 2006, in accordance with the provisions of FAS 123(R). These amounts reflect estimated forfeitures of those awards.

The estimated fair value of Vertex's stock-based awards, less estimated forfeitures, is amortized over the awards' service periods on a ratable basis. No equity compensation cost was capitalized during the first half of 2006.

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

	Three Months Ended June 30, 2006	Six Months Ended June 30, 2006
Stock-based compensation expense by type of award:		
Stock options	\$ 9,804	\$ 15,402
Restricted shares	1,412	3,139
ESPP	431	1,231
Total stock-based compensation	<u>\$ 11,647</u>	<u>\$ 19,772</u>
Effect of stock-based compensation on income by line item:		



Research and development	\$ 9,755	\$ 16,161
Sales, general and administrative	1,892	3,611
Total stock-based compensation	<u>\$ 11,647</u>	<u>\$ 19,772</u>
Cumulative effect of a change in accounting principle—FAS 123(R)	—	\$ (1,046)
Net stock-based compensation expense included in net loss	<u>\$ 11,647</u>	<u>\$ 18,726</u>

As a result of the adoption of FAS 123(R):

- the Company's net loss from continuing operations for the three and six months ended June 30, 2006 is greater by \$10.3 million and \$16.1 million, respectively;
- the Company's net loss for the three and six months ended June 30, 2006 is greater by \$10.3 million and \$15.1 million, respectively; and
- basic and diluted loss per share for the three and six months ended June 30, 2006 is greater by \$0.10 and \$0.14, respectively.

#### Options

The Company uses the Black-Scholes valuation model to estimate the fair value of stock options at the grant date. The Black-Scholes valuation model requires the Company to make certain estimates and assumptions, including assumptions related to the expected price volatility of the Company's stock, the period during which the options are outstanding, the rate of return of risk free investments, and the expected dividend yield for the Company's stock. The Company validates its estimates and assumptions through consultations with independent third parties having relevant expertise.

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The fair values of options granted during the three and six months ended June 30, 2006 were calculated using the following weighted-average assumptions:

	For the Three Months Ended June 30, 2006	For the Six Months Ended June 30, 2006
Expected stock price volatility	57.92%	57.26%
Expected term of options	5.64 years	5.64 years
Risk free interest rate	5.04%	4.61%
Expected annual dividends	—	—

The weighted-average valuation assumptions were determined as follows:

- Expected stock price volatility: In 2006, the Company changed its method of estimating expected volatility from relying exclusively on historical volatility to relying exclusively on implied volatility. Options to purchase the Company's stock with remaining terms of greater than a year are regularly traded in the market. Expected stock price volatility is calculated using the trailing one month average of daily implied volatilities prior to grant date.
- Expected term of options: The expected term of options represents the period of time options are expected to be outstanding. The Company used historical data to estimate employee exercise and post-vest termination behavior. The Company believes that all groups of employees exhibit similar exercise and post-vest termination behavior and therefore does not stratify employees into multiple groups.
- Risk-free interest rate: The Company bases the risk-free interest rate on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the expected term assumption.
- Expected annual dividends: The estimate for annual dividends is \$0.00, because the Company has not historically and does not intend for the foreseeable future to pay a dividend.

The following table summarizes information related to the outstanding and vested options during the six months ended June 30, 2006:

	Stock Options (in thousands)	Weighted-average exercise price	Weighted-average remaining contractual life (in years)	Aggregate intrinsic value (in thousands)
Outstanding at December 31, 2005	14,669	\$ 22.84		
Granted	2,060	\$ 35.36		
Exercised	(1,801)	\$ 16.11		
Forfeited	(221)	\$ 16.64		
Expired	(90)	\$ 61.19		
Outstanding at June 30, 2006	<u>14,617</u>	<u>\$ 25.30</u>	6.09	\$ 210,492
Exercisable at June 30, 2006	<u>9,669</u>	<u>\$ 27.08</u>	4.92	\$ 142,620
Exercisable and expected to vest	<u>13,972</u>	<u>\$ 25.36</u>	5.97	\$ 203,022

The aggregate intrinsic value in the table above represents the total pre-tax intrinsic value, based on the average of the high and low price of the Company's common stock of \$35.44 on June 30, 2006, which would have been received by option holders if all option holders had exercised their options on that date.

All options granted during the three and six months ended June 30, 2006 and 2005 were granted with exercise prices equal to the fair market value of the Company's common stock on the date of grant and had weighted-average grant date fair values of \$19.83 and \$6.35 for the three months, respectively and \$20.01 and \$5.38 for the six months, respectively.

The total intrinsic value of options exercised during the three months ended June 30, 2006 and 2005 was \$9.8 million and \$0.9 million, respectively. The total cash received from employees as a result of employee stock option exercises during the three months ended June 30, 2006 and 2005 was approximately \$6.7 million and \$2.2 million, respectively. The total intrinsic value of options exercised during the six months ended June 30, 2006 and 2005 was \$36.3 million and \$1.0 million, respectively. The total cash received from employees as a result of employee stock option exercises during the six months ended June 30, 2006 and 2005 was approximately \$29.0 million and \$2.8 million, respectively.

The Company settles employee stock option exercises with newly issued common shares.

As of June 30, 2006, there was \$47.1 million of total unrecognized compensation cost, net of estimated forfeitures, related to unvested options granted under the Stock and Option Plans. That cost is expected to be recognized over a weighted-average period of 2.64 years.

#### Restricted Stock

The following table summarizes the restricted stock activity of the Company during the six months ended June 30, 2006:

	Restricted Stock (Shares in thousands)	Weighted Average Grant Date Fair Value (per Share)
Outstanding at December 31, 2005	1,521	\$ 11.02
Granted	414	\$ 35.38
Vested	(155)	\$ 10.09
Cancelled	(41)	\$ 17.68
Outstanding at June 30, 2006	<u>1,739</u>	<u>\$ 16.75</u>

The total fair value of the shares vesting during the three months ended June 30, 2006 and 2005 (measured on the date of vesting) was \$0.5 million and \$0.9 million, respectively. The total fair value of the shares vesting during the six months ended June 30, 2006 and 2005 (measured on the date of vesting) was \$5.8 million and \$1.3 million, respectively.

As of June 30, 2006, there was \$17.2 million of total unrecognized compensation expense, net of estimated forfeitures, related to unvested restricted stock granted under the Stock and Option Plans. That cost is expected to be recognized over a weighted-average period of 2.94 years.

#### ESPP

Vertex adopted the ESPP on July 1, 1992. The ESPP permits eligible employees to enroll in a twelve-month offering period comprising two six-month purchase periods. Participants may purchase shares of the Company's common stock, through payroll deductions, at a price equal to 85% of the fair market value of the common stock on the first day of the applicable twelve-month offering period, or the last day of the applicable six-month purchase period, whichever is lower. Purchase dates under the ESPP occur on May 14 and November 14 of each year.

During the first half of 2006, the following shares were issued to employees under ESPP (shares in thousands):

	Six months ended June 30, 2006
Number of shares	221
Average price paid	\$ 13.20

The total stock-based compensation expense related to the ESPP for the three and six months ended June 30, 2006 is \$0.4 million and \$1.2 million, respectively. The following table reflects the weighted average assumptions used in the Black-Scholes valuation model for the ESPP at June 30, 2006:

Expected stock price volatility	57.99%
Expected term	0.87 years
Risk-free interest rate	4.07%
Expected annual dividends	—

The weighted-average fair value of each purchase right granted during the first half of 2006 and 2005 was \$11.85 and \$4.60, respectively.

The expected stock price volatility for ESPP offerings beginning before the fourth quarter of 2005 is based on historical volatility, while the volatility for offerings beginning in the fourth quarter of 2005 and the second quarter of 2006 is based on implied volatility. The expected term represents purchases and purchase periods that take place within the offering period. The Company bases the risk free interest rate on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the expected term assumption. The Company has not historically and does not intend for the foreseeable future to pay a dividend and therefore the estimate is zero.

#### Prior to the adoption of FAS 123(R)

In accordance with Statement of Financial Accounting Standards No. 148, "Accounting for Stock-Based Compensation, Transition and Disclosure," for periods prior to January 1, 2006, the Company adopted the disclosure-only provisions of FAS 123 and also applied APB 25 and related interpretations in accounting for all stock awards granted to employees. Under APB 25, provided that other criteria were met, when the exercise price of stock options granted to employees equaled the market price of the common stock on the date of the grant, no compensation expense was recognized. Additionally, under APB 25, the Company was not required to record compensation expense for the cost of options or shares issued under the ESPP. Accordingly, no expense related to options or ESPP shares was recorded prior to January 1, 2006.

Prior to January 1, 2006, the Company recorded stock-based compensation expense related to restricted stock awards over the related vesting period for an amount equal to the difference between the price per share of restricted stock issued and the fair value of the Company's common stock at the date of grant or issuance. Prior to January 1, 2006, the Company recorded forfeitures as they occurred.

The following table illustrates the effect on net loss and net loss per share for the three and six months ended June 30, 2005 if the fair value recognition provisions of FAS 123 had been applied to the Company's stock-based employee compensation. Employee stock-based compensation expense was amortized



on a straight-line basis, because the Company's valuation of options subject to FAS 123 assumed a single weighted-average expected life for each award. Included in employee stock-based compensation expense for the three and six months ended June 30, 2005 is expense related to the modification of certain stock awards in accordance with an officer's severance agreement.

	For the Three Months Ended June 30, 2005	For the Six Months Ended June 30, 2005
	(in thousands, except per share data)	
Net loss attributable to common stockholders, as reported	\$ (40,988)	\$ (85,708)
Add: Employee stock-based compensation expense included in net loss, net of tax	1,129	2,160
Deduct: Total stock-based compensation expense determined under the fair value based method for all awards, net of tax	(10,554)	(21,284)
Pro forma net loss	\$ (50,413)	\$ (104,832)
Basic and diluted net loss per common share, as reported	\$ (0.50)	\$ (1.06)
Basic and diluted net loss per common share, pro forma	\$ (0.61)	\$ (1.30)

The fair value of each option granted during the three and six months ended June 30, 2005 was estimated on the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions:

	For the Three Months ended June 30, 2005	For the Six Months ended June 30, 2005
Expected stock price volatility	60.00%	60.00%
Risk free interest rate	3.77%	3.60%
Expected term of options	4.00 years	4.13 years
Expected annual dividends	—	—

The fair value of each ESPP purchase right outstanding during the three and six months ended June 30, 2005 was estimated on the date of subscription using the Black-Scholes option pricing model with the following weighted-average assumptions:

Expected stock price volatility	60.00%
Risk free interest rate	2.63%
Expected term of options	0.82 years
Expected annual dividends	—

#### 4. Comprehensive Loss

For the three and six months ended June 30, 2006 and 2005, comprehensive loss was as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2006	2005	2006	2005
Net loss	\$ (77,658)	\$ (40,988)	\$ (127,745)	\$ (85,708)
Changes in other comprehensive loss:				
Unrealized holding gains (losses) on marketable securities	(2,849)	999	10,877	(138)
Foreign currency translation adjustment	206	(252)	248	(334)
Total change in other comprehensive loss	(2,643)	747	11,125	(472)
Total comprehensive loss	<u>\$ (80,301)</u>	<u>\$ (40,241)</u>	<u>\$ (116,620)</u>	<u>\$ (86,180)</u>

#### 5. Restructuring Expense

On June 10, 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. 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. The Company now plans to occupy approximately 120,000 square feet of the facility subject to the Kendall Square lease (the "Kendall Square Facility") beginning in 2006. As of June 30, 2006, the Company had begun occupying a portion of the building. The remaining rentable square footage of the Kendall Square Facility currently is subleased to third parties.

For the three months ended June 30, 2006, the Company recorded approximately \$0.4 million of restructuring expense, which was attributable to the imputed interest cost relating to the restructuring accrual. The activity related to the restructuring accrual and related expense for the three months ended June 30, 2006 is as follows (in thousands):

	Accrual as of March 31, 2006	Cash payments, second quarter 2006	Cash received from subleases, second quarter 2006	Charge, second quarter 2006	Accrual as of June 30, 2006
Lease restructuring expense	\$ 41,719	\$ (7,904)	\$ 2,020	\$ 443	\$ 36,278

For the six months ended June 30, 2006, the Company recorded approximately \$1.2 million of restructuring expense, which was primarily attributable to the imputed interest cost relating to the restructuring accrual. The activity related to the restructuring accrual and related expense for the six months ended June 30, 2006 is as follows (in thousands):

	Accrual as of December 31, 2005	Cash payments, six months ended June 30, 2006	Cash received from subleases, six months ended June 30, 2006	Charge, six months ended June 30, 2006	Accrual as of June 30, 2006
Lease restructuring expense	\$ 42,982	\$ (11,884)	\$ 3,970	1,210	\$ 36,278

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During the three months ended June 30, 2005, the Company recorded a restructuring net credit of approximately \$1.7 million. This net credit resulted from adjusting the portion of the restructuring accrual for the portion of the Kendall Square Facility that Vertex expects to occupy, which is partially offset by (i) a charge in the amount of the estimated incremental ongoing lease obligations associated with the portion of the Kendall Square Facility that the Company does not intend to occupy and (ii) imputed interest costs relating to the restructuring liability. The activity related to the restructuring accrual for the three months ended June 30, 2005 is as follows (in thousands):

	Accrual as of March 31, 2005	Cash Payments, second quarter 2005	Cash received from sublease, second quarter 2005	Portion of facility Vertex expects to occupy, second quarter 2005	Charge, second quarter 2005	Accrual as of June 30, 2005
Lease restructuring expense	\$ 52,305	\$ (7,242)	\$ 493	\$ (10,018)	\$ 8,275	\$ 43,813

The activity related to the restructuring accrual for the six months ended June 30, 2005 is as follows (in thousands):

	Accrual as of December 31, 2004	Cash Payments, six months ended June 30, 2005	Cash received from sublease, six months ended June 30, 2005	Portion of facility Vertex expects to occupy, six months ended June 30, 2005	Charge, Six months ended June 30, 2005	Accrual as of June 30, 2005
Lease restructuring expense	\$ 55,843	\$ (13,017)	\$ 816	\$ (10,018)	\$ 10,189	\$ 43,813

In accordance with FAS 146, the Company's initial estimate of its liability for its net ongoing costs associated with the Kendall Square lease obligation was recorded in the second quarter of 2003 at fair value. The restructuring expense incurred from the second quarter of 2003 through the end of the first quarter of 2005 (*i.e.*, immediately prior to the Company's decision to utilize a portion of the Kendall Square Facility for its operations) relates to the estimated incremental net ongoing lease obligations associated with the entire Kendall Square Facility, together with imputed interest costs relating to the restructuring liability. The restructuring expense incurred in the period beginning in the second quarter of 2005 continues to be estimated in accordance with FAS 146, but relates only to the portion of the building that the Company 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 expects to occupy and use for its operations, are recorded as rental expense in the period incurred. The Company reviews its assumptions and estimates quarterly and updates its estimates of this liability as changes in circumstances require. As required by FAS 146, the expense and liability recorded is calculated using probability-weighted discounted cash-flows of the Company's estimated ongoing lease obligations, including contractual rental and build-out commitments, net of estimated sublease rentals, offset by related sublease costs.

In estimating the expense and liability under its Kendall Square lease obligation, the Company estimated (i) the costs to be incurred to satisfy its rental and build-out commitments under the lease (including operating costs), (ii) the time necessary to sublease the space, (iii) the projected sublease rental rates, and (iv) the anticipated durations of subleases. The Company validates its estimates and assumptions through consultations with independent third parties having relevant expertise. The Company used a credit-adjusted risk-free rate of approximately 10% to discount the estimated cash flows. The Company will review its estimates and assumptions on at least a quarterly basis, until the termination of the Kendall Square lease, and will make whatever modifications management believes necessary, based on the Company's best judgment, to reflect any changed circumstances. The Company's estimates have changed in the past, and may change in the future, resulting in additional adjustments to the estimate of liability,

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and the effect of any such adjustments could be material. Because the Company's estimate of the liability includes the application of a discount rate to reflect the time-value of money, the estimate of the liability will increase each quarter simply as a result of the passage of time. Changes to the Company's estimate of the liability are recorded as additional restructuring expense/(credit).

## 6. Altus Investment

Altus Pharmaceuticals, Inc. completed the initial public offering of its common stock in January 2006. At June 30, 2006 the Company owned 817,749 shares of Altus common stock and warrants to purchase 1,962,494 shares of Altus common stock. In addition, Vertex holds 450,000 shares of Altus redeemable preferred stock, which are not convertible into common stock and which are redeemable at the Company's option on or after December 31, 2010, or by Altus at any time. The Company was restricted from trading Altus securities for a period of six months following the initial public offering.

As a result of the public offering, at June 30, 2006, Altus common stock was classified as an available-for-sale investment and recorded at fair value, based on quoted market prices. Unrealized gains and losses on the Altus common stock are included as a component of accumulated other comprehensive income, which is a separate component of stockholders' equity, until such gains and losses are realized. At June 30, 2006, the fair market value of the Altus common stock investment was \$15.1 million, with a cost basis of \$4.0 million. In July 2006, the Company sold the 817,749 shares of Altus common stock for approximately \$11.7 million, resulting in a realized gain of approximately \$7.7 million to be recognized in the third quarter of 2006.

The Company will continue to account for the Altus warrants under the cost method of accounting until the end of the lock-up period, at which time the warrants will be classified as derivatives. Gains or losses on the fair market value of the warrants, as derivatives, will be included in the consolidated statements of operations. Vertex will continue to account for the redeemable preferred stock under the cost method of accounting.

The Company continues to assess the Altus warrants and redeemable preferred stock on a quarterly basis to determine if there has been any estimated decrease in the fair value of that investment below the carrying value that might require Vertex to write down its cost basis of the investment. If any adjustment to the fair value of an investment reflects a decline in the value of that investment below its cost, the Company will consider the available evidence, including the duration and extent to which the decline is other-than-temporary. If the decline is considered other-than-temporary, the cost basis of the investment will be written down to fair value as a new cost basis, and the amount of the write-down will be included in the consolidated statements of operations. Vertex has not identified facts or circumstances which would cause the Company to determine that the investment basis of its interest in Altus should be changed.

## 7. Convertible Subordinated Notes

At June 30, 2006, the Company had approximately \$42.1 million in aggregate principal amount of 5% Convertible Subordinated Notes due in September 2007 ("2007 Notes") and approximately \$118.0 million in aggregate principal amount of 5.75% Convertible Senior Subordinated Notes due in February 2011 (the "2011 Notes") outstanding. The 2007 Notes are convertible, at the option of the holder, into common stock at a price equal to \$92.26 per share, subject to adjustment under certain circumstances. The 2007 Notes bear interest at the rate of 5% per annum, and the Company is required to make semi-annual interest payments on the outstanding principal balance of the 2007 Notes on March 19 and September 19 of each year. The 2007 Notes are redeemable by the Company at any time at specific redemption prices if the closing price of the Company's common stock exceeds 120% of the conversion price for at least 20 trading days within a period of 30 consecutive trading days. The 2011 Notes are convertible, at the option of the holder, into common stock at a price equal to \$14.94 per share, subject to adjustment under certain

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circumstances. The 2011 Notes bear interest at the rate of 5.75% per annum, and the Company is required to make semi-annual interest payments on the outstanding principal balance of the 2011 Notes on February 15 and August 15 of each year. On or after February 15, 2007, the Company may redeem the 2011 Notes at a redemption price equal to the principal amount plus accrued and unpaid interest, if any.

In August 2006, the Company agreed to exchange approximately 4.1 million shares of newly issued common stock for \$58.3 million in aggregate principal amount of outstanding 2011 Notes plus all accrued and unpaid interest thereon. As a result of these exchanges, the Company expects to incur a non-cash charge of approximately \$5.0 million in the third quarter of 2006. This charge is related to the incremental shares issued in the transaction over the number that would have been issued upon the conversion of the notes under the original conversion terms.

## 8. Significant Revenue Arrangements

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

In June 2006, the Company entered into a collaboration agreement with Janssen Pharmaceutica, N.V. for the development, manufacture and commercialization of VX-950 (telaprevir), the Company's HCV protease inhibitor currently in Phase IIb clinical trials. Under the agreement, Janssen will fund 50% of the costs incurred in developing VX-950 (telaprevir) in 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 VX-950 (telaprevir) in Europe, South America, the Middle East, Africa and Australia. The agreement provides for Janssen to make a \$165 million up-front license payment to the Company, which was included in accounts receivable and deferred revenue at June 30, 2006 and subsequently paid to the Company in July 2006. Janssen has further agreed to make additional contingent milestone payments totaling up to \$380 million based on the successful development, approval and launch of VX-950 (telaprevir). The agreement also provides the Company with royalties on any sales of VX-950 (telaprevir) in the Janssen territory, with a tiered royalty structure having a royalty rate averaging in the mid-20% range and provides that Janssen will contribute to the manufacture of VX-950 (telaprevir). Janssen may terminate the agreement without cause at any time upon six months' notice to the Company. There has been no revenue recognized related to the agreement in the first half of 2006.

### *Merck & Co.*

On June 26, 2006, the Company agreed with Merck & Co., Inc. to extend the research program term and corresponding research funding for the parties' ongoing research collaboration for three months beyond the original termination date of June 21, 2006. The research program term will now extend until September 21, 2006. For the three and six months ended June 30, 2006, the Company recognized \$9.1 million and \$28.2 million, respectively, in revenue related to its agreement with Merck, which amounts include both research funding and upfront and product candidate development milestone payments.

### *Cystic Fibrosis Foundation*

In January 2006, Vertex amended its research collaboration agreement with Cystic Fibrosis Foundation Therapeutics Incorporated ("CFFT") to extend the term during which CFFT is providing funding for research of cystic fibrosis transmembrane regulator ("CFTR") protein "corrector" compounds through the first quarter of 2008. In March 2006, Vertex and CFFT further amended the agreement to include development stage funding from CFFT for the purpose of accelerating the clinical development of VX-770, a CFTR "potentiator" compound. The agreement, as amended, provides that CFFT will pay up to \$13.3 million to Vertex for specified VX-770 development activities through the end of 2007. Under the amended agreements, Vertex retains the right to develop and commercialize VX-770 and any other compounds discovered in the research collaboration, and will pay royalties to CFFT upon the approval and

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commercialization of any compounds discovered under the collaboration. For the three and six months ended June 30, 2006, Vertex recognized \$2.8 million and \$5.2 million, respectively, in revenue related to its agreement with CFFT.

## 9. Guarantees

As permitted under Massachusetts law, Vertex's Articles of Organization and Bylaws provide that the Company will indemnify certain of its officers and directors for certain claims asserted against them in connection with their service as an officer or director. The maximum potential amount of future payments that the Company could be required to make under these indemnification provisions is unlimited. However, the Company has purchased certain directors' and officers' liability insurance policies that reduce its monetary exposure and enable it to recover a portion of any future amounts paid. The Company believes the estimated fair value of these indemnification arrangements is minimal.

Vertex customarily agrees in the ordinary course of its business to indemnification provisions in agreements with clinical trials investigators and sites in its drug development programs, in sponsored research agreements with academic and not-for-profit institutions, in various comparable agreements involving parties performing services for the Company in the ordinary course of business, and in its real estate leases. The Company also customarily agrees to certain indemnification provisions in its drug discovery and development and/or 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 for its collaborator in the event of third party claims alleging infringement of intellectual property rights. In each of the cases above, the indemnification obligation generally survives the termination of the agreement for some extended period, although the obligation typically has the most relevance during the contract term and for a short period of time thereafter. The maximum potential amount of future payments that the Company could be required to make under these provisions is generally unlimited. The Company has purchased insurance policies covering personal injury, property damage and general liability that reduce its exposure for indemnification and would enable it in many cases to recover a portion of any future amounts paid. The Company has never paid any material amounts to defend lawsuits or settle claims related to these indemnification provisions. Accordingly, the Company believes the estimated fair value of these indemnification arrangements is minimal.

Effective on March 28, 2003, the Company sold certain assets of PanVera LLC to Invitrogen Corporation for approximately \$97 million. The agreement with Invitrogen requires the Company to indemnify Invitrogen against any loss it may suffer by reason of Vertex's breach of certain representations and warranties, or failure to perform certain covenants, contained in the agreement. The representations, warranties and covenants are of a type customary in agreements of this sort. The Company's aggregate obligations under the indemnity are, with a few exceptions that the Company believes are not material, capped at one-half of the purchase price, and apply to claims under representations and warranties made within fifteen months after closing (which period has ended), although there is no corresponding time limit for claims made based on breaches of covenants. Invitrogen has made no claims to date under this indemnity, and the Company believes that the estimated fair value of the remaining indemnification obligation is minimal.

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Effective on December 3, 2003, the Company sold certain instrumentation assets to Aurora Discovery, Inc. for approximately \$4.3 million. The agreement with Aurora requires the Company to indemnify Aurora against any loss it may suffer by reason of the Company's breach of certain representations and warranties, or failure to perform certain covenants, contained in the agreement. The representations, warranties and covenants are of a type customary in agreements of this sort. The Company's aggregate obligations under the indemnity are capped at one-half of the purchase price, and apply to claims under representations and warranties made within fifteen months after closing (which period has ended), although there is no corresponding time limit for claims made based on breaches of covenants. Aurora has made no claims to date under this indemnity, and the Company believes that the estimated fair value of the remaining indemnification obligation is minimal.

On February 10, 2004, Vertex entered into a Dealer Manager Agreement with UBS Securities LLC in connection with the exchange of approximately \$153.1 million of 2011 Notes for approximately \$153.1 million of 2007 Notes. On September 13, 2004, the Company entered into a second Dealer Manager Agreement with UBS Securities in connection with the exchange of approximately \$79.3 million of 2011 Notes for approximately \$79.3 million of 2007 Notes. Each of the Dealer Manager Agreements requires the Company to indemnify UBS Securities against any loss UBS Securities may suffer by reason of the Company's breach of representations and warranties relating to the exchanges of the convertible notes, the Company's failure to perform certain covenants in those agreements, the inclusion of any untrue statement of material fact in the materials provided to potential investors in the 2011 Notes, 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 exchanges. The representations, warranties and covenants in the Dealer Manager Agreements are of a type customary in agreements of this sort. The Company believes the estimated fair value of these indemnification obligations is minimal.

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

## 10. Contingencies

The Company has certain contingent liabilities that arise in the ordinary course of its business activities. The Company accrues contingent liabilities when it is probable that future expenditures will be made and such expenditures can be reasonably estimated.

On December 17, 2003, a purported class action, *Marguerite Sacchetti v. James C. Blair et al.*, was filed in the Superior Court of the State of California, County of San Diego, naming as defendants all of the directors of Aurora who approved the merger of Aurora and Vertex, which closed in July 2001. The plaintiffs claim that Aurora's directors breached their fiduciary duty to Aurora by, among other things, negligently conducting a due diligence examination of Vertex by failing to discover alleged problems with VX-745, a Vertex drug candidate that was the subject of a development program which was terminated by Vertex in September 2001. Vertex has certain indemnity obligations to Aurora's directors under the terms of the merger agreement between Vertex and Aurora. This case was dismissed with prejudice in the first

quarter of 2006 in connection with a settlement that resulted in payment to the plaintiff by the defendants' directors' and officers' liability insurer of under \$200,000.

## 11. New Accounting Pronouncements

In May 2005, the FASB issued FAS No. 154, "Accounting Changes and Error Corrections" ("FAS 154"). FAS No. 154 replaced APB Opinion No. 20, "Accounting Changes", and FAS No. 3, "Reporting Accounting Changes in Interim Financial Statements." FAS No. 154 requires retrospective application to prior periods' financial statements of changes in accounting principle, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. The Company adopted FAS 154 beginning on January 1, 2006; its adoption did not have a material impact on the Company's consolidated financial statements.

In November 2005, FASB issued FSP FAS 115-1 and FAS 124-1, "The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments" ("FSP FAS 115-1"), which provides guidance for determining when investments in certain debt and equity securities are considered impaired, whether an impairment is other-than-temporary, and on measuring such impairment loss. FSP FAS 115-1 also includes accounting considerations subsequent to the recognition of an other-than-temporary impairment and requires certain disclosures about unrealized losses that have not been recognized as other-than-temporary impairments. FSP FAS 115-1 is required to be applied to reporting periods beginning after December 15, 2005. The Company adopted FSP FAS 115-1 in the first quarter of 2006. Adoption of FSP FAS 115-1 did not have a material impact on the Company's consolidated results of operations or financial condition.

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

### Overview

We are a biotechnology company in the business of discovering, developing and commercializing small molecule drugs for the treatment of serious diseases. We have built a drug discovery capability that integrates biology, chemistry, biophysics, automation and information technologies, with a goal of making the drug discovery process more efficient and productive. Currently, a Vertex-discovered compound for the treatment of HIV infection, fosamprenavir calcium (marketed as Lexiva in the United States and Telzir in Europe), is being marketed by our collaborator GlaxoSmithKline. We have a number of drug candidates in development and a broad-based discovery effort.

We are concentrating most of our drug development resources at the present time on three compounds in specific markets: VX-950 (telaprevir) for the treatment of hepatitis C virus (HCV) infection in North America, VX-702 for the treatment of rheumatoid arthritis (RA) in North America and Europe and VX-770 for the treatment of cystic fibrosis (CF) worldwide. We rely on collaborators for (i) financial support for certain drug development programs and (ii) to conduct all or a portion of the development, manufacturing and commercialization activities for certain of our other drug candidates, either worldwide or in the markets upon which we are not currently focused.

### *Drug Discovery and Development*

Discovery and development of a new pharmaceutical product is a lengthy and resource-intensive process, which may take 10 to 15 years or more. Throughout this entire process, potential drug candidates are subjected to rigorous evaluation, driven in part by stringent regulatory considerations, designed to generate information concerning efficacy, proper dosage levels and a variety of other physical and chemical characteristics that are important in determining whether a proposed drug candidate should be approved for marketing. The toxicity characteristics and profile of drug candidates at varying dose levels administered for varying periods of time also are monitored continually and evaluated during the nonclinical and clinical development process. Most chemical compounds that are investigated as potential drug candidates never progress into formal development, and most drug candidates that do advance to formal development never become commercial products. A drug candidate's failure to progress or advance may be the result of any one or more of a wide range of adverse experimental outcomes including, for example, the lack of acceptable absorption characteristics or other physical properties, the lack of sufficient efficacy against the disease target, difficulties in developing a cost-effective manufacturing or formulation method or the discovery of toxicities or side effects that are unacceptable for the disease indication being treated.

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

### *Business Strategy*

We have elected to diversify our research and development activities across a relatively broad array of investment opportunities, due in part to the high risks associated with the biotechnology and pharmaceutical business. We plan to expend significant resources on development and commercialization of some of our drug product candidates in certain markets, and rely on collaborators to develop and commercialize certain of our other drug candidates either worldwide or in markets upon which we are not

currently focused. This diversification strategy requires more significant financial resources than would be required if we pursued a more limited approach.

Because we have incurred losses from our inception and expect to incur losses for the foreseeable future, we are dependent in large part on our continued ability to raise significant funding to finance our discovery and development operations and our overhead and to meet our long-term contractual commitments

and obligations. In the past, we have secured funds principally through capital market transactions, strategic collaborative agreements, proceeds from the disposition of assets, investment income and the issuance of stock under our employee benefit programs. At June 30, 2006, we had \$315.9 million of cash, cash equivalents and available-for-sale securities, \$42.1 million in principal amount of 5% Convertible Subordinated Notes due 2007 (the "2007 Notes") and \$118.0 million in principal amount of 5.75% Convertible Senior Subordinated Notes due 2011 (the "2011 Notes"). In early July 2006, we received \$165.0 million as an upfront payment under our June 30, 2006 VX-950 (telaprevir) collaboration agreement with Janssen. In early August 2006, we agreed to exchange approximately 4.1 million newly issued shares of our common stock for approximately \$58.3 million in aggregate principal amount of outstanding 2011 Notes, including accrued and unpaid interest, reducing our outstanding aggregate principal amount of outstanding 2011 Notes to approximately \$59.6 million. In order to fund our research, development and manufacturing activities, particularly for later stage compounds including VX-950 (telaprevir), we expect to continue to pursue a general financing strategy that may lead us to undertake one or more additional capital transactions, which may or may not be similar to transactions in which we have engaged in the past. We cannot be sure that any such financing opportunities will be available on acceptable terms.

Collaborations have been and will continue to be an important component of our business strategy.

On June 30, 2006, we entered into a License, Development, Manufacturing and Commercialization Agreement with Janssen Pharmaceutica, N.V., an affiliate of the Johnson & Johnson Company, for the development, manufacture and commercialization of VX-950 (telaprevir), which is currently being investigated in Phase II clinical trials for the treatment of HCV infection. Under our agreement with Janssen, we will collaborate with Janssen to develop VX-950 (telaprevir) worldwide except for the Far East, and Janssen will be responsible for commercializing the compound worldwide except for North America and the Far East. We have retained exclusive commercial rights to VX-950 (telaprevir) in North America and will lead the global development program. Under the agreement, we received an upfront payment of \$165 million in July 2006. In addition, the agreement provides for up to \$380 million in milestone payments, contingent upon the successful development and commercialization of VX-950 (telaprevir). Janssen will fund 50% of costs for the VX-950 (telaprevir) development program for North America and the Janssen territories beginning on the date of the agreement. Janssen is responsible for commercialization of VX-950 (telaprevir) in Janssen's territory and will pay us tiered royalties on any product sales, averaging in the mid -20% range, and will be responsible for paying certain third party royalties. In connection with the development and commercialization of VX-950 (telaprevir), we will work with Tibotec Pharmaceuticals, also a Johnson & Johnson company, to establish a global health initiative to increase the prevention, diagnosis, treatment and cure of HCV infection, to be principally directed toward developing countries.

Also in June 2006, we extended the two-year research program term under our Exclusive Research Collaboration, License and Commercialization Agreement with Merck & Co, Inc. by an additional three months, until September 2006. Our research collaboration with Novartis Pharma AG, together with the corresponding research funding, expired during the second quarter of 2006. We expect that the revenue and funding from collaborations that support our development stage compounds, such as the Janssen agreement, will in the future provide a proportionately higher level of financial support for the Company's R&D activities than revenue from research collaboration agreements.

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Our pipeline also includes other potential drug candidates that we may choose to develop with or through a collaborator, as we maintain focus on our core product candidates. We may also seek collaborators for our research programs.

#### *Clinical Development Programs*

We are focusing our 2006 preclinical and clinical development investment on VX-950 (telaprevir), VX-702 and VX-770. As a result of our progress in the first half of 2006 in the VX-950 (telaprevir) development program, we currently plan to further increase our investment in that compound to support the global Phase IIb clinical development program. We also currently are incurring and expect to continue to incur significant costs to manufacture VX-950 (telaprevir) drug product, in advance of obtaining regulatory marketing approval, in sufficient quantities to support a timely commercial product launch if we are successful in obtaining such approval. Investment in these activities at the current stage of clinical development is subject to considerable risk that VX-950 (telaprevir) will not advance to product registration, placing our full investment in the compound at risk.

We currently are conducting two major Phase II clinical trials of VX-950 (telaprevir)—PROVE 1 in the United States and PROVE 2 in Europe, as part of a global Phase II development program for VX-950 (telaprevir). We expect that together, the two clinical trials will evaluate sustained viral response ("SVR") rates in 580 treatment-naïve patients infected with genotype 1 HCV. Our global Phase II development program in treatment-naïve patients has three objectives: (i) to evaluate the optimal SVR rate that can be achieved with VX-950 (telaprevir) therapy in combination with the current standard of care; (ii) to evaluate the optimal treatment duration for VX-950 (telaprevir) combination therapy; and (iii) to evaluate the role of ribavirin in VX-950 (telaprevir)-based therapy. We have enrolled over 100 patients in PROVE 1 to date. In addition to these two clinical trials, we expect to begin additional clinical trials of VX-950 (telaprevir) in the second half of the year, including a Phase II clinical trial in patients who have failed prior standard of care treatment. We anticipate those additional clinical trials to enroll approximately 400 patients. By the end of the first quarter of 2007, we expect to have enrolled approximately 1,000 patients in clinical trials of VX-950 (telaprevir). We collaborate in the Far East clinical development of VX-950 (telaprevir) with Mitsubishi Pharma Corporation, which began the first Phase I clinical trial of VX-950 (telaprevir) in the Far East.

We recently revised our clinical development plans for VX-702, and now expect to initiate a Phase II clinical trial of VX-702 on a background of methotrexate in patients with RA in 2007.

We have completed dosing in the first two cohorts of healthy volunteers in the single dose Phase I clinical trial of VX-770, which targets a key mechanism underlying the progression of cystic fibrosis. In the second half of 2006, we plan to evaluate multiple doses of VX-770 in healthy volunteers and assess single doses of VX-770 in patients with CF.

We believe that each of these programs requires that we make a comprehensive investment to realize its full clinical and commercial value. We also recognize that development investment at this stage is subject to the considerable risk that any one or more of these compounds will not advance to product registration. Each compound could fail to progress or advance due to a wide range of adverse experimental outcomes, placing our full investment in the compound at risk. While we attempt to stage our investments to mitigate these financial risks, drug discovery and development by its nature is a very risky undertaking. We expect to continue to evaluate and prioritize investment in our clinical development programs based on the emergence of new clinical and nonclinical data in each program throughout 2006 and in subsequent years.

In the clinical development program being conducted by our collaborator Merck for VX-680, an investigational drug candidate targeting Aurora kinase, Merck began patient enrollment in a Phase II clinical trial of VX-680 in patients with advanced lung cancer. A Phase II clinical trial of VX-680 in

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patients with advanced colorectal cancer and an extended Phase I clinical trial of patients with hematologic cancers are ongoing. We now expect that our collaborator GSK will initiate Phase III development of brecaNAVIR, a novel HIV protease inhibitor currently being evaluated in a Phase II clinical trial, in 2007.

### *Financial Guidance*

The key financial measures for which we have provided guidance are as follows:

**Net Loss:** In July 2006, we revised our expected net loss on a GAAP basis upward from our previous guidance of a range of \$205 to \$225 million, including an estimated \$34 million in stock-based compensation expense and an estimated \$6 million of restructuring expense, to incorporate additional research and development investment related to our expanded global Phase IIb program for VX-950 (telaprevir). We now expect that the net loss on a GAAP basis for 2006 will be in the range of \$222 million to \$237 million. This net loss estimate includes an estimated \$38 million in stock-based compensation expense and an estimated \$4 million of restructuring expense as a result of imputed interest charges relating to the restructuring accrual.

**Revenues:** We expect that the Company's revenue will be in the range of \$210 to \$235 million in 2006.

**Research and Development ("R&D") Expense:** We expect that R&D expense will be in the range of \$375 to \$395 million for 2006, including approximately \$31 million of stock-based compensation expense. In July 2006, we increased our estimate for R&D expense by \$25 million from a range of \$350 to \$370 million, including \$28 million of stock-based compensation expense. The increase is a result of the anticipated increased investment in our global Phase IIb program for VX-950 (telaprevir).

**Sales, General and Administrative ("SG&A") Expense:** We expect our SG&A expense will be in the range of \$55 to \$60 million for 2006, including approximately \$6 million of stock-based compensation expense.

**Cash, Cash Equivalents and Available-for-Sale Securities:** As a result of the \$165 million upfront payment that we received in early July 2006 as part of the VX-950 (telaprevir) collaboration with Janssen, we expect cash, cash equivalents and available-for-sale securities at the end of 2006 to be in excess of \$400 million.

The financial measures set forth above are forward-looking and are subject to risks and uncertainties that could cause our actual results to vary materially, including the risks and uncertainties that we describe in "Risk Factors" in Item 1A of our 2005 Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission on March 16, 2006, and in the section below entitled "Forward-Looking Statements."

### **Liquidity and Capital Resources**

We have incurred operating losses since our inception and historically have financed our operations principally through public and private offerings of our equity and debt securities, strategic collaborative agreements that include research and development funding, development milestones and royalties on the sales of products, proceeds from the disposition of assets, investment income and proceeds from the issuance of stock under our employee benefit programs.

At June 30, 2006, we had cash, cash equivalents and available-for-sale securities of \$315.9 million, a decrease of \$91.6 million from \$407.5 million at December 31, 2005. This decrease is primarily the result of investment in our clinical development activities, offset by approximately \$31.9 million received from the issuance of common stock under our employee benefit plans. Expenditures for property and equipment during the six months ended June 30, 2006 were \$18.2 million.

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In July 2006, we received a \$165.0 million upfront payment under our collaboration with Janssen for the development, manufacture and commercialization of VX-950 (telaprevir). Under the terms of the Agreement, Janssen will fund 50% of drug development costs incurred on or after June 30, 2006 in the global development program for VX-950 (telaprevir).

At June 30, 2006, we had approximately \$42.1 million in aggregate principal amount of 2007 Notes and approximately \$118.0 million in aggregate principal amount of 2011 Notes outstanding. The 2011 Notes are convertible into common stock at the option of the holder at a price equal to \$14.94 per share, subject to adjustment under certain circumstances. The 2007 Notes are convertible into common stock at the option of the holder at a price equal to \$92.26 per share, subject to adjustment under certain circumstances. In August 2006, we exchanged approximately 4.1 million shares of newly issued common stock for approximately \$58.3 million in aggregate principal amount of outstanding 2011 Notes, plus accrued interest. As a result of these exchanges we expect to incur a non-cash charge of approximately \$5.0 million in the third quarter of 2006. This charge is related to the incremental shares issued in the transaction over the number that would have been issued upon the conversion of the notes under the original conversion terms.

In July 2006, we sold 817,749 shares of Altus Pharmaceuticals common stock for approximately \$11.7 million, resulting in a realized gain of approximately \$7.7 million, to be recognized in the third quarter of 2006.

We expect to continue to make significant investments in our pipeline, particularly in clinical trials for certain of our product candidates, in our ion channel and kinase discovery efforts and in our effort to prepare for potential registration, regulatory approval and commercial launch of our existing and future product candidates. We also expect to continue incurring significant costs to manufacture VX-950 (telaprevir) drug products in advance of obtaining regulatory marketing approval, in sufficient quantities to support a timely commercial product launch if we are successful in obtaining such approval. Consequently, we expect to incur losses on a quarterly and annual basis for the foreseeable future.

As part of our strategy for managing our capital structure, we have from time to time adjusted the amount and maturity of our debt obligations through new issues, privately negotiated transactions and market purchases, depending on market conditions and our perceived needs at the time. During the remainder of 2006, we expect to continue pursuing a general financial strategy that may lead us to undertake one or more additional capital transactions. Any such capital transactions may or may not be similar to transactions in which we have engaged in the past.

To the extent that our current cash and marketable securities, in addition to the above-mentioned sources, are not sufficient to fund our activities, it will be necessary to raise additional funds through public offerings or private placements of our securities or other methods of financing. We also will continue to manage our capital structure and consider all financing opportunities, whenever they may occur, that could strengthen our long-term liquidity profile. There can be no assurance that any such financing opportunities will be available on acceptable terms, if at all.

There have been no significant changes to our commitments and obligations as reported in our 2005 Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission on March 16, 2006.

## Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements prepared in accordance with GAAP. The preparation of these financial statements requires us to make certain estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated

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financial statements and the reported amounts of revenue and expense during the reported periods. These items are constantly 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 recorded in the period in which they become known. We base our estimates on historical experience and various other assumptions that we believe to be reasonable under the circumstances. Actual results may differ from our estimates if past experience or other assumptions do not turn out to be substantially accurate.

We believe that the application of the accounting policies for restructuring and other expense, revenue recognition, research and development expenses, investments and stock-based compensation, all of which are important to our financial condition and results of operations, require significant judgments and estimates on the part of management. Our accounting policies, including the ones discussed below, are more fully described in Note B, "Accounting Policies," to our consolidated financial statements included in our Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission on March 16, 2006.

### *Restructuring Expense*

We record liabilities associated with restructuring activities based on estimates of fair value in the period the liabilities are incurred, in accordance with FAS 146. As prescribed by FAS 146, we use a probability-weighted discounted cash-flow analysis to calculate the amount of the liability. The probability-weighted discounted cash-flow analysis is based on management's assumptions and estimates of our ongoing lease obligations, including contractual rental commitments, build-out commitments and building operating costs, and estimates of income from subleases, based on the term and timing of such subleases. We discount the estimated cash flows using a discount rate of approximately 10%. These cash flow estimates are reviewed and may be adjusted in subsequent periods. Adjustments are based, among other things, on management's assessment of changes in factors underlying the estimates. Because our estimate of the liability includes the application of a discount rate to reflect the time-value of money, the estimate will increase simply as a result of the passage of time, even if all other factors remain unchanged.

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

The accrual for restructuring expense of \$36.3 million at June 30, 2006 is related to the portion of the Kendall Square Facility that we do not intend to occupy. This estimate represents our best judgment of the assumptions and estimates most appropriate in measuring the ongoing obligation.

### *Revenue Recognition*

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

Our revenues are generated primarily through collaborative research, development and commercialization agreements. The terms of the agreements typically include payment to us of non-

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refundable up-front license fees, funding of research and development efforts, milestone payments and/or royalties on product sales.

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

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

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

- In those circumstances where collection of a substantive milestone is reasonably assured, we have remaining obligations to perform under the collaboration arrangements and we have evidence of fair value for our remaining obligations, we consider the milestone payment and the remaining obligations to be separate units of accounting. In these circumstances, we use the residual method under EITF 00-21, Revenue Arrangements with Multiple Deliverables to allocate revenue among the milestones and the remaining obligations.
- In those circumstances where collection of a substantive milestone is reasonably assured, we have remaining obligations to perform under the collaboration arrangement, and we do not have sufficient evidence of fair value for our remaining obligations, we consider the milestone payment and the remaining obligations on the contract as a single unit of accounting. In those circumstances where the collaboration does not require specific deliverables at specific times or at the end of the contract term, but rather our obligations are satisfied over a period of time, substantive milestones are recognized over the period of performance. This typically results in a portion of the milestone payment being recognized as revenue at the date

the milestone is achieved equal to the applicable percentage of the performance period that has elapsed as of the date the milestone is achieved, with the balance being deferred and recognized over the remaining period of performance.

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

Payments received after performance obligations are met completely are recognized when earned.

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

#### *Research and Development Costs*

All research and development costs, including amounts funded by research and development collaborations, are expensed as incurred. Research and development expenses are comprised of costs incurred in performing research and development activities including salaries and benefits; laboratory supplies; contract services, including clinical trial costs; and infrastructure costs, including facilities costs

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and depreciation. To record clinical trial, contract services and other outside costs, we are required to make estimates of the costs incurred in a given accounting period and record accruals at period-end, because the third party service periods and billing terms do not always coincide with our period-end. We base our estimates on our knowledge of the research and development programs, services performed for the period, past history for related activities and the expected duration of the third party service contract, where applicable.

#### *Altus Investment*

Altus Pharmaceuticals, Inc. completed an initial public offering in January 2006. At June 30, 2006, we owned 817,749 shares of Altus common stock and warrants to purchase 1,962,494 shares of Altus common stock. In addition, we hold 450,000 shares of Altus redeemable preferred stock, which are not convertible into common stock and which are redeemable at our option on or after December 31, 2010, or by Altus at any time. We were restricted from trading Altus securities for a period of six months following the initial public offering. The period ended in July 2006.

As a result of the public offering, the common stock is classified as an available-for-sale investment and is recorded at fair value, based on quoted market prices, with unrealized gains and losses included as a component of accumulated other comprehensive income, which is a separate component of stockholders' equity, until such gains and losses are realized. At June 30, 2006, the fair market value of the Altus common stock investment was \$15.1 million, with a cost value of \$4.0 million. In July 2006, we sold the 817,749 shares of common stock for approximately \$11.7 million. We expect to record a gain of approximately \$7.7 million on this sale in the third quarter of 2006.

We continued to account for the warrants under the cost method of accounting until the end of the restricted trading period in July 2006, after which time the warrants have been classified as derivatives. Gains or losses on the fair market value of the warrants, as derivatives, will be included in the consolidated statements of operations beginning in the third quarter of 2006. We continue to account for the redeemable preferred stock under the cost method of accounting.

We continue to assess the Altus warrants and redeemable preferred stock on a quarterly basis to determine if there has been any estimated decrease in the fair value of that investment below the carrying value that might require us to write down the cost basis of the investment. If any adjustment to the fair value of an investment reflects a decline in the value of that investment below its cost, we consider the evidence available to us, including the duration and extent to which the decline is other-than-temporary. If the decline is considered other-than-temporary, the cost basis of the investment is written down to fair value as a new cost basis and the amount of the write-down is included in the consolidated statements of operations. We have not identified facts or circumstances which would cause us to determine that the investment basis of our interest in Altus should be changed.

#### *Stock-based compensation*

We adopted the provisions of Statement of Financial Accounting Standards Board No. 123(R), "Share-Based Payments" ("FAS 123(R)"), on January 1, 2006. FAS 123(R) requires us to measure compensation cost of stock-based compensation at the grant date, based on the fair value of the award, and to recognize that cost as an expense over the employee's requisite service period (generally the vesting period of the equity award). Prior to January 1, 2006, we accounted for stock-based compensation to employees in accordance with Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25"), and related interpretations. We also followed the disclosure requirements of Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation" ("FAS 123"). We elected to adopt the modified prospective transition method as provided by FAS 123(R) and accordingly, financial statement amounts for the periods prior to January 1, 2006 that are presented in this Form 10-Q have not been restated to reflect the fair value method.

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

## **Results of Operations**

### ***Three Months Ended June 30, 2006 Compared with Three Months Ended June 30, 2005***

Our net loss for the three months ended June 30, 2006 was \$77,658,000, or \$0.72 per basic and diluted common share, compared to net loss of \$40,988,000, or \$0.50 per basic and diluted common share for the three months ended June 30, 2005. Included in the net loss for the quarter ended June 30, 2006 is stock-based compensation expense of \$11,647,000 and restructuring expense of \$443,000. Included in the net loss for the quarter ended June 30, 2005 is stock-based compensation expense of \$1,129,000 and a credit to restructuring expense of \$1,743,000. The increase in the net loss is primarily the result of increased development investment related to VX-950 (telaprevir) as well as increased charges for stock-based compensation due to the adoption of FAS 123(R) on January 1, 2006.

#### Revenues

Total revenues decreased \$2,595,000 to \$29,726,000 for the three months ended June 30, 2006, compared to \$32,321,000 for the three months ended June 30, 2005. In the second quarter of 2006, revenue was comprised of \$9,005,000 in royalties and \$20,721,000 in collaborative research and development revenue. In the second quarter of 2005, revenue was comprised of \$7,467,000 in royalties and \$24,854,000 in collaborative research and development revenue.

Royalties consist principally of Lexiva/Telzir royalty revenue, based on actual and estimated worldwide net sales. We began earning royalties on sales of Lexiva in the United States in the fourth quarter of 2003 and on Telzir in the European Union in third quarter of 2004. The increase in royalty revenue is due to an increase in Lexiva/Telzir sales. We pay a royalty to a third party on sales of Lexiva/Telzir.

Collaborative research and development revenue decreased \$4,133,000, or 17%, for the three months ended June 30, 2006, as compared with the same period in 2005. This decrease is primarily related to the expiration of our research collaboration with Novartis in April 2006.

With the signing of the VX-950 (telaprevir) collaboration with Janssen, we expect that for the foreseeable future the revenue and funding from collaborations that support our development-stage compounds, including development cost reimbursements and milestones, will provide a proportionately higher level of financial support for the Company's research and development activities than revenue from research collaboration agreements.

#### Costs and Expenses

Research and development expenses increased \$31,893,000, or 54%, to \$91,250,000, including \$9.8 million of stock-based compensation, for the three months ended June 30, 2006, from \$59,357,000, including \$0.9 million of stock-based compensation, for the same period in 2005. The increase in research and development expenses was driven primarily by investment in our clinical development programs for VX-950 (telaprevir) and VX-702 as well as an increase in stock-based compensation expense of \$8,828,000

due to the adoption of FAS 123(R). Development expenses accounted for 79%, or \$25,284,000, of the aggregate increase in research and development expenses.

Research and development expenses consist primarily of salary and benefits, laboratory supplies, contractual services and infrastructure costs, including facilities costs and depreciation. Set forth below is a summary that reconciles our total research and development expenses for the three months ended June 30, 2006 and 2005 (in thousands):

	Three Months Ended June 30,		\$ Change	% Change
	2006	2005		
<b>Research Expenses:</b>				
Salary and benefits	\$ 16,136	\$ 10,066	\$ 6,070	60%
Laboratory supplies and other direct expenses	5,965	5,419	546	10%
Contractual services	1,772	1,750	22	1%
Infrastructure costs	12,548	12,577	(29)	—%
Total research expenses	<u>\$36,421</u>	<u>\$ 29,812</u>	\$ 6,609	
<b>Development Expenses:</b>				
Salary and benefits	\$ 14,292	\$ 6,330	\$ 7,962	126%
Laboratory supplies and other direct expenses	4,610	2,763	1,847	67%
Contractual services	25,376	13,844	11,532	83%
Infrastructure costs	10,551	6,608	3,943	60%
Total development expenses	<u>\$54,829</u>	<u>\$ 29,545</u>	\$ 25,284	
<b>Total Research and Development Expenses:</b>				
Salary and benefits	\$ 30,428	\$ 16,396	\$ 14,032	86%
Laboratory supplies and other direct expenses	10,575	8,182	2,393	29%
Contractual services	27,148	15,594	11,554	74%
Infrastructure costs	23,099	19,185	3,914	20%
Total research and development expenses	<u>\$91,250</u>	<u>\$ 59,357</u>	\$ 31,893	

Sales, general and administrative expenses increased to \$14,370,000, including \$1,892,000 of stock-based compensation, for the three months ended June 30, 2006, compared to \$10,814,000, including \$202,000 of stock-based compensation, for the same period in 2005. The change is due to an increase in infrastructure costs to support increases in research and development.

Restructuring expense for the three months ended June 30, 2006 was \$443,000, compared to a restructuring credit for the three months ended June 30, 2005 of \$1,743,000. The charge in the three months ended June 30, 2006 resulted primarily from an imputed interest cost related to the restructuring accrual. The restructuring credit for the three months ended June 30, 2005 resulted from an adjustment of the portion of restructuring accrual relating to the portion of the Kendall Square Facility that we are occupying, offset by (i) a charge in the amount of the estimated incremental net ongoing lease obligation associated with the portion of the Kendall Square Facility that we still do not intend to occupy and (ii) imputed interest costs relating to the restructuring liability.

The activity related to the restructuring accrual and related expense for the three months ended June 30, 2006 is as follows (in thousands):

	Accrual as of March 31, 2006	Cash payments, second quarter 2006	Cash received from subleases, second quarter 2006	Charge, second quarter 2006	Accrual as of June 30, 2006
Lease restructuring expense	\$ 41,719	\$ (7,904)	\$ 2,020	\$ 443	\$ 36,278

The activity related to the restructuring accrual and related expense for the three months ended June 30, 2005 is as follows (in thousands):

	Accrual as of March 31, 2005	Cash payments, second quarter 2005	Cash received from sublease, second quarter 2005	Portion of facility Vertex expects to occupy, second quarter 2005	Charge, second quarter 2005	Accrual as of June 30, 2005
Lease restructuring expense	\$ 52,305	\$ (7,242)	\$ 493	\$ (10,018)	\$ 8,275	\$ 43,813

Interest income increased \$1,674,000, or 74%, to \$3,921,000 for the three months ended June 30, 2006 from \$2,247,000 for the three months ended June 30, 2005. The increase is a result of higher portfolio yields.

Interest expense decreased \$2,282,000, or 49%, to \$2,357,000 for the three months ended June 30, 2006 from \$4,639,000 for the three months ended June 30, 2005. The decrease resulted from reduction of outstanding debt in 2005.

As of June 30, 2006, there was approximately \$64,353,000 of unrecognized compensation cost, net of forfeitures, related to stock-based awards granted under the Stock and Option Plans. We expect to recognize that cost over a weighted-average period of 2.72 years.

#### Six Months Ended June 30, 2006 Compared with Six Months Ended June 30, 2005

Our net loss for the six months ended June 30, 2006 was \$127,745,000, or \$1.18 per basic and diluted common share, compared to net loss of \$85,708,000, or \$1.06 per basic and diluted common share for the six months ended June 30, 2005. Included in the net loss for the six months ended June 30, 2006 is stock-based compensation expense of \$19,772,000, restructuring expense of \$1,210,000 and the effect of a cumulative benefit of accounting change of \$1,046,000, related to the adoption of FAS 123(R). Included in the net loss for the six months ended June 30, 2005 is stock-based compensation expense of \$2,160,000 and restructuring expense of \$171,000.

#### Revenues

Total revenues increased \$7,886,000 to \$68,813,000 for the six months ended June 30, 2006, compared to \$60,927,000 for the six months ended June 30, 2005. In the first half of 2006, revenue was comprised of \$18,184,000 in royalties and \$50,629,000 in collaborative research and development revenue. In the first half of 2005, revenue was comprised of \$13,620,000 in royalties and \$47,307,000 in collaborative research and development revenue.

Collaborative research and development revenue increased \$3,322,000, or 7%, in the first half of 2006, as compared with the same period in 2005. This increase primarily relates to milestone payments from Merck upon the initiation of Phase II clinical trials of VX-680, partially offset by reduced research funding under our Novartis collaboration, which expired in April 2006.

#### Costs and Expenses

Research and development expenses increased \$49,660,000, or 43%, to \$166,452,000, including \$16.2 million of stock-based compensation, for the six months ended June 30, 2006 from \$116,792,000, including \$1.8 million of stock-based compensation, for the same period in 2005. The increase in research and development expenses was driven primarily by investment in our clinical development programs for VX-950 (telaprevir) and VX-702 as well as an increase in stock-based compensation expense of \$14,397,000 due to the adoption of FAS 123(R). Development expenses accounted for 74%, or \$36,781,000, of the aggregate increase in research and development expenses.

Research and development expenses consist primarily of salary and benefits, laboratory supplies, contractual services and infrastructure costs, including facilities costs and depreciation. Set forth below is a summary that reconciles our total research and development expenses for the six months ended June 30, 2006 and 2005 (in thousands):

	Six Months Ended June 30,		\$ Change	% Change
	2006	2005		
<b>Research Expenses:</b>				
Salary and benefits	\$ 30,843	\$ 20,143	\$ 10,700	53%
Laboratory supplies and other direct expenses	11,866	11,012	854	8%
Contractual services	3,581	3,511	70	2%
Infrastructure costs	26,403	25,148	1,255	5%
Total research expenses	\$ 72,693	\$ 59,814	\$ 12,879	
<b>Development Expenses:</b>				
Salary and benefits	\$ 26,080	\$ 12,589	\$ 13,491	107%
Laboratory supplies and other direct expenses	8,445	4,829	3,616	75%
Contractual services	41,035	26,743	14,292	53%
Infrastructure costs	18,199	12,817	5,382	42%
Total development expenses	\$ 93,759	\$ 56,978	\$ 36,781	
<b>Total Research and Development Expenses:</b>				
Salary and benefits	\$ 56,923	\$ 32,732	\$ 24,191	74%
Laboratory supplies and other direct expenses	20,311	15,841	4,470	28%
Contractual services	44,616	30,254	14,362	47%

Infrastructure costs	44,602	37,965	6,637	17%
Total research and development expenses	<u>\$ 166,452</u>	<u>\$ 116,792</u>	\$ 49,660	

Sales, general and administrative expenses increased to \$27,249,000, including \$3,611,000 of stock-based compensation, for the six months ended June 30, 2006, compared to \$20,441,000, including \$396,000 of stock-based compensation, for the same period in 2005. The change is due to an increase in infrastructure costs to support the growing research and development effort.

Restructuring expense for the six months ended June 30, 2006 was \$1,210,000, compared to a restructuring expense for the six months ended June 30, 2005 of \$171,000. The charge in the six months ended June 30, 2006 resulted primarily from an imputed interest cost related to the restructuring accrual. The expense for the six months ended June 30, 2005 includes an adjustment of the portion of restructuring relating to the portion of the Kendall Square Facility that we expect to occupy, offset by (i) a charge in the amount of the estimated incremental net ongoing lease obligation associated with the portion of the Kendall Square Facility that we still do not intend to occupy and (ii) imputed interest costs relating to the restructuring liability.

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The activity related to the restructuring accrual and related expense for the six months ended June 30, 2006 is as follows (in thousands):

	Accrual as of Dec. 31, 2005	Cash, payments six months ended June 30, 2006	Cash received from subleases, six months ended June 30, 2006	Charge six months ended June 30, 2006	Accrual as of June 30, 2006
Lease restructuring expense	<u>\$ 42,982</u>	<u>\$ (11,884)</u>	<u>\$ 3,970</u>	<u>1,210</u>	<u>\$ 36,278</u>

The activity related to the restructuring accrual and related expense for the six months ended June 30, 2005 is as follows (in thousands):

	Accrual as of December 31, 2004	Cash payments, six months ended June 30, 2005	Cash received from sublease, six months ended June 30, 2005	Portion of facility Vertex expects to occupy, six months ended June 30, 2005	Charge, Six months ended June 30, 2005	Accrual as of June 30, 2005
Lease restructuring expense	<u>\$ 55,843</u>	<u>\$ (13,017)</u>	<u>\$ 816</u>	<u>\$ (10,018)</u>	<u>\$ 10,189</u>	<u>\$ 43,813</u>

Interest income increased \$3,335,000, or 73%, to \$7,901,000 for the six months ended June 30, 2006 from \$4,566,000 for the six months ended June 30, 2005. The increase is a result of higher portfolio yields.

Interest expense decreased \$4,564,000, or 49%, to \$4,714,000 for the six months ended June 30, 2006 from \$9,278,000 for the six months ended June 30, 2005. The decrease resulted from our reduction of outstanding debt in 2005.

Pursuant to the adoption of FAS 123(R), stock-based compensation expense is recognized over the service period, including an estimate of awards that will be forfeited. Previously, we recorded the impact of forfeitures as they occurred. In connection with the adoption of FAS 123(R) during the first half of fiscal year 2006, we recorded a \$1,046,000 benefit from the cumulative effect of changing from recording forfeitures related to restricted stock awards as they occurred to estimating forfeitures during the service period.

#### New Accounting Pronouncements

In May 2005, the FASB issued FAS No. 154, "Accounting Changes and Error Corrections" ("FAS 154"). FAS No. 154 replaces APB Opinion No. 20, "Accounting Changes" and FAS No. 3, "Reporting Accounting Changes in Interim Financial Statements." FAS No. 154 requires retrospective application to prior periods' financial statements of changes in accounting principle, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. We adopted FAS 154 beginning on January 1, 2006; its adoption did not have a material impact on our consolidated financial statements.

In November 2005, FASB issued FSP FAS 115-1 and FAS 124-1, "The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments" ("FSP FAS 115-1"), which provides guidance on determining when investments in certain debt and equity securities are considered impaired, whether an impairment is other-than-temporary, and on measuring such impairment loss. FSP FAS 115-1 also includes accounting considerations subsequent to the recognition of an other-than-temporary impairment and requires certain disclosures about unrealized losses that have not been recognized as other-than-temporary impairments. FSP FAS 115-1 is required to be applied to reporting periods beginning after December 15, 2005. We adopted FSP FAS 115-1 in the first quarter of 2006. Adoption of

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FSP FAS 115-1 did not have a material impact on our consolidated results of operations or financial condition.

#### Forward-Looking Statements

Our disclosure in this Quarterly Report on Form 10-Q contains forward-looking statements. Forward-looking statements give our current expectations or present forecasts of future events. You can identify these statements by the fact that they do not relate strictly to historical or current facts. Such statements may include words such as "anticipate," "estimate," "expect," "project," "intend," "plan," "believe" and other words and phrases of similar meaning in connection with any discussion of future operating or financial performance. In particular, these statements include forward-looking statements about our business, including our expectations that:

- we will incur a substantial loss for the year ending December 31, 2006;
- the estimates and assumptions used in determining the value of stock-based compensation under FAS 123(R), including assumptions relating to future stock volatility, award forfeiture rates and employee behavior, will prove accurate;



- the estimates and assumptions used in evaluating the future obligations arising from the Kendall Square lease, including assumptions relating the costs to be incurred to satisfy our buildout requirements under the lease, the time necessary to sublease the space, projected sublease rental rates and the duration of future subleases, will prove accurate;
- we will rely on collaborators to develop and commercialize certain of our drug candidates either worldwide or in markets upon which we are not currently focused;
- the timing of our drug development activities will be as set forth in this Quarterly Report;
- we may choose to develop some of our drug candidates with or through a collaborator, as we maintain focus on our core product candidates;
- we may seek collaborators for our research programs;
- our increased clinical investment will be as a result of our investment in our core programs;
- we will continue to evaluate and prioritize investment in our clinical development programs based on the emergence of new clinical and nonclinical data in each program in 2006 and in subsequent years;
- we will further increase our investment in VX-950 (telaprevir) to support the global Phase IIb development program;
- we will continue to incur significant manufacturing costs for VX-950 (telaprevir) drug product in quantities to support a timely commercial launch;
- our timelines for development and commercialization of VX-950 (telaprevir) will be as we have projected;
- PROVE 1 and PROVE 2 together will evaluate sustained viral response (“SVR”) rates in 580 treatment naïve patients infected with genotype 1 HCV;
- we will begin additional clinical trials of VX-950 (telaprevir) in approximately 400 patients in the second half of the year, including a Phase IIb study in patients who failed prior standard of care treatment;
- by the end of the first quarter of 2007, we will have enrolled approximately 1,000 patients in clinical trials of VX-950 (telaprevir);
- we will initiate a Phase II clinical trial of VX-702 on a background of methotrexate in patients with RA in 2007;

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- we will evaluate multiple doses of VX-770 in healthy volunteers and assess single doses of VX-770 in patients with CF;
  - GSK will initiate a Phase III clinical trial of brecanavir in 2007;
  - our net loss on a GAAP basis for 2006 will be in the range of \$222 million to \$237 million, including an estimated \$38 million in stock-based compensation expense and an estimated \$4 million of restructuring expense;
  - our 2006 revenue will be in the range of \$210 to \$235 million;
  - our SG&A expense will be in the range of \$55 to \$60 million for 2006, including approximately \$6 million of stock-based compensation expense;
  - our R&D expense in 2006 will be in the range of \$375 million to \$395 million, including approximately \$31 million of stock-based compensation expense;
  - our cash, cash equivalents and available-for-sale securities at the end of 2006 will be in excess of \$400 million;
  - we will incur a non-cash charge of approximately \$5.0 million related to the August 2006 debt exchange in the third quarter of 2006;
  - we will record a gain of approximately \$7.7 million on the sale of Altus common stock in the third quarter of 2006;
  - we will continue to make significant investments in our pipeline, particularly in clinical trials for certain of our product candidates, in our ion channel and kinase discovery efforts and in our effort to prepare for potential registration, regulatory approval and commercial launch of our existing and future product candidates;
  - we will incur losses on a quarterly and annual basis for the foreseeable future;
  - for the foreseeable future, revenue and funding from collaborations that support our development-stage compounds will provide a proportionately higher level of financial support for the Company’s research and development activities than revenue and funding from research collaborations;
  - we will continue pursuing a general financial strategy that may lead us to undertake one or more additional capital transactions, which may or may not be similar to transactions in which we have engaged in the past; and
  - we will continue to manage our capital structure and consider all financing opportunities, whenever they may occur, that could strengthen our long-term liquidity profile.

Any or all of our forward-looking statements in this Quarterly Report may turn out to be wrong. They can be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties. Many factors mentioned in our discussion in this Quarterly Report will be important in determining future results. While management makes its best efforts to be accurate in making forward-looking statements, such statements are subject to risks and uncertainties that could cause our actual results to vary materially. These risks and uncertainties include, among other things, the risk that (1) any one or more of our internal drug development programs or our development programs with collaborators will not proceed as planned for technical, scientific or commercial reasons, due to U.S. Food and Drug Administration disagreement on trial designs, due to patient enrollment issues, due to manufacturing delay or due to judgments based on new information from non-clinical studies or clinical trials or from other sources, (2) one or more of our assumptions underlying our revenue expectations or our expense expectations will not be realized, (3) we will be unable to realize one or more of our financial objectives for 2006 due to unexpected and costly program delays (including delays due to regulatory action or lack of action) or any number of other financial, technical or collaboration considerations, (4) unexpected costs associated with one or more of

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our programs will necessitate a reduction in our investment in other programs or a change in our financial projections, (5) future competitive or other market factors may adversely impact the commercial potential for our product candidates in HCV and inflammation and other areas, (6) due to scientific, medical or technical developments, our drug discovery efforts will not ultimately result in commercial products or assets that can generate revenue, (7) we will be unable to enter into new collaborative relationships to support our research and development programs on acceptable terms, or at all, (8) the key estimates and

assumptions underlying our forward-looking statements will turn out to be incorrect or not reflective of changing scientific knowledge or business conditions in the future, as well as other risks set forth under the heading "Risk Factors" appearing in Item 1A of our Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 16, 2006 and updated on this Quarterly Report on Form 10-Q, which are factors that we think could cause our actual results to differ materially from expected results. Other factors besides those listed there could also adversely affect us. Consequently, no forward-looking statement can be guaranteed. We disclaim any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

### **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. As of June 30, 2006, there were no derivative financial instruments in our investment portfolio.

#### **Interest Rate Risk**

We invest our cash in a variety of financial instruments, principally securities issued by the U.S. government and its agencies, investment grade corporate bonds and notes and money market instruments. These investments are denominated in U.S. dollars. All of our interest-bearing securities are subject to interest rate risk, and could decline in value if interest rates fluctuate. Substantially all of our investment portfolio consists of marketable securities with active secondary or resale markets to help ensure portfolio liquidity, and we have implemented guidelines limiting the term to maturity of our investment instruments. Due to the conservative nature of these instruments, we do not believe that we have a material exposure to interest rate risk.

### **Item 4. Controls and Procedures**

#### *Evaluation of Disclosure Controls and Procedures*

The Company's chief executive officer and chief financial officer, after evaluating the effectiveness of the Company's disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this Quarterly Report on Form 10-Q, have concluded that, based on such evaluation, at the end of the period covered by this report, our disclosure controls and procedures were effective and designed to provide reasonable assurance that the information required to be disclosed is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms. These procedures and controls include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, our Company's 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.

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

No change in our internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) occurred during the second fiscal quarter, ended June 30, 2006, that has affected, or is reasonably likely to affect, our internal control over financial reporting.

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## **Part II. Other Information**

### **Item 1A. Risk Factors**

#### **We depend on our collaborators to work with us to develop, manufacture and commercialize many of our drug candidates.**

We are currently focusing our development activities on three drug candidates, VX-950 (telaprevir), VX-702, and VX-770. We have granted development and commercialization rights to VX-950 (telaprevir) to Mitsubishi Pharma Corp. (Far East) and to Janssen Pharmaceutica, N.V. (rest of world other than North America and Far East). The success of our collaborations depends on the efforts and activities of our collaborators. We also have granted Far East rights to VX-702 to our collaborator Kissei Pharmaceuticals. For some compounds on which we are not currently focusing our development efforts, we have granted worldwide rights to a collaborator, such as our VX-680 collaboration with Merck and Co., Inc., our Lexiva/Telzir, breacanavir and VX-409 collaborations with GlaxoSmithKline and our VX-944 collaboration with Avalon Pharmaceuticals.

We expect to receive significant financial support under our Janssen collaboration agreement, as well as meaningful technical and manufacturing contributions to the VX-950 (telaprevir) program. The success of our global collaborations depends on the efforts and activities of our collaborators. Similarly, the success of our key in-house programs, such as for VX-950 (telaprevir) and VX-702, is dependent upon the continued financial and other support that our collaborators have agreed to provide. Each of our collaborators has significant discretion in determining the efforts and resources that it will apply to the collaboration. Our existing and any future collaborations may not be scientifically or commercially successful.

The risks that we face in connection with these existing and any future collaborations include the following:

- Our collaboration agreements are subject to termination under various circumstances, including, as in the case of our agreement with Janssen, termination without cause. Any such termination could delay the development and commercial sale of our drug candidates, including VX-950 (telaprevir).
- Our collaborators may change the focus of their development and commercialization efforts. Pharmaceutical and biotechnology companies historically have re-evaluated their development and commercialization priorities following mergers and consolidations, which have been common in recent years in these industries. The ability of some of our product candidates to reach their potential could be limited if our collaborators decrease or fail to increase development or commercialization efforts related to those products.
- Our collaboration agreements may have the effect of limiting the areas of research and development that we may pursue, either alone or in collaboration with third parties.

- Our collaborators may develop and commercialize, either alone or with others, products that are similar to or competitive with the products that are the subject of the collaboration with us.

For additional risk factors relating to the Company and its business, see Item 1A of our 2005 Annual Report on Form 10-K, which was filed with the Commission on March 16, 2006.

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

(c) The table set forth below shows all repurchases of securities by the Company during the three months ended June 30, 2006:

Period	Total Number of Shares Purchased(1)	Average Price Paid per Share	Total Number of Shares Purchased as part of publicly announced Plans or Programs	Maximum Number of Shares that may yet be purchased under Plans or Programs
April 1, 2006 to April 30, 2006	3,070	\$ 0.01	—	—
May 1, 2006 to May 31, 2006	9,863	\$ 0.01	—	—
June 1, 2006 to June 30, 2006	10,497	\$ 0.01	—	—

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

## Item 4. Submission of Matters to a Vote of Security Holders

The Company's annual meeting of stockholders was held on May 11, 2006.

The stockholders elected Mr. Eric K. Brandt, Mr. Bruce I. Sachs and Dr. Eve E. Slater to serve on the Board of Directors until the annual meeting of stockholders to be held in 2009. The tabulation of votes with respect to the election of such directors is as follows:

	For	Withheld
<b>Eric K. Brandt</b>	88,536,811	1,731,254
<b>Bruce I. Sachs</b>	82,425,075	7,842,991
<b>Eve E. Slater</b>	89,937,730	330,336

Following the meeting, the Company's Board of Directors consists of Charles A. Sanders (Chairman), Joshua S. Boger, Eric K. Brandt, Roger W. Brimblecombe, Stuart J.M. Collinson, Eugene Cordes, Matthew W. Emmens, Bruce I. Sachs, Eve E. Slater and Elaine S. Ullian.

In addition, the stockholders approved the adoption of the Company's 2006 Stock and Option Plan at the annual meeting. The tabulation of votes with respect to the adoption of the 2006 Stock and Option Plan is as follows:

For	Against	Abstain
47,050,901	25,806,926	62,757

## Item 6. Exhibits

Exhibit No.	Description
10.1	License, Development, Manufacturing and Commercialization Agreement, dated June 30, 2006, by and between Vertex Pharmaceuticals Incorporated and Janssen Pharmaceutica, N.V. †
10.2	Letter Agreement, dated June 26, 2006, by and between Merck & Co., Inc. and Vertex Pharmaceuticals Incorporated.
31.1	Certification of the Chief Executive Officer under Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Chief Financial Officer under Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

† Confidential portions of this document have been filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

## 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.

By: /s/ IAN F. SMITH

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

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**Exhibit Index**

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*Confidential Treatment Requested. Confidential portions of this document have been redacted and have been separately filed with the Commission.*

**LICENSE, DEVELOPMENT, MANUFACTURING AND COMMERCIALIZATION AGREEMENT**

by and between

**Vertex Pharmaceuticals Incorporated**

and

**Janssen Pharmaceutica, N.V.**

CONFIDENTIAL TREATMENT REQUESTED

*Information redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

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## **License, Development, Manufacturing and Commercialization Agreement**

This License, Development, Manufacturing and Commercialization Agreement (this “Agreement”) is effective as of June 30, 2006 (the “Effective Date”) and is entered into by and between Vertex Pharmaceuticals Incorporated, a Massachusetts corporation with corporate offices at 130 Waverly Street, Cambridge, MA 02139-4242, United States of America (“Vertex”) and Janssen Pharmaceutica, N.V., a Belgium corporation with corporate offices at 30, Turnhoutsesteenweg, B-2340 Beerse, Belgium (“Janssen”).

### Background

WHEREAS, Vertex is developing VX-950, a novel inhibitor of the NS3/4A hepatitis C viral protease, under a global development plan; and

WHEREAS, Vertex and Janssen would like Janssen to assist in the development of, and to commercialize, VX-950 in the Territory (as defined below).

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows.

### **Article 1 - Definitions**

1.1 (Intentionally left blank)

1.2 “**Additional Development Activities**” shall have the meaning set forth in Section 3.5.

1.3 “**Affiliate**” shall mean, with respect to any Person, any other Person that directly or indirectly controls, is controlled by or is under direct or indirect common control with, such Person. For purposes of this Section 1.3, the term “control” means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities, by contract or otherwise. Control of any Person by another Person will be presumed if fifty percent (50%) or more of the securities or other ownership interests representing the equity, the voting stock or general partnership interest of the first Person are owned, controlled or held, directly or indirectly, by the other Person, or by an Affiliate of the other Person.

1.4 “**API**” means the active pharmaceutical ingredient that is intended to be used in the manufacture of a Product Candidate or a Product.

1.5 \*\*\*

1.6 “**Business Day**” means a day in which banking institutions in Boston, Massachusetts are open for business.

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1.7 “**Calendar Quarter**” shall mean a calendar quarter during any Calendar Year based on the Janssen Universal Calendar for that year, a copy of which, for 2006, is attached hereto as Schedule 1.7, and which shall be updated by Janssen for each Calendar Year during the term of this Agreement consistent with the Janssen Universal Calendar used for Janssen’s internal business purposes; provided, however, that the first Calendar Quarter under this Agreement shall extend from the Effective Date to the end of the then-current Calendar Quarter and the last Calendar Quarter under this Agreement shall extend from the first day of such Calendar Quarter until the effective date of the termination or expiration of the Agreement.

1.8 “**Calendar Year**” shall mean a calendar year during the term of this Agreement based on the Janssen Universal Calendar for that year, a copy of which, for 2006, is attached hereto as Schedule 1.7, and which shall be updated by Janssen for each Calendar Year during the term of this Agreement consistent with the Janssen Universal Calendar used for Janssen’s internal business purposes. For the first Calendar Year, the Calendar Year shall begin on the Effective Date and the last day shall be December 31, 2006. The last Calendar Year of the term of this Agreement shall begin on the first day of the Janssen Universal Calendar Year for the year during which termination or expiration of the Agreement will occur, and the last day of such Calendar Year shall be the effective date of such termination or expiration.

- 1.9 **“Change of Control”** means a transaction or series of related transactions that results in (a) the holders of outstanding voting securities of a Party immediately prior to such transaction ceasing to represent at least [\*\*\*] of the combined outstanding voting power of that Party, or if the surviving entity (or its parent) into which that Party may have merged or been combined, immediately after such transaction or series of transactions; (b) any Third Party (other than a trustee or other fiduciary holding securities under an employee benefit plan) becoming the beneficial owner of [\*\*\*] of the combined voting power of the outstanding securities of a Party, including as a single Third Party all Third Parties who act together as a “group” for purposes of acquiring shares of a Party, as referenced in Section 13(d) of the Securities Act of 1934; or (c) a sale or other disposition to a Third Party of all or substantially all of a Party’s assets or business.
- 1.10 **“Clinical Trial”** means a Phase I Clinical Trial, a Phase II Clinical Trial, a Phase III Clinical Trial or a Pivotal Clinical Trial.
- 1.11 **“Code”** shall have the meaning set forth in Section 13.4.2.
- 1.12 **“Combination Product”** means a single product that includes one or more therapeutically active ingredients other than a Product Candidate or a Product, in combination with a Product Candidate or Product. All references to Product in this Agreement shall be deemed to include a Combination Product unless otherwise specifically noted.
- 1.13 **“Commercialization”** or **“Commercialize”** means to take any action directed to marketing, promoting, distributing, importing or selling a Product, or obtaining pricing and reimbursement approvals for that Product. Commercialization shall also include post-approval Investigator-Initiated Clinical Studies and Phase IV Clinical Trials.

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- 1.14 **“Committees”** shall have the meaning set forth in Section 2.3.
- 1.15 Intentionally left blank.
- 1.16 **“Compound”** means VX-950, [\*\*\*], and all of its or their prodrugs and metabolites, its or their stereoisomers and tautomers, and all of the esters, salts, hydrates, solvates, inclusion complexes and polymorphs of any of the foregoing.
- 1.17 **“Control”** or **“Controlled by”** means the ownership or other legal authority or right of a Party to grant a license or sublicense of intellectual property to another Party without breaching the terms of any agreement with a Third Party, infringing the intellectual property rights of a Third Party, or misappropriating the proprietary or trade secret information of a Third Party.
- 1.18 **“Desired Label”** shall have the meaning set forth in Section 1.41.
- 1.19 **“Development”** or **“Develop”** means any non-clinical and clinical drug development activities that are customarily undertaken after a compound has been designated as a development candidate [\*\*\*] including but not limited to [\*\*\*]
- 1.20 **“Development Program”** means all activities associated with the Development of Product Candidates pursuant to the Global Development Plan and all Additional Development Activities.
- 1.21 [\*\*\*]
- 1.22 [\*\*\*]
- 1.23 **“Diligent Efforts”** means, with respect to each Party’s obligations related to Developing, Manufacturing and Commercializing Product Candidates and Products, the carrying out of those obligations [\*\*\*]
- 1.24 **“Effective Date”** shall have the meaning set forth in the preamble to this Agreement.
- 1.25 **“EMEA”** means the European Medicines Evaluation Agency or any successor EU agency that is responsible for approving the sale of pharmaceuticals in the EU.
- 1.26 **“European Union”** or **“EU”** means the countries of the European Union, as the European Union is constituted as of the Effective Date and as it may be expanded from time to time, [\*\*\*]
- 1.27 **“Excluded Claim”** shall have the meaning set forth in Section 14.5.7.
- 1.28 **“Excluded Territory”** means the Far East and North America.
- 1.29 **“Exclusivity Period”** means the [\*\*\*] beginning on the Effective Date.
- 1.30 **“Executive Officers”** means the Chief Executive Officer of Vertex and the World Wide Chairman, Pharmaceuticals Group of Johnson & Johnson.

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- 1.31 **“Existing Third Party Agreements”** means the agreements between Vertex and Third Parties listed on Schedule 1.31 hereto.

- 1.32 “Far East” means the countries listed on Schedule 1.32 hereto.
- 1.33 “FDA” means the United States Food and Drug Administration, or any successor U.S. governmental agency that is responsible for approving the sale of pharmaceuticals in the United States.
- 1.34 “Field” means all human and animal therapeutic and/or prophylactic uses of Product Candidates and Products.
- 1.35 “First Commercial Sale” means, with respect to any Product, the first arm’s-length sale of that Product to a Third Party in a country of the Territory for use or consumption by the general public in such country (rather than, *e.g.*, in a Phase IV Clinical Trial) after Marketing Authorization for such Product has been obtained in such country. For the avoidance of doubt, a sale in a particular country prior to receipt of all marketing approvals necessary to commence regular commercial sales in that country, such as so-called “treatment IND sales,” “named patient sales” and “compassionate use sales,” shall not be construed as a First Commercial Sale in that country. Any such sale shall however constitute a part of Net Sales.
- 1.36 “FTE” means the equivalent in time of the work of one scientist or other professional conducting activities hereunder on a full time basis for a Calendar Year, [\*\*\*]
- 1.37 “FTE Rate” means, for 2006, [\*\*\*] per FTE; provided that effective January 1 of each Calendar Year, commencing with January 1, 2007, the FTE Rate applicable to each Party’s FTE’s will be the amount obtained by multiplying the FTE Rate applicable on December 31 of the immediately preceding Calendar Year by  $1 + ((CPI_x - CPI_y) / CPI_y)$ , where  $CPI_x$  is the Consumer Price Index for All Urban Consumers in the Boston Metropolitan Area published by the Bureau of Labor Statistics of the United States Department of Labor for December of the immediately preceding Calendar Year and  $CPI_y$  is the Consumer Price Index for All Urban Consumers in the Boston Metropolitan Area published by the Bureau of Labor Statistics of the United States Department of Labor for the month immediately preceding the Effective Date, [\*\*\*] Any such increase shall be rounded to the nearest [\*\*\*].
- 1.38 “GAAP” means accounting principles generally accepted in the United States, applied on a consistent basis.
- 1.39 “Generic Version” shall have the meaning set forth in Section 9.4.2.
- 1.40 “Global Development Costs” [\*\*\*]  
     [\*\*\*]  
     [\*\*\*]

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- [\*\*\*]
  - [\*\*\*]
  - [\*\*\*]
  - 1.41 “Global Development Plan” or “GDP” means the initial plan outlining the Parties’ intended program to Develop Product Candidates or Products in North America and the Territory, including a general description of all related activities therefor, all as reflected in the Global Development Plan, with associated budgets, discussed by the Parties immediately prior to the Effective Date and to which the Parties have agreed. The Parties have designed the Global Development Plan to support certain anticipated Product indications and label claims and related necessary label information (the “Desired Label”), and the Development activities listed in the Global Development Plan are considered critical to obtaining Regulatory Approval in both the United States and the EU for the Desired Label. Other Development activities that are critical to obtaining Regulatory Approval for the Desired Label in the United States or the EU, or that are required by a Regulatory Authority in either the United States or the EU for the Desired Label, may be added to the Global Development Plan from time to time by amendment as provided herein. Development activities that are not critical to obtaining Regulatory Approval in the United States or the EU for the Desired Label shall be considered Additional Development Activities, unless the Parties mutually agree to include such activities in the Global Development Plan. The Global Development Plan as amended from time to time in accordance with the terms of this Agreement shall constitute, as so amended, the Global Development Plan.
  - 1.42 “Good Clinical Practice” or “GCP” means the current good clinical practice applicable to the clinical Development of the Product under applicable law including without limitation the ICH guidelines, or in the event such standards are less stringent than the current U.S. Good Clinical Practice, then “Good Clinical Practice” or “GCP” shall mean current U.S. Good Clinical Practice.
  - 1.43 “Good Laboratory Practice” or “GLP” means the current good laboratory practice applicable to the Development of the Product under applicable law, including without limitation 21 C.F.R. Part 58, or in the event such standards are less stringent than the current U.S. Good Laboratory Practice, then “Good Laboratory Practice” or “GLP” shall mean current U.S. Good Laboratory Practice.
  - 1.44 “Good Manufacturing Practice” or “GMP” means the current good manufacturing practice applicable to the Manufacturing of the Product under applicable law, including without limitation 21 C.F.R. parts 210 and 211 (as the same may be amended) and all applicable FDA rules, regulations, orders and guidances.
  - 1.45 “HCV Infection” means human infection with the hepatitis C virus.
  - 1.46 “Improvement” means any enhancement, whether or not patentable, in the formulation, use, preparation, presentation, means of delivery, or dosage of a Product Candidate or Product.

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- 1.47 “**IND**” shall mean an Investigational New Drug Application filed with FDA or a similar application filed with an applicable Regulatory Authority outside of the United States, such as a clinical trial application (CTA) or a clinical trial exemption (CTX).
- 1.48 “**Indemnitee**” shall have the meaning set forth in Section 12.3.3.
- 1.49 “**Indemnitor**” shall have the meaning set forth in Section 12.3.3.
- 1.50 “**Information**” means any and all information and data, including all scientific, pre-clinical, clinical, regulatory, manufacturing, marketing, financial and commercial information or data, whether communicated in writing, electronically or orally or by any other method, which is provided by one Party to the other Party in connection with this Agreement.
- 1.51 “**Initiation**” means, with respect to a particular Clinical Trial, the administration of the [\*\*\*] dose of a Product Candidate to the [\*\*\*] patient in that Clinical Trial.
- 1.52 “**Invention**” means any process, method, use, composition of matter, article of manufacture, discovery or finding that is conceived or reduced to practice (whether or not patentable).
- 1.53 “**Investigator-Initiated Clinical Study**” means a human clinical trial or study of the Product that is sponsored and conducted by a Third Party who is a health-care professional, under an agreement with a Party pursuant to which that Party provides clinical supplies of the Product and/or funding for the clinical trial or study.
- 1.54 “**Janssen Know-How**” means all information, materials, discoveries, Improvements, processes, methods, protocols, formulas, data, Inventions and trade secrets, patentable or otherwise, that do not fall within Janssen Patent Rights, and (i) that are Controlled by Janssen or any of its Affiliates as of the Effective Date or (ii) are discovered, created or developed, and Controlled, by Janssen or its Affiliates in the course of Janssen’s performance of the Development Program, or of Manufacturing activities, under this Agreement or any supply agreement under which Janssen or any of its Affiliates supplies Compounds, Product Candidates or Products to Vertex, or during studies of a Compound, Product Candidate or Product undertaken after the end of the Development Program, or as part of the Commercialization of a Compound, Product Candidate or Product, and (iii) that are related to the Development, utilization, Manufacture or Commercialization of any Compound, Product Candidate or Product.
- 1.55 “**Janssen Patent Rights**” means all patents and patent applications that generically or specifically claim (a) (i) a Compound, a Product Candidate or a Product, (ii) a process for manufacturing a Compound, a Product Candidate or a Product, or an Intermediate used in such process; or (iii) a use of the Compound, a Product Candidate or a Product, and that are Controlled by Janssen or any of its Affiliates as of the Effective Date, or (b) Inventions Controlled by Janssen or any of its Affiliates that are conceived or reduced to practice in the course of Janssen’s performance of the Development Program, or of Manufacturing activities, under this Agreement or any supply agreement under which Janssen or any of its Affiliates supplies Product Candidates or Products to Vertex, or during studies of a Product

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Candidate or Product undertaken after the end of the Development Program, or as part of the Commercialization of a Product Candidate or Product, and that are related to the Development, utilization, Manufacture or Commercialization of the Compound or any Product Candidate or Product. Included within the definition of Janssen Patent Rights are all continuations, continuations-in-part, divisions, patents of addition, reissues, renewals or extensions, substitutions, re-examinations or restorations, registrations and revalidations thereof, and all supplementary protection certificates and the like. Schedule 1.55 lists all patent applications and patents encompassed within Janssen Patent Rights on the Effective Date.

- 1.56 “**Joint Commercialization Committee**” and “**JCC**” have the meaning set forth in Section 5.2.
- 1.57 “**Joint Development Committee**” and “**JDC**” have the meaning set forth in Section 3.1.
- 1.58 “**Joint Know-How**” means all information, Improvements and Inventions created, developed or invented jointly by employees of Janssen and Vertex or their Affiliates, or by others acting on behalf of Janssen and Vertex, in the course of activities undertaken under this Agreement.
- 1.59 “**Joint Manufacturing Committee**” and “**JMC**” have the meaning set forth in Section 4.2.
- 1.60 “**Joint Patent Rights**” means all national, regional and international patents and patent applications, certificates of invention and applications for certificates of invention, including divisions, continuations, continuations-in-part, additions, reissues, renewals, extensions, substitutions, re-examinations or restorations, registrations and revalidations, and supplementary protection certificates or the like or any of the foregoing and all foreign equivalents thereof, that, when granted, recite a claim directed to Joint Know-How.
- 1.61 “**Joint Philanthropic Committee**” and “**JPC**” shall have the meaning set forth in Article 6.
- 1.62 “**Joint Steering Committee**” and “**JSC**” have the meaning set forth in Section 2.2.
- 1.63 “**Key Countries**” means at the time of measurement the Major Market Countries, and to the extent not included as a Major Market Country, the [\*\*\*] in the Territory with respect to all pharmaceutical sales as reported by IMS, or by another independent Third Party source of market data selected by the Parties by mutual agreement.



- 1.64 “**Key Opinion Leaders**” or “**KOLs**” means scientific or health care professionals who are recognized experts in the relevant scientific or health care field, which in the context of this Agreement is the investigation and treatment of HCV Infection.
- 1.65 “**MAA**” means a Marketing Authorization Application, or similar application or submission for Marketing Authorization, that is filed to obtain marketing approval for a Product Candidate or Product in the EU.

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- 1.66 “**Major Market Countries**” means [\*\*\*]
- 1.67 “**Manufacturing**” or “**Manufacture**” means all of the activities relating to production of a Product Candidate or Product, including without limitation, purchasing raw materials and Intermediates, production of API, [\*\*\*], tableting, and all related quality control and quality assurance and all storage, shipping and handling. Manufacturing also includes Packaging and manufacturing technical transfer activities. “**Intermediate**” as used herein means [\*\*\*].
- 1.68 “**Manufacturing Cost**” means the cost of [\*\*\*]
- 1.69 Intentionally left blank.
- 1.70 “**Marketing Authorization**” means all approvals from the relevant Regulatory Authority necessary to market and sell a Product in a particular country. For countries where governmental approval is required for pricing or reimbursement for the Product, “Marketing Authorization” shall not be deemed to occur until such pricing or reimbursement approval is obtained.
- 1.71 “**Material Adverse Effect**” means, with respect to any action by a Party or its Related Parties, [\*\*\*]
- 1.72 “**Medical Science Liaisons**” or “**MSL**” shall have the meaning set forth in Section 5.11.
- 1.73 “**Milestone Event**” shall have the meaning set forth in Section 9.2.1.
- 1.74 “**Milestone Payment**” shall have the meaning set forth in Section 9.2.1.
- 1.75 “**NDA**” means a New Drug Application or similar application or submission for Marketing Authorization that is filed with the FDA to obtain marketing approval for a Product Candidate or Product in the United States.
- 1.76 [\*\*\*]
- 1.77 “**Net Sales**” means the gross amount billed or invoiced by Janssen or its Related Parties on arms-length sales of Product Candidates and Products (for purposes of this definition, Product Candidates and Products are referred to collectively as “Products” or a “Product”) to a Third Party other than a Related Party, less Permitted Deductions. “Permitted Deductions” for any Product includes only the following, to the extent permitted by applicable law and specifically related to the gross amount billed or invoiced:
- (i) customary transportation charges relating to the Product, including handling charges and insurance premiums relating thereto;
  - (ii) sales taxes, excise taxes and duties paid by and not refunded to the selling party and directly related to sale of the Product, and any other equivalent governmental charges imposed upon the importation, use or sale of the Product, but excluding income and similar taxes;

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- (iii) government-mandated rebates;
- (iv) customary trade, quantity and prompt payment discounts allowed on the Product;
- (v) allowances or credits to customers on account of retrospective price reductions affecting the Product; and
- (vi) customary Product rebates and Product wholesaler charge-backs including those customarily granted to managed care entities
- (vii) [\*\*\*]

[\*\*\*]

For the purposes of determining royalty rates and the royalties payable on Combination Products, Net Sales of a Product shall be calculated as follows:  
[\*\*\*]

For purposes of clarity, no permitted deduction to Net Sales will be counted more than once or, with the exception of [\*\*\*], adjusted more than [\*\*\*] following the calculation of Net Sales for a given month.

Solely for the purposes of this Section 1.77, a Related Party of Janssen or of any of its Affiliates shall include a distributor acting as an actual or constructive sublicensee of rights granted hereunder with respect to sales of a Product in a particular country in the Territory, as evidenced by the fact

that the distributor holds (A) sales and distribution rights for the Product in that country, coupled with (B) pricing authority or government pricing negotiation authority with respect to wholesalers or sub-distributors in that country.

If Janssen or any of its Related Parties makes any transfer of a Product to a Third Party as part of a multiproduct transaction, Net Sales of each unit of the Product transferred will be determined on a country-by-country basis, and will be equal to [\*\*\*]

1.78 “**Non-Incurred Amount**” shall have the meaning set forth in Section 3.4.3.

1.79 “**Non-Publishing Party**” shall have the meaning set forth in Section 11.3.

1.80 [\*\*\*]

1.81 (a) “**North America**” means the United States, Canada and Mexico, and the territories and possessions of each of them.

(b) “**North America Product Materials**” shall have the meaning set forth in Section 5.5(a).

1.82 [\*\*\*]

1.83 “**Packaging**” means importation, quality control, testing, primary and secondary packaging (including all labeling), qualified person release, storage and shipping and handling.

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1.84 “**Packaging Regulatory Approval**” means all requisite approvals of applicable Regulatory Authorities necessary for the Packaging of a Product.

1.85 “**Party**” means Janssen or Vertex, and “**Parties**” means Janssen and Vertex.

1.86 “**Patent Costs**” shall mean all reasonable costs and expenses incurred by Vertex in preparing, filing, prosecuting and/or maintaining Vertex Patent Rights, including, without limitation, out-of-pocket costs and reasonable time spent by Vertex’s professional personnel in patent preparation and prosecution, measured at the FTE Rate then in effect.

1.87 “**Permitted Sublicensee**” means a sublicensee of either Party under a sublicense permitted under Article 7 of this Agreement.

1.88 “**Person**” means any individual, corporation, partnership, limited liability company, association, joint-stock company, trust, unincorporated organization or government or political subdivision thereof.

1.89 “**Phase I Clinical Trial**” means a human clinical trial for a Product Candidate or Product, in any country, that would satisfy the requirements of 21 CFR §312.21(a).

1.90 “**Phase II Clinical Trial**” means a human clinical trial in any country that would satisfy the requirements of 21 CFR §312.21(b) and is intended to explore one or more doses, dose response, and duration of effect, and to generate initial evidence of clinical activity and safety, for a Product Candidate or Product in the target patient population

1.91 “**Phase III Clinical Trial**” means a human clinical trial in any country that would satisfy the requirements of 21 CFR §312.21(c) and is intended to confirm with statistical significance the efficacy and safety of the Product Candidate or Product, and is performed to obtain Regulatory Approval.

1.92 “**Phase IV Clinical Trial**” means a study or data collection effort for the Product that is initiated after receipt of Regulatory Approval for the Product and is not principally intended to support or maintain a Regulatory Approval, maintain a label or otherwise obtain a labeling change. Phase IV Clinical Trials shall include, without limitation, studies related to the Product that are sponsored by a Third Party but supported by a Party (either through financial support or through the provision of study drugs). Phase IV Clinical Trials may also include a human clinical trial of the Product that is required by the Regulatory Authority in a country to be conducted following Regulatory Approval of the Product in that country, as an explicit condition of that Regulatory Approval.

1.93 “**Philanthropic Funds**” shall have the meaning set forth in Article 6.

1.94 “**Pivotal Clinical Trial**” means a Phase III Clinical Trial or, under the following circumstances, a Phase II Clinical Trial. A Phase II Clinical Trial shall be considered a Pivotal Clinical Trial if and when (a) in the United States, the protocol for that Phase II Clinical Trial shall have been reviewed by the FDA under its current Special Protocol Assessment Guidelines (or equivalent guidelines issued in the future), and any comments from the FDA on that protocol are incorporated in the final protocol for that Phase II

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Clinical Trial or are resolved to the FDA’s satisfaction as evidenced by further written communications from the FDA; [\*\*\*]

1.95 “**Primary Detail**” means a Sales Call for the Product in which the Product receives the predominant portion of emphasis and time during the Sales Call (i.e., no other product or service receives more emphasis or time during the Sales Call, where such calculation of emphasis and time is conducted and measured in accordance with Janssen’s standard operating procedures for its own products to the target physician group for the Product.

- 1.96 **“Product”** means any pharmaceutical preparation in final commercial form containing the Product Candidate, for sale by prescription, over-the-counter or any other method. Product includes without limitation any Combination Product.
- 1.97 **“Product Candidate”** means a pharmaceutical composition containing a Compound as an active ingredient.
- 1.98 **“Publishing Party”** shall have the meaning set forth in Section 11.3.
- 1.99 **“Regulatory Approval”** means, with respect to any country or region, all authorizations by the appropriate governmental entity or entities necessary for commercial sale of a Product in that country or region (not including pricing or reimbursement approval). “Regulatory Approval” in the United States shall mean final approval of an NDA pursuant to 21 CFR §314 (or any successor regulation having the same purpose or effect), permitting marketing of a Product in interstate commerce in the United States. “Regulatory Approval” in the European Union shall mean final approval of a MAA pursuant to Council Directive 75/319/EEC, as amended, or Council Regulation 2309/93/EEC, as amended, or pursuant to any successor regulation having the same purpose or effect.
- 1.100 **“Regulatory Authority”** shall mean any applicable government regulatory authority involved in granting approvals for the manufacturing, marketing and sale of a Product.
- 1.101 **“Related Party”** shall mean each of a Party’s Affiliates and any Permitted Sublicensees, and **“Related Parties”** means all of a Party’s Affiliates and Permitted Licensees.
- 1.102 **“Results”** shall have the meaning set forth in Section 11.3.
- 1.103 **“Sales Call”** means face-to-face contact (or other contact which in the future is employed to substitute, in whole or in part, for face-to-face contact) of a Sales Representative with a health care professional with prescribing authority during which scientific and/or medical information is discussed about the use of a Product for the treatment of indications for which the Product has received Regulatory Approval.
- 1.104 **“Sales Representative”** means an individual who engages in or manages Sales Calls and other promotional efforts with respect to a Product and who is employed by a Party or its Related Parties. For purposes of clarity, an MSL is not a Sales Representative.

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- 1.105 **“Specifications”** means the manufacturing specifications for the Product to be filed with the FDA in the NDA.
- 1.106 **“Supply Agreement”** shall have the meaning set forth in Section 4.5.
- 1.107 **“Tablet”** means the form of the Product or Product Candidate that is ready for Packaging.
- 1.108 **“Territory”** means all of the countries in the world, and their territories and possessions, outside of the Excluded Territory.
- 1.109 **“Territory Product Materials”** shall have the meaning set forth in Section 5.5.
- 1.110 **“Third Party”** means an entity other than a Party or any of its Related Parties.
- 1.111 **“Third Party Product”** shall have the meaning set forth in Section 9.4.2.
- 1.112 **“Trademark”** shall mean the mark or marks used to promote and sell the Product.
- 1.113 **“U.S.”** and **“United States”** and **“United States of America”** shall mean the United States of America and its territories and possessions.
- 1.114 **“Valid Patent Claim”** means a claim of an issued and unexpired patent included within the Vertex Patent Rights or Joint Patent Rights that (a) claims (i) the Compound, a Product Candidate or a Product as a composition of matter, or (ii) the formulation, method of manufacture or use of the Compound, a Product Candidate or a Product; (b) has not been revoked or held unenforceable, unpatentable or invalid by a decision of a court or other governmental agency of competent jurisdiction (which decision is not appealable or has not been appealed within the time allowed for appeal); and (c) has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue, re-examination or disclaimer or otherwise.
- 1.115 **“Vertex Know-How”** means all information, materials, discoveries, Improvements, processes, methods, protocols, formulas, data, Inventions and trade secrets, patentable or otherwise, that do not fall within the Vertex Patent Rights, and (i) that are Controlled by Vertex or any of its Affiliates as of the Effective Date or (ii) are discovered, created or developed, and Controlled, by Vertex or its Affiliates in the course of Vertex’s performance of the Development Program or Additional Development Activities, or of Manufacturing activities, under this Agreement or the Supply Agreement, or during studies of a Compound, Product Candidate or Product undertaken after the end of the Development Program, or as part of the Commercialization of a Compound, Product Candidate or Product, and (iii) that are related to the Development, utilization, Manufacture or Commercialization of any Compound, Product Candidate or Product; provided, however, that the term “Vertex Know-How” shall not apply to Vertex’s general drug design technology whether in hardware or software form, tangible or intangible.
- 1.116 **“Vertex Patent Rights”** means all patents and patent applications that generically or specifically claim (a) (i) a Compound, a Product Candidate or a Product; (ii) a process for manufacturing a Compound, a Product Candidate or a Product, or an Intermediate used in

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such process; or (iii) a use of the Compound, a Product Candidate or a Product, and that are Controlled by Vertex or any of its Affiliates as of the Effective Date, or (b) inventions Controlled by Vertex or any of its Affiliates that are conceived or reduced to practice in the course of either Vertex's performance of the Development Program or Additional Development Activities, or of Manufacturing activities, under this Agreement or the Supply Agreement, or during studies of a Compound, Product Candidate or Product undertaken after the end of the Development Program, or as part of the Commercialization of a Compound, Product Candidate or Product and that are related to the Development, utilization, Manufacture or Commercialization of a Compound or any Product Candidate or Product. Included within the definition of Vertex Patent Rights are all continuations, continuations-in-part, divisions, patents of addition, reissues, renewals or extensions, substitutions, re-examinations or restorations, registrations and revalidations thereof, and all supplementary protection certificates and the like. Schedule 1.116 lists all patent applications and patents encompassed within Vertex Patent Rights as of the Effective Date.

1.117 "VX-950" means the chemical compound referred to by Vertex as VX-950 and having the chemical structure referenced on Schedule 1.117.

## Article 2 - Collaboration Scope and Governance

- 2.1 **Purposes of the Collaboration.** The purpose of the collaboration between Vertex and Janssen established under this Agreement is to advance the Development and Commercialization of Product Candidates and Products as rapidly as reasonably practicable, for the treatment of Hepatitis C Infection in North America and the Territory.
- 2.2 **Joint Steering Committee.** Promptly after the Effective Date, the Parties will establish a Joint Steering Committee (the "Joint Steering Committee" or "JSC"), as more fully described in this Section 2.2, to review all Development, Manufacturing, Commercialization and philanthropic activities being conducted by the Parties under this Agreement. Each Party will keep the Joint Steering Committee, and other relevant committees referenced in Section 2.3 below, [\*\*\*] of its progress and activities under this Agreement. The Joint Steering Committee shall have no authority to amend this Agreement.
- 2.2.1 **Membership.** The Joint Steering Committee shall be comprised of [\*\*\*] The exact number of such representatives [\*\*\*] or such other number as the Parties may agree. Each Party shall provide the other with a list of its initial members of the Joint Steering Committee within [\*\*\*]. Each Party will use all reasonable efforts to maintain the continuity of its representation, although each Party may nevertheless replace or substitute any or all of its representatives at any time. On an annual basis, the JSC shall meet [\*\*\*] with [\*\*\*] meetings being in person. Either Party may request that the JSC meet at any time upon [\*\*\*] notice to the other Party, for any purpose properly addressed by the JSC pursuant to this Agreement, and the Parties shall use best efforts to ensure that a meeting occurs within [\*\*\*] period or as soon thereafter as practicable.

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2.2.2 **Responsibilities.** The JSC shall oversee the collaborative relationship between Janssen and Vertex. To that end, the JSC shall also be responsible, without limitation, for the following:

- 2.2.2.1 oversight of the Development Program and Manufacturing activities undertaken with respect to any Product Candidate or Product hereunder;
- 2.2.2.2 reviewing matters referred to it by the other Committees (as defined below);
- 2.2.2.3 ensuring the exchange of relevant information and materials on a timely basis as required under this Agreement;
- 2.2.2.4 reviewing and approving substantive amendments and updates to the Global Development Plan, and to any Additional Development Activities, consistent with this Agreement; and
- 2.2.2.5 such other responsibilities as may be assigned to the Joint Steering Committee pursuant to this Agreement or as may be agreed upon by the Parties in writing from time to time.

- 2.3 **Committee Governance.** In addition to the JSC, the Parties will participate in the collaboration created by this Agreement through a number of other committees, including a Joint Development Committee ("JDC"), a Joint Manufacturing Committee ("JMC"), a Joint Commercialization Committee ("JCC") and a Joint Philanthropic Committee ("JPC") (each, including the JSC, a "Committee" and together, the "Committees"). Each Committee shall meet [\*\*\*] or as otherwise agreed by the Committee. Meetings will be held either in person or by teleconference or video conference, on such dates, and at such places and times, as provided herein or as the Parties shall agree. Meetings of each Committee that are held in person shall alternate between the offices of the Parties, or shall be conducted at such other place as the Parties may agree. Either Party may propose matters to the Committee Chair for inclusion on the Committee agenda for an upcoming meeting. Each Party shall initially have [\*\*\*] members on each Committee, or such other number as the Parties may agree with respect to any particular Committee. Each Party will provide the other with a list of its initial members of each Committee [\*\*\*] Each Party may thereafter replace any or all of its representatives at any time. A Committee meeting shall have a quorum if there are [\*\*\*] of each of Janssen and Vertex in attendance. The Chair of each Committee shall be responsible for scheduling each meeting, and for issuing appropriate minutes of each meeting of that Committee within [\*\*\*] of the date of such meeting. The minutes shall be considered as accepted by a Party if, [\*\*\*], none of that Party's Committee members have objected to the draft of such minutes in writing or by email to the Chair. [\*\*\*] Where decisions are required of a Committee, the members of that Committee will attempt in good faith to reach consensus with respect to the matter at hand. If agreement cannot be reached after a good faith discussion among the members of [\*\*\*] Any decision required or permitted to be taken by any Committee may be taken without a meeting in person taking place, if (i) a consent in writing, setting forth the decision so taken, is signed by all designated members of that Committee; or (ii) by mutual

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agreement of the Parties, the meeting is conducted by teleconference or videoconference; provided, however, that a Party that has requested a JSC meeting on [\*\*\*] may not object to the conduct of that meeting by teleconference or videoconference. Each Party may, in its reasonable discretion, invite non-member representatives of such Party to attend meetings of a Committee; provided, however that (i) the attendance by any such non-member representative shall be reasonably acceptable to both Parties and (ii) the requirements of Section 11.2 of this Agreement with respect to obligations of confidentiality and non-use shall have been satisfied with respect to any such non-member representative. Each Party will be responsible for its representatives' expenses incurred in attending Committee meetings.

- 2.4 **Alliance Managers.** Promptly after the Effective Date, each Party may appoint an individual(s) to act as the alliance manager(s) for such Party (the "Alliance Managers"). Each Alliance Manager who is not otherwise a member shall thereafter be permitted to attend meetings of the Committees. The Alliance Managers, if appointed, shall be a significant point of contact for the Parties regarding the administration of this Agreement.

### Article 3 - Global Development of Product Candidate

- 3.1 **Current Status.** Prior to the Effective Date, Vertex independently initiated Phase II Clinical Studies of VX-950 in North America and the EU, and has conducted or is conducting other clinical and non-clinical studies in support of the overall Development of VX-950. The Parties have agreed to continue the Development of Product Candidates under the Development Program and in accordance with the terms of this Agreement.
- 3.2 **Development Program.** Product Candidates will be Developed in the Territory and in North America pursuant to a Global Development Plan and in connection with any Additional Development Activities that may be undertaken by either Party. The Global Development Plan and any such Additional Development Activities together constitute the Development Program for a Product Candidate. The Global Development Plan identifies the type and timing of all planned Development activities to be undertaken in the Territory and in North America with the goal of securing Regulatory Approvals for the sale of Products in North America and the Territory with the Desired Label. The Global Development Plan also includes preliminary budgets covering all Development activities included in the Plan and allocates responsibilities for Development activities between the Parties.
- 3.3 **Joint Development Committee.** The Parties shall establish a JDC promptly after the Effective Date. The JDC shall be led by [\*\*\*]. Subject to oversight by the JSC, the JDC shall coordinate the Development of Product Candidates with the objective of obtaining Regulatory Approvals in North America and the Territory as soon as practicable, for each Product Candidate. The JDC may establish sub teams having representatives from both Parties for important functional areas, including but not limited to clinical trial teams, regulatory teams and the like. Each Party will keep the JDC reasonably informed of its Development activities and its progress in executing its responsibilities under the

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Development Program. The JDC's responsibilities shall include, without limitation, the following:

- 3.3.1 consider and discuss strategies for the Development of Product Candidates; and
- 3.3.2 at least [\*\*\*], review and discuss the Global Development Plan and related budgets and allocation of responsibilities between the Parties and, from time to time, present to the JSC for review and approval (i) proposed substantive amendments to the Global Development Plan in accordance with Section 3.4.3, and (ii) Additional Development Activities in accordance with Section 3.5.

#### 3.4 Global Development Plan.

3.4.1 **Global Development.** The Development of Product Candidates in North America and the Territory shall be governed by the Global Development Plan, and the Parties agree that all Development activities relating to Product Candidates shall be conducted in accordance with the Global Development Plan, except for those activities that are specifically included within Additional Development Activities undertaken in accordance with Section 3.5. Each Party will contribute to the operational execution of the Global Development Plan, and will make best use of each Party's established technological and process excellence for the optimal execution of the Global Development Plan. The JDC shall review the Global Development Plan not less frequently than [\*\*\*] and shall develop detailed and specific Global Development Plan updates, which shall include annual Development budgets and allocation of responsibilities between the Parties, for each Calendar Year under the Global Development Plan. The JDC shall submit all such updates to the JSC for review and approval such that JSC preliminary approval of the plan and budget for any Calendar Year would occur [\*\*\*]. Updates with the JSC's preliminary approval shall be submitted to each Party for its internal budgeting process with a target for final approval by the JSC [\*\*\*], at which time any updates will be appended to the Global Development Plan.

3.4.2 **Conduct of Activities under the Global Development Plan.** Each Party will initially be responsible for conducting the Development activities assigned to it under the Global Development Plan. The allocation of responsibilities will be periodically reviewed by the JDC after the Effective Date, and may be supplemented or adjusted as determined by the JDC to be in the best interests of the collaboration, subject to review and approval by the JSC.

3.4.3 **Amendments to the Global Development Plan.** The JDC may develop and submit to the JSC from time to time proposed substantive amendments (which shall include necessary budget and allocation of responsibility updates) to the Global Development Plan as may be necessary or appropriate in its judgment to reflect changing circumstances. The JSC shall review any such proposed amendments presented by the JDC and may approve those proposed amendments and/or any other amendments proposed from time to time by members of the JDC and, upon approval of any such proposals by the JSC, the Global Development Plan shall be amended accordingly (provided that the JSC shall not be empowered to amend this Agreement). Amendments

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to the Global Development Plan, associated budgets and allocation of responsibilities shall not be effective without the approval of the JSC. Except as provided below, disagreements that cannot be resolved within the JDC concerning any proposed amendment shall be submitted for resolution to the JSC. Disagreements that cannot be resolved by the JSC shall be submitted for resolution as Unresolved Matters under the provisions of Sections 14.2 and 14.3. Notwithstanding the foregoing, mutual agreement among the Parties' representatives on the JSC shall be required for any proposed amendment to the Global Development Plan that would: (i) increase the aggregate amount of Global Development Costs [\*\*\*] In the event that during any Calendar Year any Development activity expressly provided for in the approved Global Development Plan budget to be completed during that year is not completed, and therefore the full expense budgeted for that activity for that year is not incurred (to the extent not incurred, a "Non-Incurred Amount"), then to the extent that the incomplete activity is scheduled for the next succeeding Calendar Year, the Non-Incurred Amount shall be included in the Global Development Plan budget for the succeeding Calendar Year.

### 3.5 Additional Development Activities.

If the JDC is unable to reach agreement on the inclusion in the Global Development Plan of (i) additional Development activities relating to the Development of a Product Candidate that are not critical to obtaining Regulatory Approval for the Desired Label, or (ii) that constitute an Out-of-Budget Proposal ("Additional Development Activities"), then the Party wishing to conduct those activities may do so at its own expense, but only after review and approval of the Additional Development Activities with the JSC and, failing approval by the JSC, subject to the provisions of Sections 14.2 and 14.3 hereof. If the results of any such activities are included by the other Party in a filing with a Regulatory Authority (other than a required submission for safety purposes) to support a label claim or a change in an approved label in that other Party's territory, then the other Party using that data [\*\*\*]

#### 3.5.1 [\*\*\*]

[\*\*\*]

[\*\*\*]

### 3.6 Development Efforts; Manner of Performance; Reports

**3.6.1 Standards for Conduct of Development Program.** Each of Vertex and Janssen shall use Diligent Efforts to execute and to perform, or cause to be performed, the activities for which it is responsible under the Global Development Plan and to cooperate with and comply with all reasonable requests of the other Party in carrying out the Global Development Plan, in each case in good scientific manner and in compliance with applicable law, Good Clinical Practice and Good Laboratory Practice. Janssen shall use Diligent Efforts to seek Regulatory Approval to market the Product in the Territory including in each of the Key Countries. [\*\*\*]

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**3.6.2 Development Progress Reports.** The minutes of the Committees will serve as Development Progress Reports.

**3.6.3 Coordination of Certain Activities.** The Parties will use reasonable efforts to coordinate their Development activities to effect the most efficient and reasonable contacts and [\*\*\*]

**3.6.4 Drug Supply for Non-Clinical and Clinical Trials.** During the Development Program prior to the First Commercial Sale, Vertex shall use Diligent Efforts to supply clinical trial material of the Product Candidate for use in clinical studies conducted in accordance with the Global Development Plan and, if applicable, for Additional Development Activities. [\*\*\*] With respect to supply for any Additional Development Activities prior to the First Commercial Sale, Vertex shall use Diligent Efforts to provide clinical trial material, subject to the primary commitment to supply clinical trial material for the Global Development Plan. Clinical trial material for Additional Development Activities conducted by Janssen shall be supplied to Janssen by Vertex [\*\*\*], and otherwise as further described in a Development Supply Agreement to be executed by the Parties in advance of Janssen's need for such clinical trial material. In the event that Janssen conducts one or more clinical trials under the Global Development Plan, or as Additional Development Activities, Vertex shall supply the Product Candidate in bulk Tablet form, and Janssen will be responsible for Packaging and distribution, unless Vertex, after discussion at the JMC, elects in its sole discretion to take on that responsibility. Notwithstanding the foregoing, in the event Janssen is unable to perform Packaging due to regulatory requirements, Vertex will use commercially reasonable efforts to perform Packaging, consistent with Vertex's current capabilities, upon Janssen request.

### 3.7 Regulatory Submissions and Regulatory Approvals

**3.7.1 Regulatory Submissions.** Vertex shall be solely and exclusively responsible for obtaining all Regulatory Approvals for Products in North America and shall own all regulatory submissions, including all applications for and dossiers relating to Regulatory Approval made by or at its direction under this Agreement. Janssen shall be solely and exclusively responsible for obtaining Regulatory Approvals for Products in the countries in the Territory, and shall own all regulatory submissions directed toward Regulatory Approval, including all applications for and dossiers relating to Regulatory Approval made by or at its direction under this Agreement. All activities conducted by each Party in their territory in connection with the preparation, filing and prosecution of applications for Regulatory Approval of a Product Candidate or Product, or with respect to pricing or reimbursement activities, shall be at each Party's sole cost and expense. Each Party shall provide the other Party documentation to support the regulatory submissions of the other Party.

**3.7.2 Discussions with Regulatory Authorities.** Each Party will have the right to participate as an observer in all material meetings and other material contacts with Regulatory Authorities pertaining to the Development of a Product Candidate for Regulatory Approval in the territory of the other Party (excluding the Far East) to the

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extent not prohibited by law. Each Party shall provide the other Party with reasonable advance notice of all such meetings and other contacts, and to the extent practicable will supply advance copies of all related documents and other relevant information sufficiently in advance of any such meetings or other contacts as may provide the receiving Party with a reasonable opportunity to comment on the substance of the documents or correspondence. Material submissions made by a Party to, or correspondence with, Regulatory Authorities in such Party's territory [\*\*\*], will be provided to the other Party sufficiently in advance to enable translation, if any such submissions or correspondence are not available in English. Janssen and Vertex shall discuss any material documents or other material correspondence [\*\*\*] that either Party is planning to submit in connection with Regulatory Approvals, and each Party will consider the other Party's comments in good faith.

**3.7.3 Labeling.** The Parties will use reasonable efforts to establish and maintain a core label for each Product. [\*\*\*] Each Party shall promptly provide to the other Party copies of all initially proposed labeling, Packaging and package inserts for a Product, in each case sufficiently in advance of submission to FDA and EMEA so that the other Party may review and have a reasonable opportunity to comment on the substance of such submissions. In addition, each Party shall promptly provide to the other Party copies of all initially proposed labeling, Packaging and package inserts for a Product that are materially different from the core label, in each case sufficiently in advance of submission to Regulatory Authorities, so that the other Party may review and have a reasonable opportunity to comment on the substance of such submissions. Thereafter, each Party will use reasonable efforts to provide the other Party with advance copies of any material changes to (i) the label, (ii) Packaging and (iii) package insert for review and comment. Vertex shall promptly provide to Janssen copies of any documents or correspondence pertaining to labeling received by Vertex or its Related Parties from the FDA. Janssen shall promptly provide to Vertex copies of any documents or correspondence pertaining to labeling received by Janssen or its Related Parties from EMEA or Regulatory Authorities in the Major Market Countries, and in addition, any such documents or correspondence, irrespective of the country to which the documents or correspondence relate, which address material issues concerning the label. Upon Vertex's reasonable request, Janssen shall provide Vertex with any English translations of the documents and correspondence described in the preceding sentence that are produced for Janssen's own use. Neither Party shall have the right to approve the proposed labeling for the Product in any country in the other Party's territory. However, each Party shall have the right to object to the labeling to be initially submitted (or resubmitted following receipt of comments from, or negotiations with, Regulatory Authorities) for the Product in any country in the other Party's territory or to any proposed variations or modifications to any labeling that has received Regulatory Approval, but in each case solely on the grounds that such labeling could in such Party's reasonable judgment have a Material Adverse Effect; and provided, further, that such Party shall not be entitled to object to any variations or modifications to any labeling required by law or by any Regulatory Authority. Any objection or response to the other Party's label or proposed label shall be made promptly so as to not delay the submission or approval of the label. Any such objection shall be submitted in writing to the JSC, with a full explanation of the concerns underlying the objection, and the matter shall be addressed by the JSC at a meeting called

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for that purpose as soon as reasonably practicable. Failing agreement by the JSC, the objection shall be referred for resolution under Section 14.2 hereof.

**3.7.4 Right to Cross-Reference.** Each Party shall have the right to cross-reference and make any other use of the other Party's NDAs/MAAs and INDs/CTAs for the Product that it would have if it were the owner [\*\*\*] including without limitation access to all data Controlled by the other Party and contained or referenced in such NDAs/MAAs and INDs/CTAs, in each case as may be reasonably necessary to enable such Party to Develop, Manufacture or Commercialize Products as permitted under this Agreement. In addition, each Party shall have the right to cross-reference the other Party's drug master file ("DME") in connection with the performance of its obligations under this Agreement.

**3.7.5 [\*\*\*].** Subject to applicable law, Janssen shall provide Vertex at its request with all material information relating to Janssen's [\*\*\*] in the EU and material information that serves as the basis for [\*\*\*] in the EU.

#### **Article 4 -Manufacture and Supply**

**4.1 General Background.** In general, the Parties intend that the provision of supply of raw materials, Intermediates, API and Product for both clinical and commercial purposes in the Territory will occur in accordance with the terms of this Agreement as follows:

- (a) Clinical.** Vertex will be responsible for providing Product Candidate supply under the Global Development Plan and, subject to availability, for Additional Development Activities pursuant to the provisions of Section 3.6.4.
- (b) Commercial.** The Parties intend that (i) Janssen will be responsible for the Manufacture of Product for Commercialization in the Territory including but not limited to Intermediates, API, and Product, and (ii) Vertex will be responsible for the Manufacture of Product for Commercialization outside the Territory, provided that Janssen will, as a secondary source for Vertex, also be responsible for the Manufacture of Product for Commercialization by Vertex outside the Territory as described in Section 4.5(d).
- (c) Technical Transfer.** Accordingly, the Parties will commence technical transfer activities [\*\*\*] with the goal of enabling Janssen to supply Product for Commercialization in the Territory at Product launch and, as soon as practicable, to serve as a secondary source for Product for Commercialization outside the Territory as described in Section 4.5(d). In the event the Joint Manufacturing Committee determines that Janssen's progress under the Technical Transfer Plan (as defined in Section 4.5(b)) [\*\*\*] Vertex shall [\*\*\*] to supply Product to Janssen in accordance with the terms of the Supply Agreement (as defined in Section 4.5(a)).
- (d) [\*\*\*]**

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- 4.2 Joint Manufacturing Committee.** Promptly after the Effective Date, the Parties shall establish a Joint Manufacturing Committee (the “Joint Manufacturing Committee” or “JMC”) to oversee Manufacturing activities related to the Territory, subject to the terms of this Agreement and the oversight of the JSC. The JMC shall be responsible, without limitation, for the following:
- 4.2.1** consider and discuss the strategy for the Manufacture of the Product and Product Candidates in the Territory with the goal of synchronizing supply and demand; and
  - 4.2.2** review and approve the Technical Transfer Plan described in Section 4.5(b), and monitor Janssen progress under such Technical Transfer Plan.
- 4.3 Manufacturing Director.** Promptly following the Effective Date, each Party shall appoint one of its representatives to the JMC to direct all matters related to Manufacturing within its organization and to coordinate with the appointed representatives’ counterpart designated by the other Party.
- 4.4 Initial Forecast.** [\*\*\*] As a necessary component of estimating supply chain capacity requirements, the Parties will deliver to each other [\*\*\*] forecast for Product [\*\*\*] which will also include [\*\*\*]
- 4.5 Supply of Product.**
- (a) Supply Agreement.** Within [\*\*\*] of the Effective Date, Janssen and Vertex will negotiate [\*\*\*], and separately enter into a supply agreement for the supply by Vertex, [\*\*\*], of Janssen’s requirements of Product for distribution and sale in the Territory (the “Supply Agreement”). The Supply Agreement shall include the Supply Agreement Key Elements attached hereto as Exhibit 4.5(a) and such customary representations, warranties, covenants and conditions as are necessary or appropriate for transactions of this type, not inconsistent with the terms and conditions hereof; [\*\*\*] Vertex will supply Product to Janssen [\*\*\*] In the event Regulatory Authorities in the Territory require different specifications, [\*\*\*]
  - (b) Technical Transfer to Janssen.** Within [\*\*\*] Janssen will propose to the JMC a plan for establishing manufacturing capabilities necessary for Janssen to manufacture the Product for the Territory and for use outside the Territory as a secondary source for Vertex (the “Technical Transfer Plan”). Following approval of the Technical Transfer Plan by the JMC, Janssen will commence and use Diligent Efforts to perform technical transfer activities and achieve its supply and secondary source obligations in accordance with such plan, the capacity expectations described in section 4.5(d) below and any applicable supply agreement. Janssen will provide Vertex with all documentation that is required and useful to effect regulatory filings necessary for regulatory approval of secondary source manufacturing facilities. Vertex will assist with such technical transfer by providing both technical documentation and FTE resources as may be reasonably requested to inform Janssen about the manufacturing process, subject to the understanding that Vertex will provide [\*\*\*] at the initiation of the

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technical transfer for each discrete aspect of the manufacturing process: [\*\*\*] Following the initiation of the technical transfer, individuals having the expertise shared with Janssen at the initiation of the technical transfer (as provided above) will be available to participate in [\*\*\*] project teleconferences with Janssen during the execution of the Technical Transfer Plan. If requested by Janssen and agreed by Vertex’s Third Party suppliers, Vertex will use reasonable efforts [\*\*\*] Notwithstanding the foregoing, Janssen will retain sole responsibility for the implementation and progress of the Technical Transfer Plan and for meeting its needs for Product Supply (either through its own Manufacturing activities or through the supply agreement) at launch and thereafter.

**(c) Sale of Intermediates.** [\*\*\*], and subject to the terms of the Supply Agreement, Vertex will use Diligent Efforts to supply Janssen with the raw materials, Intermediates required for its manufacture of the API to be converted into Product for Commercialization in the Territory and, as a secondary source to Vertex, for Product to be sold outside the Territory. [\*\*\*]

**(d) Notice of Establishment of Supply Capability; Secondary Source Capacity.** Janssen shall notify Vertex promptly following its establishment of supply capability for Manufacture of Product for Commercialization in the Territory. [\*\*\*] following delivery of such notice, the Parties will enter into a supply agreement for Janssen to be a secondary supplier, which supply agreement shall include usual and customary terms including, but not limited to, provisions for good faith forecasts, binding purchase orders for periodic orders by Vertex from Janssen, purchase price, and term, for supply of [\*\*\*] provided the purchase price shall be [\*\*\*]

In addition, Janssen agrees to use [\*\*\*] to supply additional quantities of [\*\*\*] if requested by Vertex, provided, however, [\*\*\*]

**(e) Third Party Agreements.** Vertex will provide Janssen with copies of draft Third Party manufacturer agreements for the commercial supply of VX-950 and will consider in good faith Janssen’s comments provided [\*\*\*].

**4.6 Packaging.** Janssen will be responsible for Packaging of Products for commercial sale in the Territory.

**4.7 Support for Establishment of Supply Capabilities.** [\*\*\*] Vertex will invoice Janssen for costs incurred under Section 4.7 as they occur and Janssen will pay such invoice within [\*\*\*] Vertex may sell Product from its inventory following Regulatory Approval of the Product in Vertex’s territory and, [\*\*\*]

## Article 5 - Commercialization in the Territory

**5.1 Janssen Commercialization Efforts.** Janssen shall warehouse and distribute the Product in the Territory and shall be responsible for recording sales and handling all aspects of Product order processing, invoicing, collection, inventory and receivables in the Territory. In this work and in all other aspects of Commercialization of the Product in the Territory, Janssen shall use Diligent Efforts, including without limitation by [\*\*\*] Except relating to the philanthropic and access programs and activities pursuant to Article 6, Janssen will use



Diligent Efforts to maximize Net Sales of Products in the Territory through its commercial marketing, pricing and contracting strategies [\*\*\*] Janssen shall bear all of its own costs and expenses of Commercializing the Product in the Territory.

**5.2 Joint Commercialization Committee.** Promptly after the Effective Date, the Parties shall establish a Joint Commercialization Committee (the “Joint Commercialization Committee” or “JCC”). The JCC shall be led by co-chairs, one of which shall be selected by Vertex and one of which shall be selected by Janssen.

**5.2.1 Responsibilities.** The JCC shall be responsible for the following:

- 5.2.1.1** use reasonable efforts to establish a global brand for the Product including but not limited to, establishing overall strategic objectives for the Product;
- 5.2.1.2** review and discuss the Territory Commercialization Plan and the North American Commercialization Plan; and
- 5.2.1.3** discuss commercial activities that may benefit from joint involvement or coordination, including but not limited to [\*\*\*] other matters of mutual interest.

**5.3 Commercialization Plans.** The JCC will review and discuss the Territory Commercialization Plan and the North American Commercialization Plan, each of which will be provided to the JCC by Janssen or Vertex, respectively, no later than [\*\*\*] prior to the projected commercial launch for the Product in the United States (with respect to the North American Commercialization Plan) or the European Union (with respect to the Territory Commercialization Plan). [\*\*\*] The responsible Party will also provide to the JCC, for review and discussion, any subsequent material amendments to the most recent Commercialization Plan that it provided to the JCC and in any event shall submit an updated plan on an annual basis. [\*\*\*] prior to the projected commercial launch for the Product in either the United States or the European Union, the JCC will consider plans for sharing certain global Commercialization activities (i.e., activities that benefit the Product in both the Vertex’ and Janssen’s territories, including without limitation such activities that relate to [\*\*\*] and the appropriate allocation of responsibilities and budget for such activities. Any such plan (including the allocation of responsibilities and budget) recommended by the JCC will be referred to the JSC for approval and if approved, will be reviewed and updated annually thereafter by the JSC upon referral from the JCC. The Territory Commercialization Plan will contain the annual Commercialization plans and budgets for [\*\*\*] with sufficient detail with respect to Commercialization, including but not limited to details [\*\*\*] to enable the JCC to conduct a meaningful review of such plans. Comparable information will be provided for the Territory as a whole and on a regional basis. Amendments and updates to the Territory Commercialization Plan and particularly the Commercialization plans for [\*\*\*] shall not be effective without review and discussion by the JCC.

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Notwithstanding the foregoing, Janssen shall be solely responsible for all decisions regarding the prices charged for the Product in the Territory, as well as discounts, rebates and all other deductions from Net Sales allowed under Section 1.77.

**5.4 Scientific Meetings; [\*\*\*]** Commencing [\*\*\*], the Parties will discuss the scientific meetings inside and outside the Territory to which each Party intends to send a representative(s) during the balance of 2006 and for the following year, and will periodically review their respective plan in this regard with each other. The discussions will be for the purpose of coordinating efforts in connection with [\*\*\*] in connection with supporting the worldwide exchange of scientific information. [\*\*\*]

**5.5 Advertising and Promotional Materials.**

(a) Janssen shall develop relevant educational, sales, promotion and advertising materials relating to the Product (“Territory Product Materials”), for use in the Territory, that shall be consistent with the Territory Commercialization Plan and compliant with applicable law and the provisions of applicable Regulatory Approvals. Copies of all Territory Product Materials used in the Territory will be archived by Janssen in accordance with applicable law. Upon Vertex’s request, Janssen shall provide copies of the material core Territory Product Materials for the Key Countries to Vertex for its review and comment prior to their first use. Moreover, upon request, Janssen shall provide copies of any other Territory Product Materials for other countries in the Territory to Vertex for its review and comment. Janssen will provide Vertex with any English translations, if available, of such Territory Product Materials that are produced for its own use. Janssen will consider in good faith any comments Vertex may have with respect to such Territory Product Materials. Upon Janssen’s request, Vertex shall provide Janssen with copies of the material core educational, sales, promotion and advertising materials relating to the Product in North America (“North American Product Material”), for review and comment prior to their use. Vertex will consider in good faith any comments Janssen may have with respect to such North American Product Material. Requests for North American Product Material and Territory Product Materials shall be made through a member of the JCC or his or her designee.

(b) Subject to any limitations imposed by applicable law, all Territory Product Materials and all documentary information and oral presentations, whether in hard-copy written, electronic or other media form regarding the education, marketing and promotion for the Product in countries of the Territory shall acknowledge the Parties’ license arrangement and shall display the Janssen or Janssen Affiliate and Vertex names and logos with equal prominence.

(c) In the event that Janssen uses, in a majority of the Major Market Countries in the Territory, the same Trademark for the Product used by Vertex in the United States, at Vertex’s option the Parties will coordinate the establishment, content, operation, and maintenance of any site or domain on the internet which incorporates the Trademark, and the related annual cost [\*\*\*] The costs incurred by Vertex in the search for and selection of the Trademark will be shared in the same proportion.

(d) Where not prohibited by law or regulation, and subject to any required Regulatory Approval, which Janssen shall use diligent efforts to obtain, Vertex's name and logo will be carried on all Product packaging, package inserts, labels and containers, and on all printed, electronic and digital material related thereto (including educational materials and advertisements), with a prominence substantially equivalent to that of Janssen, or the Janssen Affiliate that is the most prominent name listed on any such material.

**5.6 Referral of Orders; Returns.** If Vertex receives any orders for the Product in the Territory, it shall refer such orders to Janssen. If Janssen receives any orders for the Product outside the Territory, it shall refer such orders to Vertex. Janssen shall be solely responsible for handling all returns of the Product sold in the Territory. If Product sold in the Territory is returned to Vertex, Vertex shall promptly ship such Product to a facility designated by Janssen. If Product sold in North America is returned to Janssen, Janssen shall promptly ship such Product to a facility designated by Vertex, at Vertex's expense.

**5.7 Adverse Event and Product Complaint Reporting Procedures.** Each Party will (i) provide the other Party with all Product complaints, adverse event information, and safety data in its control necessary or desirable for the other Party to comply with all applicable law with respect to the Product and (ii) report and provide such information to the other Party in such a manner and time so as to enable the other Party to comply with all applicable law. Vertex shall maintain a global adverse event database for the Product and shall generate adverse event reports for Janssen's use in the Territory. Janssen shall have access to all data in the global adverse event database. Janssen shall be responsible for submitting adverse events reports to the applicable Regulatory Authorities in the Territory. The Parties will enter into a Pharmacovigilance Agreement along with any other sublicensees of Vertex and Janssen (the "Pharmacovigilance Agreement") within [\*\*\*], setting forth the product complaint procedures to which each Party will adhere; provided that in any event, the Pharmacovigilance Agreement will be in place prior to (a) the earlier of initiation by Janssen of any activities under the Global Development Plan, or any Additional Development Activities, or (b) the submission by Janssen of any applications for Regulatory Approval of the Product in the Territory. The costs and expenses of maintaining the global adverse event database shall be borne [\*\*\*] Notwithstanding the foregoing, [\*\*\*] the Parties will enter into a new Pharmacovigilance Agreement and Vertex and its sublicensees will have benefits and relevant obligations substantially similar to those which Janssen had in the initial Pharmacovigilance Agreement. The foregoing shall not be interpreted as requiring either Vertex or Janssen, respectively, to be responsible for the cost of maintenance of the global adverse event database, except as otherwise required by law, beyond the point at which Vertex or Janssen, respectively, terminates Development or Commercialization of Products under this Agreement.

[\*\*\*] of this Agreement, the Parties shall meet to establish a safety oversight working group (the "Safety Oversight Working Group") composed of members of both Parties, which during the [\*\*\*] and as otherwise provided in the Pharmacovigilance Agreement, shall discuss processes and procedures for sharing information needed to support each Party's respective regulatory responsibilities and to comply with applicable regulatory pharmacovigilance requirements. Any such procedures shall not be construed to restrict either Party's ability to take action that it deems to be appropriate or required of it under

the applicable regulatory requirements, but when permitted by applicable laws and regulations, the Parties shall consult with each other before taking such action.

**5.8 Commercial Information.** In addition to royalty reports required pursuant to Section 9.6, Janssen will provide Vertex, on an annual basis as part of the Territory Commercialization Plan, with information relating to Sales Call metrics on a country-by-country basis in the [\*\*\*] on a country-by-country basis for the [\*\*\*].

**5.9 [\*\*\*]**

**5.10 Recalls, Market Withdrawals or Corrective Actions.**

**5.10.1 In the Territory.** If any Regulatory Authority issues or requests a recall or takes a similar action in connection with the Product in the Territory, or if either Party determines that an event, incident or circumstance has occurred that may result in the need for a recall or market withdrawal in the Territory, the Party notified of such recall or similar action, or the Party that desires such recall or similar action, shall [\*\*\*] advise the other Party thereof by telephone or facsimile. Janssen, in consultation with Vertex, shall decide whether to conduct a recall in the Territory (except in the case of a government mandated recall, when Janssen may act without such advance notice but shall notify Vertex as soon as possible) and the manner in which any such recall shall be conducted. Vertex will make available to Janssen, upon request, all pertinent records within Vertex's control that Janssen may reasonably request to assist Janssen in effecting any recall. Janssen shall bear the expense of any such recall in the Territory, subject to the terms of the Supply Agreement.

**5.10.2 Outside the Territory.** In the event that any Regulatory Authority issues or requests a recall or takes a similar action in connection with the Product in any country outside the Territory, or in the event either Party determines that an event, incident or circumstance has occurred that may result in the need for a recall or market withdrawal in any country outside the Territory, the Party notified of such recall or similar action, or the Party that desires such recall or similar action, shall [\*\*\*], advise the other Party thereof by telephone or facsimile. Vertex and/or its Related Parties, in consultation with Janssen, shall decide whether to conduct a recall in any country outside the Territory and the manner in which any such recall shall be conducted. Janssen will make available to Vertex, upon request, all pertinent records within Janssen's control that Vertex may reasonably request to assist Vertex in effecting any recall. Vertex and/or its Related Parties shall bear the expense of any such recall.

**5.11 Medical Inquiries.**

**5.11.1 In the Territory.** After the First Commercial Sale, Janssen shall handle all medical questions or inquiries from members of the medical profession in the Territory regarding the Product [\*\*\*] Vertex shall, and shall cause its medical affairs and/or sales department to, refer to Janssen all such questions and inquiries within [\*\*\*] of receipt. In no event will Vertex or its Sales Representatives or MSLs respond to any such medical question or inquiry. Notwithstanding the foregoing, [\*\*\*]

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**5.11.2 Outside the Territory.** Vertex shall handle all medical questions or inquiries from members of the medical profession outside the Territory regarding the Product. Janssen shall, and shall cause its medical affairs and/or sales department to refer to Vertex all such questions and inquiries within [\*\*\*] of receipt. In no event will Janssen or its Sales Representatives or MSLs respond to any such medical question or inquiry.

#### **Article 6 -Philanthropic Program.**

Vertex and Janssen along with their respective Affiliates share the goal of promoting the diagnosis, prevention, treatment and cure of HCV Infection worldwide. In addition to Developing and Commercializing the Product in their respective territories, the Parties intend to engage in worldwide philanthropic activities directed toward this goal. Accordingly, the Parties agree that, [\*\*\*], each Party will set aside an amount [\*\*\*] to apply in furtherance of such philanthropic objectives (the "Philanthropic Funds"). Each Party shall make its contribution no later than [\*\*\*]. The Philanthropic Funds will be provided by each Party in any one of a variety of approved forms at such Party's election, such as [\*\*\*] Also as part of this philanthropic program, the Parties shall consider in good faith activities and programs to increase the access to the Product, especially in countries identified by the World Health Organization as developing countries. In addition, as part of the Philanthropic program, Janssen may [\*\*\*] The disposition of the Philanthropic Funds shall be determined by consensus of the members of a Joint Philanthropic Committee ("JPC"), with equal representation from each Party; provided, however, that the Philanthropic Funds shall be allocated in such a way as to maximally benefit the causes of the diagnosis, prevention, treatment and cure of HCV Infection. If the JPC is unable to reach consensus, either Party may refer the matter to the Executive Officers in accordance with Section 14.2. Each Party will afford equal recognition to the other Party in any public description by that Party of activities under this Article 6.

#### **Article 7 -License Grants**

- 7.1 Development License.** Vertex and its Affiliates hereby grant to Janssen a co-exclusive (with Vertex) right and license under Vertex Patent Rights and Vertex's rights under Joint Patent Rights, to Develop Product Candidates and Products in the Territory in the Field, provided however, that such license shall not include a license to Vertex Patent Rights resulting from inventions conceived or reduced to practice as a result of Additional Development Activities, if Janssen elected not to participate in those activities, unless and until Janssen has paid the amounts specified in Section 3.5 hereof with respect to those Additional Development Activities.
- 7.2 Commercialization License.** Vertex and its Affiliates hereby grant to Janssen an exclusive right and license under Vertex Patent Rights and Vertex's rights under Joint Patent Rights, to Commercialize Product Candidates and Products in the Territory in the Field, provided however, that such license shall not include a license to Vertex Patent Rights resulting from inventions conceived or reduced to practice as a result of Additional Development Activities, if Janssen elected not to participate in those activities, unless and

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until Janssen has paid the amounts specified in Section 3.5 hereof with respect to those Additional Development Activities.

- 7.3 Know-How License.** Vertex and its Affiliates hereby grant to Janssen an exclusive license in the Field in the Territory under all Vertex Know-How to the extent that it relates exclusively to Compounds, Product Candidates or Products, solely to discharge Janssen's obligations and exercise its rights under this Agreement, provided however, that such license shall not include a license to Vertex Know-How resulting from inventions conceived or reduced to practice as a result of Additional Development Activities, if Janssen elected not to participate in those activities, unless and until Janssen has paid the amounts specified in Section 3.5 hereof with respect to those Additional Development Activities.
- 7.4 Licenses from Janssen.** Janssen and its Affiliates hereby grant to Vertex a non-exclusive, royalty-free license in the Field under all Janssen Patent Rights, Janssen Know-How and Janssen's rights under Joint Patent Rights, solely for the purpose of Developing or Manufacturing Product Candidates or Products worldwide, and an exclusive, royalty-free license in the Field under all Janssen Patent Rights, Janssen Know-How and Janssen's rights under Joint Patent Rights, for Commercializing Product Candidates and/or Products outside the Territory, provided however, that such license shall not include a license to Janssen Patent Rights or Know-How resulting from inventions conceived or reduced to practice as a result of Additional Development Activities, if Vertex elected not to participate in those activities, unless and until Vertex has paid the amounts specified in Section 3.5 hereof with respect to those Additional Development Activities.
- 7.5 Manufacturing License.** Vertex and its Affiliates hereby grant to Janssen an exclusive license in the Field in the Territory to Manufacture Product Candidates and Products for Commercial use in the Territory, and a co-exclusive (with Vertex) right and license to Manufacture Product Candidates and Products for purposes of exercising its rights under the Development License granted under Section 7.1 above, in each case under Vertex Patent Rights, Vertex Know-How and Vertex's right under Joint Patent Rights. Any license provided to Janssen under the Supply Agreement shall be incremental to the license right granted in this section.
- 7.6 License of Trademarks.** Prior to Commercialization of a Product, the Parties shall enter into a trademark licensing agreement under which Vertex and its Affiliates grant to Janssen a [\*\*\*] license during the term of the Agreement to use (i) logos chosen and owned by Vertex (the "Vertex Logo") and (ii) the Trademarks Controlled by Vertex, on labeling, package inserts, monographs and packaging materials for the Product, Product Materials and samples, and other materials used in connection with the performance of this Agreement during its term. Janssen shall have no rights under this Agreement in or to the Vertex Logo, the Vertex Trademarks or the goodwill pertaining thereto except as specifically provided in the trademark licensing agreement. Janssen agrees that upon termination or expiration of this Agreement, it will discontinue all use of the Vertex Logo and the Vertex

Trademarks, provided, however, Janssen shall have the right to sell off any inventory of Product containing Vertex Logo or Vertex Trademarks in accordance with the terms of this Agreement.

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**7.7 Right to Sublicense.** Each Party shall have the right to grant sublicenses under the rights and licenses granted to it under Sections 7.1, 7.2, 7.3, 7.4 and 7.5 of this Agreement, provided that any such sublicense obliges the sublicensee to comply with all relevant terms of this Agreement and that each Party remains liable to the other for all material acts and omissions of any such sublicensee.

Notwithstanding the foregoing, if Janssen wishes to grant a sublicense to a Third Party of its Development or Commercialization rights in [\*\*\*] For the avoidance of doubt, Janssen shall not be required to seek the consent of Vertex in respect of sublicenses granted to its Affiliates.

**7.8 Vertex Retained Rights.** Notwithstanding the foregoing, Vertex shall retain rights under the Vertex Patent Rights and the Joint Patent Rights to the extent necessary or useful to discharge its obligations and exercise its rights under this Agreement, including but not limited to performing all activities (directly or with Related Parties) included in the Global Development Plan from time to time.

**7.9 No Implied Licenses.** Except as specifically set forth in this Agreement, neither Party shall acquire any license or other intellectual property interest, by implication or otherwise, in any Information disclosed to it under this Agreement or under any patents or patent applications owned or Controlled by the other Party or its Affiliates.

**7.10 [\*\*\*]**

**7.11 [\*\*\*]**

### Article 8 -

(This Article is intentionally left blank).

### Article 9 -Financial Provisions

**9.1 Upfront License Fee.** In consideration of the licenses granted pursuant to Article 7, Janssen shall pay to Vertex a one-time non-refundable, non-creditable payment of One Hundred Sixty Five Million Dollars (US \$165,000,000) within [\*\*\*] the Effective Date.

#### 9.2 Milestones

**9.2.1 Milestone Payment.** In further consideration of the licenses granted pursuant to Article 7, Janssen shall also pay each of the amounts set forth in the table below (each, a "Milestone Payment") if and when the corresponding development milestone event (each, a "Milestone Event") is achieved.

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<u>Milestone Event</u>	<u>Milestone Amount (USD)</u>
[***] [***]	[***]
[***]	
[***]	

**9.2.2** Each Milestone Payment shall be payable only once upon the initial achievement of the associated Milestone Event. Vertex will invoice Janssen upon the occurrence of each of the Milestone Events [\*\*\*], and the invoiced amount shall be payable within [\*\*\*] of receipt of invoice. Janssen will notify Vertex in writing not later than [\*\*\*] after the occurrence (or deemed occurrence) of each of the Development Milestone Events [\*\*\*], and shall pay the appropriate Milestone Payment within [\*\*\*] of receipt of an invoice thereafter from Vertex.

**9.3 Development Cost Reimbursement.** Janssen will pay to Vertex fifty (50%) percent of the Global Development Costs. Not later than [\*\*\*] after the end of each calendar quarter, Vertex will submit to Janssen a summary of Global Development Costs for the Calendar Quarter just ended, including a brief description of the aggregate internal and external costs and an allocation of the Global Development Costs across various Development activities. With the summary, Vertex will include an invoice for fifty (50%) percent of the reported Global Development Costs, which invoice shall be due and payable by Janssen [\*\*\*] If Janssen has responsibility for Development activities under the Global Development Plan, Janssen will provide to Vertex, also on a quarterly basis and with a description as set forth above, a summary of the Janssen's Global Development Costs under the Global Development Plan for the preceding quarter. Janssen may apply fifty (50%) percent of any such Global Development Costs appropriately incurred and disclosed hereunder against any unpaid amounts otherwise due to Vertex on account of Global Development Costs previously incurred by Vertex, and if the amount of any such offset exceeds the amount otherwise due and payable to Vertex, [\*\*\*] The books and records of each Party and any of that Party's Related Parties relating to Global Development Costs to be charged to the other Party hereunder will be subject to inspection as provided below [\*\*\*] upon reasonable notice from the Party charged to the charging Party, for the purpose of verifying the accuracy of the summary of submitted Global Development Costs. Those records will be made available during normal business hours and will include all appropriate supporting

information, such as a record of time expended on Development activities and invoices received covering all Third Party costs included in any summary of Global Development Costs submitted by the Party being audited. The inspection shall be conducted by an independent certified public accounting firm of nationally recognized standing, selected by (and at the expense of) the Party exercising its inspection right and reasonably acceptable to the Party being audited. The accounting firm conducting any such inspection shall only

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disclose to the Party exercising its inspection right whether the summary of Global Development Costs being audited is accurate, and if not, by what aggregate amount the summary is inaccurate. The books and records of each Party pertaining to Global Development Costs shall be retained by such Party for a period of [\*\*\*] The summary information provided by either Party under the reporting provisions set forth above and any additional information disclosed by that Party upon audit shall be Information of the Party providing the information and subject to the confidentiality and non-use obligations of Section 11.1.

#### 9.4 Royalties.

**9.4.1 Royalties Payable By Janssen.** In further consideration of the licenses granted pursuant to Article 7, Janssen shall pay to Vertex royalties on cumulative Net Sales of Products in the Territory as set out in this Section 9.4. The royalty rate payable shall be determined [\*\*\*]:

[\*\*\*]

[\*\*\*]

Royalties on sales of Products, at the royalty rates determined as set forth above with reference to annual aggregate Net Sales in the Territory, shall be payable on a country-by-country basis until, [\*\*\*] For purposes of determining aggregate Calendar Year Net Sales under this Section 9.4.1 for any Calendar Year, [\*\*\*].

**9.4.2 Unlicensed Competition.** Notwithstanding Section 9.4.1, if a Third Party sells a pharmaceutical product in any country that is a “Generic Version” of a Product being sold in that country (the generic version, a “Third Party Product”), then [\*\*\*] For purposes of this subsection 9.4.2, a “Generic Version” of a product is [\*\*\*] This Section 9.4.2 shall not be applicable to any product being sold by a Third Party to which Janssen has granted a sublicense hereunder. The [\*\*\*] provided in this Section 9.4.2 shall not be applied to any Net Sales in respect of which a royalty report has already been provided pursuant to Section 9.7 prior to receipt by Vertex from Janssen of written notice that sales of a Generic Version of a Product covered by that royalty report [\*\*\*]

**9.5 Third Party Licenses.** Janssen shall be responsible for [\*\*\*] of any royalties, or other amounts relating to intellectual property rights, payable on account of Products sold in the Territory, including without limitation, royalties due under any of the Existing Third Party Agreements. Neither Party shall enter into any agreement with a Third Party, without the other Party’s written consent, obligating the other Party to pay royalties or other amounts relating to the Third Party’s intellectual property rights in connection with the

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Development, Manufacture or Commercialization by that other Party of Product Candidate or Products in that other Party’s territory. If Vertex pays any such royalties or other payments otherwise the responsibility of Janssen, those payments will be deemed to have been made on behalf of Janssen and Janssen shall promptly reimburse Vertex for any such payments [\*\*\*] days of receipt of an invoice therefor from Vertex. The Parties shall establish such procedures as are reasonably necessary to permit them to reconcile Vertex’s actual payments pursuant to the foregoing with Janssen’s payments to Vertex or to any Third Party under this Section 9.5.

**9.6 Reports; Payment of Royalty.** During the term of this Agreement following the First Commercial Sale of a Product, Janssen shall furnish to Vertex [\*\*\*], at the end of each [\*\*\*], showing (i) the Net Sales of Products in each country in the Territory during the reporting period, and any permitted deductions from gross sales taken to arrive at the Net Sales calculation as set forth in Section 1.77 of this Agreement; (ii) the royalties payable under this Agreement on account of those Net Sales and the basis for calculating those royalties; (iii) the exchange rates and other methodology used in converting Net Sales into U.S. dollars, from the currencies in which sales were made in order to determine the appropriate royalty tier; and (iv) dispositions of Products other than pursuant to sale for cash. Net Sales in countries invoiced in currency other than U.S. Dollars shall be translated to U.S. Dollars using Janssen’s then-current standard exchange rate methodology, fairly applied, for the translation of foreign currency into U.S. dollars, as employed on a consistent basis throughout Janssen’s operations and disclosed to Vertex in advance. Should Janssen change its foreign currency translation methodology, the new methodology will be disclosed in writing to Vertex. [\*\*\*] Royalties shown to have accrued by each [\*\*\*] royalty report shall be due and payable to Vertex no later than the [\*\*\*]. Janssen shall keep complete and accurate records in sufficient detail to enable the royalties payable hereunder to be determined and the information provided hereunder to be verified by Vertex’s accounting firm pursuant to Section 9.7.

**9.7 Audits.** Upon the written request of Vertex, with [\*\*\*] prior written notice to Janssen, [\*\*\*], Janssen shall permit an independent certified public accounting firm of nationally recognized standing selected by Vertex and reasonably acceptable to Janssen, [\*\*\*], to have access during normal business hours to such of the records of Janssen and its Affiliates as may be reasonably necessary to verify the accuracy of the royalty reports hereunder for any [\*\*\*]. Those records shall include, without limitation, gross sales of each Product or Product Candidate on a country-by-country basis, as well as all deductions taken from gross sales in that country to arrive at Net Sales in that country. The accounting firm shall disclose to Vertex only whether the royalty reports are correct or incorrect and the specific details concerning any discrepancies.

If such independent accountant's review of Janssen's royalty reports shows an underpayment, Janssen shall remit or cause its Related Parties to remit to Vertex within [\*\*\*] after Janssen's receipt of such report: (i) the amount of such underpayment plus interest as determined under Section 9.10 below, and (ii) if such underpayment exceeds [\*\*\*] of the total amount owed for the period being audited, the reasonable and necessary fees and expenses of the independent accountant performing the audit. If such underpayment does not exceed [\*\*\*], the fees and expenses of the independent accountant

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performing any such audit shall be paid by Vertex. [\*\*\*] Upon prior written notice to Janssen as provided above, Vertex shall have a further right, exercisable not more frequently than once [\*\*\*], to audit Net Sales, deductions taken from gross sales, and royalties earned by Vertex in any country in which a prior audit has shown an understatement of royalties due of at least [\*\*\*].

Janssen shall include in each sublicense granted by it pursuant to this Agreement a provision requiring the sublicensee to make reports to Janssen, to keep and maintain records of sales made pursuant to such sublicense and to grant access to such records by Vertex's independent accountant to the same extent required of Janssen under this Agreement.

Upon the expiration of [\*\*\*] the calculation of royalties payable with respect to such year shall be binding and conclusive upon the Parties, and Janssen and its Related Parties shall be released from any liability or accountability with respect to royalties for such Calendar Year.

Vertex shall treat all financial Information subject to review under this Section 9.7 or under any sublicense agreement in accordance with the confidentiality and non-use provisions of this Agreement, and shall cause its accounting firm to enter into an acceptable confidentiality agreement with Janssen and/or its Related Parties obligating it to retain all such Information in confidence pursuant to such confidentiality agreement.

**9.8 Payments.** All payments to be made by Janssen to Vertex under this Agreement shall be made in U.S. dollars and shall be paid by bank wire transfer in immediately available funds to such bank account in the United States or elsewhere as may be designated in writing by Vertex from time to time.

**9.9 Income Tax Withholding.**

(a) Janssen will make all payments to Vertex under this Agreement without deduction or withholding for taxes except to the extent that any such deduction or withholding is required by law in effect at the time of payment, and Janssen has notified Vertex of any such deduction or withholding in the royalty report.

(b) Any tax required to be withheld on amounts payable under this Agreement will promptly be paid by Janssen on behalf of Vertex to the appropriate governmental authority, and Janssen will furnish Vertex with proof of payment of such tax. Any such tax required to be withheld will be an expense of and borne by Vertex.

(c) Janssen and Vertex will cooperate with respect to all documentation required by any taxing authority or reasonably requested by Janssen or Vertex to secure a reduction in the rate of applicable withholding taxes.

(d) If Janssen had a duty to withhold taxes in connection with any payment it made to Vertex under this Agreement but Janssen failed to withhold, and such taxes were assessed against and paid by Janssen, then Vertex will indemnify and hold harmless Janssen from and against such taxes (including interest but excluding penalties). If Janssen makes a

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claim under this Section 9.9(d), it will comply with the obligations imposed by Section 9.9(b) as if Janssen had withheld taxes from a payment to Vertex.

**9.10 Interest Penalty.** In case of any delay in payment by Janssen to Vertex (including a delay in payment identified in connection with an audit under Section 9.7 above) [\*\*\*] interest at the [\*\*\*] assessed from the [\*\*\*] after the due date of the payment, shall be due from Janssen and payable [\*\*\*].

**9.11 [\*\*\*]**

**Article 10 -Intellectual Property Ownership,  
Protection and Related Matters**

**10.1 Filing, Prosecution and Maintenance of Vertex Patent Rights.** Vertex shall have the exclusive right and the obligation (subject to Vertex's election not to file, prosecute, or maintain pursuant to Section 10.3), to diligently file, prosecute and maintain (by timely paying all maintenance fees, renewal fees, and other such fees and costs required under applicable laws) the Vertex Patent Rights worldwide, and to conduct any interference, opposition and re-examination or other similar proceeding with respect thereto, in all such countries as is customary for Vertex to file, prosecute and maintain patent rights covering pharmaceutical products. [\*\*\*] If Janssen notifies Vertex that it wishes Vertex to file and prosecute patent applications covering Vertex Patent Rights in any country or countries in the Territory in which it is not customary for Vertex to do so, or to conduct any interference, opposition and re-examination or other similar proceedings with respect to the Vertex Patent Rights in the Territory, [\*\*\*] Vertex shall keep Janssen advised of the status of all actual and prospective patent filings in the Territory and upon the request of Janssen, provide advance copies of any papers related to the filing, prosecution and maintenance of such patent filings. Vertex shall promptly give reasonable advance notice to Janssen of the grant, lapse, revocation, surrender, invalidation or abandonment of any Vertex Patent Rights in the Territory for which Vertex is responsible for the filing, prosecution and maintenance. Vertex shall solicit Janssen's advice and review of the nature and text of such patent applications and important prosecution matters related thereto in reasonably sufficient time prior to filing thereof, and Vertex shall consider Janssen's comments related thereto.

**10.2 Filing, Prosecution and Maintenance of Joint Patent Rights.** In respect of any Joint Information and Inventions, the Parties shall agree, without prejudice to ownership, which Party shall have the right and/or obligation to prepare and file a priority patent application, and prosecute such application(s) and maintain any patents derived therefrom, with the Parties equally sharing the Patent Costs for the preparation, filing, prosecution and maintenance of such priority patent application. Should the agreed-upon Party elect not to prepare and/or file any such patent application, it shall (i) provide the other Party with written notice as soon as reasonably possible after making such election but in any event no later than [\*\*\*] before the other Party would be faced with a possible loss of rights, (ii)

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give the other Party the right, at the other Party's discretion and sole expense, to prepare and file the priority application(s), and (iii) offer reasonable assistance in connection with such preparation and filing [\*\*\*] The other Party, at its discretion and cost, may prosecute such application(s) and maintain any patents derived therefrom.

### **10.3 Option to Prosecute and Maintain Patents.**

**10.3.1** Vertex shall give notice to Janssen of any desire to cease prosecution and/or maintenance of Vertex Patent Rights or Joint Patent Rights on a country-by-country basis in the Territory and, in such case, shall permit Janssen, at its sole discretion, to continue prosecution or maintenance of such Vertex Patent Rights [\*\*\*]. If Janssen elects to continue prosecution or maintenance or to file based on Vertex's election not to file pursuant to this Section 10.3, Vertex shall execute such documents and perform such acts at [\*\*\*] expense as may be reasonably necessary to allow Janssen to initiate or continue such filing, prosecution or maintenance.

**10.3.2** Janssen shall give notice to Vertex of any desire to cease prosecution and/or maintenance of Janssen Patent Rights or Joint Patent Rights in any country and, in such case, shall permit Vertex at its sole discretion, to continue prosecution or maintenance of such Janssen Patent Rights [\*\*\*]. If Vertex elects to continue prosecution or maintenance or to file based on Janssen's election not to file pursuant to this Section 10.3, Janssen shall execute such documents and perform such acts at [\*\*\*] expense as may be reasonably necessary to allow Vertex to initiate or continue such filing, prosecution or maintenance.

### **10.4 Interference, Opposition, Re-examination and Re-issue.**

**10.4.1** Vertex shall promptly, but in any case within [\*\*\*] of learning of such event, inform Janssen of any request for, or filing or declaration of, any interference, opposition, or re-examination by a Third Party relating to Vertex Patent Rights or Joint Patent Rights for which Vertex is responsible, in the Territory. Janssen and Vertex shall thereafter consult and cooperate fully to determine a course of action with respect to any such proceeding. Janssen shall have the right to review and approve any submission to be made in connection with such proceeding.

**10.4.2** Vertex shall not initiate any re-examination, interference or re-issue proceeding relating to Vertex Patent Rights or Joint Patent Rights in the Territory without the prior written consent of Janssen, which consent shall not be unreasonably withheld.

**10.4.3** In connection with any interference, opposition, re-issue, or re-examination proceeding relating to Vertex Patent Rights or Joint Patent Rights in the Territory, Janssen and Vertex will cooperate fully and will provide each other with any information or assistance that either may reasonably request. Vertex shall keep Janssen informed of developments in any such action or proceeding, including, to the extent permissible by law, consultation and approval of any settlement, the status of any settlement negotiations and the terms of any offer related thereto.

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**10.4.4** The expense of any interference, re-examination or re-issue proceeding, and the expense of any opposition or similar two-party proceeding conducted under rules of the U.S. Patent and Trademark Office, or any comparable foreign authority shall, unless agreed otherwise, [\*\*\*]

### **10.5 Enforcement and Defense.**

**10.5.1** Each Party shall promptly give the other Party notice of (i) any infringement of Vertex Patent Rights, Janssen Patent Rights or Joint Patent Rights, or (ii) any misappropriation or misuse of Vertex Know-How or Janssen Know-How, that may come to the first Party's attention. Janssen and Vertex shall thereafter consult and cooperate fully to determine a course of action, including but not limited to the commencement of legal action by either or both Janssen and Vertex, to terminate any infringement of Vertex Patent Rights, Janssen Patent Rights or Joint Patent Rights or any misappropriation or misuse of Vertex Know-How or Janssen Know-How, in the Territory. Vertex, upon notice to Janssen, shall have the first right to initiate and prosecute any such legal action in the name of Vertex and Janssen, or to control the defense of any declaratory judgment action, relating to Vertex Patent Rights, Joint Patent Rights or Vertex Know-How in the Territory. Janssen, upon notice to Vertex, shall have the first right to initiate and prosecute any such legal action in the name of Janssen and Vertex, or to control the defense of any declaratory judgment action, relating to Janssen Patent Rights or Janssen Know-How in the Territory. [\*\*\*] Each Party shall promptly inform the other Party if it elects not to exercise its first right as described above and the other Party shall thereafter have the right to either initiate and prosecute such action or to control the defense of such declaratory judgment action in its name of and, if necessary, the name of the first Party. Each Party shall have the right to be represented by counsel of its own choice [\*\*\*]

**10.5.2** For any action to terminate any infringement of Vertex Patent Rights, Janssen Patent Rights or Joint Patent Rights or any misappropriation or misuse of Vertex Know-How or Janssen Know-How, as permitted in accordance with Section 10.5.1, in the event that the Party initiating the action is unable to initiate or prosecute such action solely in its own name, the other Party will join such action voluntarily and will execute and cause its Affiliates to execute all documents necessary for the first Party to initiate litigation to prosecute and maintain such action. In connection with any such action, Janssen and Vertex will cooperate fully and will provide each other with any information or assistance that either may

reasonably request. Each Party shall keep the other informed of developments in any such action or proceeding, including, to the extent permissible by law, the consultation and approval of any settlement negotiations and the terms of any offer related thereto.

**10.5.3** Any recovery obtained by either or both Janssen and Vertex in connection with or as a result of any action contemplated by this Section, whether by settlement or otherwise, shall be shared in order as follows:

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**10.5.4** Vertex shall inform Janssen of any certification regarding any Vertex Patent Rights it has received pursuant to either 21 U.S.C. §§355(b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) or its successor provisions or any similar provisions in a country in the Territory and shall provide Janssen with a copy of such certification \*\*\* Vertex's and Janssen's rights with respect to the initiation and prosecution of any legal action as a result of such certification or any recovery obtained as a result of such legal action shall be as defined in subsections 10.5.1 through 10.5.4; provided, however, that Vertex shall have the first right to initiate and prosecute any action and shall inform Janssen of such decision \*\*\*, in the case of certification regarding any Vertex Patent Rights it has received pursuant to either 21 U.S.C. §§355(b)(2)(A)(iv) or (j)(2)(A)(vii)(IV), or within a similarly appropriate time in the case of certifications or the like in countries outside of the United States, of receipt of the certification, after which time Janssen shall have the right to initiate and prosecute such action.

**10.6 Patent Term Restoration.** Vertex shall be responsible for obtaining patent term restoration or supplemental protection certificates or their equivalents in any country in the Territory where applicable to Vertex Patent Rights and Joint Patent Rights. Janssen shall be responsible for obtaining patent term restoration or supplemental protection certificates or their equivalents in any country in the Territory where applicable to Janssen Patent Rights. The Parties hereto shall cooperate with each other in obtaining patent term restoration or supplemental protection certificates or their equivalents in any country in the Territory where applicable to Vertex Patent Rights, Janssen Patent Rights and Joint Patent Rights. In the event that elections with respect to obtaining such patent term restoration are to be made, Vertex shall have the right to make the election with respect to Vertex Patent Rights and Joint Patent Rights and Janssen shall have the right to make the election with respect to Janssen Patent Rights.

**10.7 Third Party Claims.**

**10.7.1** Without prejudice to Section 12.3.2, if any action, suit or proceeding is brought against Janssen or Vertex or any Affiliate or sublicensee of either Party alleging the infringement of the intellectual property rights of a Third Party by reason of the discovery, development, manufacture, use, sale, importation or offer for sale of a Product Candidate or Product in the Territory, Janssen shall have the sole right but not the obligation to defend itself and Vertex in such action, suit or proceeding \*\*\* The Parties shall cooperate with each other in any defense of any such suit, action or proceeding. The Parties will give each other prompt written notice of the commencement of any such suit, action or proceeding, or receipt of any claim of infringement, and will furnish each other a copy of each communication relating to the alleged infringement. Without regard to which Party defends an Infringement Claim under this Section 10.7, all damages (including all reasonable costs and expenses associated with any defense of a claim hereunder) associated with any such infringement claim in the Territory shall be borne equally by the Parties.

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**10.7.2** Neither Party shall compromise, litigate, settle or otherwise dispose of any such suit, action or proceeding without the other Party's advice and prior consent, provided that the Party not having the right to defend the suit shall not unreasonably withhold its consent to any settlement which does not have a material adverse effect on its rights, obligations or benefits, either under this Agreement or otherwise. Notwithstanding the foregoing, if Janssen decides to seek a license, and Vertex elects not to seek such license, Janssen may seek to obtain such license for its benefit \*\*\* provided that the terms and conditions of such license do not include an admission of invalidity of any Vertex Patent Rights or Joint Patent Rights, or restrict Vertex's ability to challenge or litigate the validity or applicability of any intellectual property to which the license relates.

**10.7.3** The Party first having actual notice of any claim, action or proceeding referenced in Section 10.7.1 above shall promptly notify the other Party in writing, setting forth in reasonable detail, to its knowledge, the facts related to any such claim, action or proceeding. The Parties shall promptly discuss proposed responses to any such matters.

**10.8 Trademarks.** Janssen shall have the right but not the obligation to use Vertex' Trademarks to market and promote the Product in its Territory, subject to the provisions of the license to be provided under Section 7.6 hereof. Janssen may, however, select all Trademarks which it employs in connection with Product in the Territory, and subject to the following sentence, shall own and control, and shall be responsible for registration and maintenance of all such Trademarks. In the event Janssen selects a Product Trademark for any country in the Territory that is the same as the Product Trademark selected by Vertex for use in the United States, Vertex will own the related Trademark and will provide Janssen with a license as provided in Section 7.6 of this Agreement to use that Trademark in the Territory. \*\*\* Nothing in this Agreement shall be construed as a grant of rights, by license or otherwise, to Vertex to use any Trademarks owned by Janssen for any purpose, except as might otherwise be permitted under applicable law or as provided in Article 13 hereof in the event of the termination of this Agreement by Vertex with cause or by Janssen without cause.

**Article 11 - Confidentiality, Publication and Publicity**

**11.1 Nondisclosure Obligation.** All Information disclosed by one Party to the other Party shall be maintained in confidence by the receiving Party and shall not be disclosed to a Third Party or used for any purpose except as set forth herein without the prior written consent of the disclosing Party,



except to the extent that such Information:

**11.1.1** is known by the receiving Party at the time of its receipt, and not through a prior disclosure by the disclosing Party, as documented by the receiving Party's contemporaneous business records;

**11.1.2** is in the public domain through no breach of this Agreement by the receiving Party;

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**11.1.3** is subsequently disclosed to the receiving Party by a Third Party who may lawfully make such disclosure and is not to the best of the receiving Party's knowledge under an obligation of confidentiality to the disclosing Party;

**11.1.4** is developed by the receiving Party independently of Information received from the disclosing Party, as documented by the receiving Party's contemporaneous business records;

**11.1.5** is disclosed to governmental or other regulatory agencies to comply with applicable law or regulations, provided the receiving Party provides to the disclosing Party prompt prior written notice of its obligation to make such disclosure and takes reasonable and lawful actions to avoid or minimize the degree of such disclosure; or

**11.1.6** is deemed necessary by the receiving Party in the reasonable exercise of its judgment to be disclosed to Related Parties, agents or consultants, to the extent the receiving Party deems necessary or advisable, in connection with the Development, Manufacturing and/or Commercialization of a Product or Product Candidate (or for such entities to determine their interest in performing such activities) in accordance with this Agreement, on the condition that any such Third Parties agree to be bound by confidentiality and non-use obligations that are no less stringent than those confidentiality and non-use provisions contained in this Agreement.

A combination consisting of multiple components shall not be deemed to fall within the foregoing exclusions merely because one or more individual components of that disclosure are published or available to the general public or in the rightful possession of the receiving Party, unless the combination itself is published or available to the general public or otherwise falls within one of the foregoing exclusions.

If a Party is required by judicial or administrative process to disclose Information that is subject to the non-disclosure provisions of this Section 11.1, such Party shall promptly inform the other Party of the disclosure that is being sought in order to provide the other Party an opportunity to challenge or limit the disclosure obligations. Information that is disclosed by judicial or administrative process shall remain otherwise subject to the confidentiality and non-use provisions of this Section 11.1, and the receiving Party shall cooperate with any reasonable attempts of the disclosing Party to limit any such disclosure required by law, including without limitation by way of obtaining an order of confidentiality, to ensure the continued confidential treatment of such Information.

The confidential and non-use obligations of this Section 11.1 shall survive the termination or expiration of this Agreement.

**11.2 Employee, Consultant and Advisor Obligations.** Each Party agrees that it and its Affiliates shall provide or permit access to Information received from the other Party and such Party's Affiliates and representatives only to the receiving Party's employees, consultants, Permitted Sublicensees and subcontractors, and to the employees, consultants, Permitted Sublicensees and subcontractors of the receiving Party's Affiliates, who in such Party's reasonable judgment have a need to know such Information to assist the receiving Party with the activities contemplated by this Agreement and who are subject to

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obligations of confidentiality and non-use with respect to such Information no less restrictive than the obligations of confidentiality and non-use of the receiving Party pursuant to Section 11.1; provided that each Party shall remain responsible for any failure by its Affiliates, and its and its Affiliates' respective employees, consultants, permitted subcontractors and sublicensees, to treat such Information as required under Section 11.1 (as if such Affiliates, employees, consultants, permitted subcontractors and sublicensees were Parties directly bound to the requirements of Section 11.1).

**11.3 Publication.** Each of Janssen and Vertex reserves the right to publish or publicly present the results (the "Results") of the Development Program, subject to the following terms and conditions. The Party proposing to publish or publicly present the Results (the "Publishing Party") will submit a draft of any proposed manuscript, abstract or speech to the other Party (the "Non-Publishing Party") for comments [\*\*\*] prior to submission for publication or oral presentation. The Non-Publishing Party shall notify the Publishing Party in writing [\*\*\*] of receipt of such draft whether such draft contains (i) information of the Non-Publishing Party which it considers to be confidential under the provisions of Section 11.1 hereof, (ii) information that if published would have an adverse effect on a patent application covering the subject matter of this Agreement, or (iii) information that the Non-Publishing Party reasonably believes would be likely to have a material adverse impact on the Development, Manufacture or Commercialization of a Product Candidate or Product. In any such notification, the Non-Publishing Party shall indicate with specificity its suggestions regarding the manner and degree to which the Publishing Party may disclose such information. In the case of item (i) above, no Party may publish Information of the other Party without its consent in violation of Section 11.1 of this Agreement. In the case of item (ii) above, the Non-Publishing Party may request a delay and the Publishing Party shall delay such publication or presentation, for a period [\*\*\*], to permit the timely preparation and filing of a patent application or an application for a certificate of invention covering the information at issue. In the case of item (iii) above, if the Publishing Party shall disagree with the Non-Publishing Party's assessment of the impact of the publication or presentation, then the issue shall be referred by the Publishing Party to the JSC for resolution, or if there is no JSC at the time of referral, then to the Parties' respective Chief Executive Officers for discussion and resolution. The decision of the JSC or the Chief Executive Officers, if the referral is made to them, shall be final, provided that such decision shall always be subject to the confidentiality provisions of Section 11.1 hereof and shall be made with reasonable regard for the interests of the Non-Publishing Party and provided further that no decision shall be made to publish or present information if the publication or presentation would have a

material adverse effect on the commercial prospects of any Product Candidate or Product. The Parties agree that authorship of any publication or presentation will be determined based on the customary standards then being applied in the relevant scientific journal or conference. The Parties will require any agents conducting the Development Program on their behalf to comply with publication and presentation restrictions comparable to those set forth herein. The forgoing provisions shall not be interpreted to prevent the publication by a Party of information required by law to be published by that Party.

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This Section 11.3 shall terminate with the termination of this Agreement, but the provisions of Section 11.1 hereof shall continue to govern the disclosure by one Party, whether by publication or otherwise, of Information of the other.

**11.4 Publicity/Use of Names.** Prior to the Effective Date, the Parties shall agree upon the timing and content of an initial press release relating to the execution of this Agreement and its terms. Except to the extent already disclosed in that initial press release, no disclosure of the existence of this Agreement or its terms may be made by either Party, and no Party shall use the name, trademark, trade name or logo of the other Party or its employees in any publicity, news release or promotional materials relating to this Agreement or its subject matter, without the prior express written permission of the other Party, except as permitted by this Agreement or as may be required by applicable laws, regulations, or judicial order. The Party desiring to make any such public announcement shall provide the other Party with a written copy of the proposed announcement sufficiently in advance of the public release to allow such other Party to comment upon such announcement, prior to its release.

In addition to the foregoing restrictions on public disclosure, if either Party concludes that a copy of this Agreement must be filed with a securities exchange or regulatory or governmental body to which that Party is subject, wherever situated, such Party shall provide the other Party with a copy of this Agreement showing any sections as to which the filing Party proposes to request confidential treatment, will provide the other Party with an opportunity and a reasonable time period to comment on any such proposal and to suggest additional portions of the Agreement for confidential treatment and will take such Party's comments into consideration before filing the Agreement. If the filing Party disagrees with the other Party's additional confidential treatment request, the Parties shall attempt in good faith to discuss the matter before the Agreement is filed.

## **Article 12 -Representations and Warranties; Indemnification**

**12.1 Representations and Warranties of Vertex.** Vertex, for itself and its Affiliates, represents and warrants to Janssen that, as of the Effective Date:

**12.1.1 Authorization.** This Agreement has been duly executed and delivered by Vertex and constitutes the valid and binding obligation of Vertex, enforceable against Vertex in accordance with its terms except as enforceability may be limited by bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium and other laws relating to or affecting creditors' rights generally and by general equitable principles. The execution, delivery and performance of this Agreement have been duly authorized by all necessary action on the part of Vertex, its officers and directors.

**12.1.2 Intellectual Property.** The Vertex Patent Rights are existing and, to Vertex's knowledge, the patents in Vertex Patent Rights are not invalid or unenforceable. Vertex has disclosed to Janssen all patent applications and issued patents comprising the Vertex Patent Rights, and all prosecution history relating thereto, which patent applications and issued patents are listed in Schedule 1.116. Except for [\*\*\*], Vertex has full right and

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interest in all Vertex Know-How and Vertex Patent Rights. Vertex has not granted any right, title or interest in or to any Vertex Know-How or Vertex Patent Rights that are inconsistent with the rights, licenses and interests granted under the terms of this Agreement.

**12.1.3 Encumbrances.** To Vertex's knowledge, Vertex Patent Rights are free of any liens, charges and encumbrances.

**12.1.4 Mitsubishi.** Vertex has the right to sublicense to Janssen hereunder any rights to know-how or patents that it obtains from Mitsubishi Pharma Corporation under its existing agreement with Mitsubishi in connection with Products incorporating VX-950.

**12.1.5 Government Funding.** Vertex is not a party to any agreement with the U.S. Federal government or an agency thereof pursuant to which the U.S. federal government or such agency provided funding for the development of the Compound or Product.

**12.1.6 No Third Party Patents.** To Vertex's knowledge, no Third Party right or patent would necessarily be infringed by the Development, Manufacture, use or Commercialization of VX-950 pursuant to this Agreement, and Vertex is not aware of any pending patent application that, if issued, would necessarily be infringed by the Development, Manufacture, use or Commercialization of VX-950 pursuant to this Agreement.

**12.1.7 No Interference.** The Vertex Patent Rights are not the subject of any interference proceeding known to Vertex, and Vertex is not aware of any pending or threatened action, suit, proceeding or claim by a Third Party challenging Vertex's ownership rights in, or the validity or scope of, the Vertex Patent Rights.

**12.1.8 [\*\*\*]**

**12.1.9 VX-950 Patents.** Schedule 1.116 contains a complete list of all patents and patent applications Controlled by Vertex, as of the Effective Date, that [\*\*\*]

**12.1.10 No Debarment.** Neither Vertex nor any of its Affiliates has been debarred or is subject to debarment. During the term of the Development Program and any Supply Agreement adopted hereunder, Vertex and its Affiliates will use commercially reasonable efforts to avoid using in any capacity, in connection with the Development, Manufacture or Commercialization of the Product Candidate or Product, any Person who to Vertex's

knowledge has been debarred pursuant to Section 306 (or comparable law or regulation) of the United States Federal Food, Drug, and Cosmetic Act, or who to Vertex's knowledge is the subject of a conviction described in such section. Vertex agrees to inform Janssen in writing immediately if it or any Person who is performing services hereunder is debarred or is the subject of a conviction described in Section 306 (or comparable law or regulation), or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the best of Vertex's knowledge, is threatened, relating to the debarment or conviction of Vertex or any Person used in any capacity by Vertex or any of its Affiliates in connection with the Development, Manufacture or Commercialization of any Product.

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**12.1.11 [\*\*\*]**

**12.2 Representations and Warranties of Janssen.** Janssen, for itself and its Affiliates, represents and warrants to Vertex that, as of the Effective Date:

**12.2.1 Authorization.** This Agreement has been duly executed and delivered by Janssen and constitutes the valid and binding obligation of Janssen, enforceable against Janssen in accordance with its terms, except as enforceability may be limited by bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium and other laws relating to creditors' rights generally and by general equitable principles. The execution, delivery and performance of this Agreement have been duly authorized by all necessary action on the part of Janssen, its officers and directors.

**12.2.2 No Debarment.** Neither Janssen nor any of its Affiliates has been debarred or is subject to debarment. During the term of the Development Program and any Supply Agreement adopted hereunder, Janssen and its Affiliates will use commercially reasonable efforts to avoid using in any capacity, in connection with the Development, Manufacture or Commercialization of the Product Candidate or Product, any Person who to Janssen's knowledge has been debarred pursuant to Section 306 (or comparable law or regulation) of the United States Federal Food, Drug, and Cosmetic Act, or who to Janssen's knowledge is the subject of a conviction described in such section. Janssen agrees to inform Vertex in writing immediately if it or any Person who is performing services hereunder is debarred or is the subject of a conviction described in Section 306 (or comparable law or regulation), or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the best of Janssen's knowledge, is threatened, relating to the debarment or conviction of Janssen or any Person used in any capacity by Janssen or any of its Affiliates in connection with the Development, Manufacture or Commercialization of any Product.

**12.2.3 [\*\*\*]**

**12.3 Indemnification.**

**12.3.1 Indemnification by Vertex.** Except to the extent due to the negligence or willful misconduct of Janssen or its Affiliates, and subject to Section 12.3.5, Vertex shall indemnify, defend and hold Janssen and its Affiliates, and their respective directors, officers, employees and agents, harmless from and against any claims of damages (except to the extent arising from any claims of intellectual property infringement), bodily injury, death, or property damage made by a Third Party (a "Third Party Claim") to the extent arising from: (i) the negligence or willful misconduct of Vertex under this Agreement or the Supply Agreement; (ii) the material breach by Vertex of any material warranty, representation or obligation of Vertex under this Agreement; or (iii) any product liability claims related to the Product and arising from Commercialization in North America and the Far East.

**12.3.2 Indemnification by Janssen.** Except to the extent due to the negligence or willful misconduct of Vertex or its Affiliates, and subject to Section 12.3.5, Janssen shall

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indemnify, defend and hold Vertex and its Affiliates, and their respective directors, officers, employees and agents, harmless from and against any Third Party Claim resulting from (i) the negligence or willful misconduct of Janssen or its Affiliates under this Agreement, the Supply Agreement or any other supply agreement under which Janssen supplies Product Candidates or Products to Vertex; (ii) the material breach by Janssen of any material warranty, representation or obligation of Janssen under this Agreement; or (iii) any product liability claims related to the Product and arising from Commercialization in the Territory.

**12.3.3 Claims for Indemnification.** If a Party (the "Indemnitee") intends to claim indemnification under this Section, it shall promptly notify the other Party (the "Indemnitor") in writing of any Third Party Claim for which the Indemnitee intends to claim such indemnification. The failure of the Indemnitee to deliver written notice to the Indemnitor within a reasonable time after the commencement of any such action shall relieve the Indemnitor of any obligation to the Indemnitee under this Section with respect to any such action, to the extent that the failure prejudices the Indemnitor's ability to defend a Third Party Claim. The Indemnitee shall permit the Indemnitor to control the litigation and/or settlement of such Third Party Claim, and cooperate fully with Indemnitor in all matters related thereto, provided that unless agreed by Indemnitee (i) counsel appointed by Indemnitor to defend Indemnitee shall not take any position which, if sustained, would cause Indemnitee not to be indemnified by Indemnitor and (ii) no settlement will involve any terms binding on Indemnitee except payment of money to be paid by Indemnitor.

**12.3.4 Direct Damage Claims Only.** Neither Party shall be liable to the other for indirect, consequential, special or punitive damages under this Agreement.

**12.3.5 Claims Arising in Connection with Development.** Except to the extent due to the negligence or willful misconduct of a Party,

(a) [\*\*\*]

(b) Janssen will indemnify Vertex from and against any Third Party Claims arising out of any Additional Development Activities conducted by or at the direction of Janssen or its Affiliates, and

(c) Vertex will indemnify Janssen from and against any Third Party Claims arising out of any Additional Development Activities conducted by or at the direction of Vertex.

### Article 13 -Term and Termination

**13.1 Term and Expiration.** This Agreement shall be effective as of the Effective Date and unless terminated earlier pursuant to Sections 13.2, 13.3, 13.6 or 13.7, this Agreement shall continue in effect until expiration of all royalty obligations under Article 9.

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**13.2 Termination by Janssen Without Cause.** Notwithstanding anything contained herein to the contrary, Janssen shall have the right to terminate this Agreement at any time in its sole discretion by giving six months' advance written notice to Vertex; provided, however, if a Product has received a Marketing Authorization in any Major Market Country, the notice required shall be [\*\*\*] unless such termination is for a reason other than a Valid Safety Issue, in which case termination may be with immediate effect. For the purposes of this Agreement, a "Valid Safety Issue" [\*\*\*]

Following any delivery by Janssen of notice of termination pursuant to this Section 13.2, Janssen and Vertex will cooperate in good faith to agree and implement a transition plan, in order to give effect to Section 13.5. Until the earlier of (i) transfer of any central marketing authorization from Janssen to Vertex or its designee or the effective date of any such termination, Janssen will use all reasonable efforts to agree and implement a transition plan and will continue to use Diligent Efforts to Develop, Manufacture and Commercialize Product Candidates and Products in the Territory in accordance with the plans then in effect and approved by the JDC and/or JCC, and will otherwise conduct itself with the objective of avoiding a negative impact, either by its actions or inaction, on the value of a Product Candidate or Product.

**13.3 Termination for Cause.** This Agreement may be terminated at any time during the term of this Agreement:

**13.3.1** upon written notice by either Party if the other Party is in breach of its material obligations hereunder and has not cured such breach after notice from the terminating Party requesting cure of the breach; provided, however, in the event of a good faith dispute with respect to the existence of a material breach, the cure period shall be tolled until such time as the dispute is resolved pursuant to Section 14.5; and provided that the terminating Party has given the defaulting Party the following opportunities to remedy any breach:

- (i) the written notice of breach referenced above shall detail the specific obligation under this Agreement which is alleged to have been breached; the manner of such alleged breach; and the steps which must be taken in order to remedy such breach; and
- (ii) the terminating Party has provided the defaulting Party with a reasonable amount of time (but no more than [\*\*\*]) in which to complete any steps which might be taken to remedy the breach, as stated in the notification of breach;

**13.3.2** by either Party upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors, by the other Party; provided, however, in the case of any involuntary bankruptcy proceeding such right to terminate shall only become effective if the Party consents to the involuntary bankruptcy or such proceeding is not dismissed within [\*\*\*] after the filing thereof.

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**13.4 Effect on License of Termination by Janssen for Cause.**

**13.4.1** If Janssen terminates this Agreement under Section 13.3.1, then (i) Janssen's licenses pursuant to Article 7 shall become perpetual, exclusive licenses subject to the financial provisions of Article 9; and (ii) Janssen shall have the right to offset against any monies owed to Vertex (pursuant to Article 9 of this Agreement) all of its direct costs, losses and expenses incurred as a result of Vertex's breach, [\*\*\*] Notwithstanding the foregoing, no offsets may be taken by Janssen in any Calendar Year that would reduce the aggregate royalties payable to Vertex on account of Net Sales in that Calendar Year [\*\*\*]

**13.4.2** If Janssen terminates this Agreement pursuant to subsection 13.3.2, all licenses and rights to licenses granted under or pursuant to this Agreement by Vertex to Janssen are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the United States Bankruptcy Code (the "Code"), licenses of rights to "intellectual property" as defined under Section 101(35A) of the Code. The Parties agree that Janssen, as a licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Code, and that upon commencement of a bankruptcy proceeding by Vertex under the Code, or against Vertex if such proceeding is not dismissed within [\*\*\*] of its initial filing, Janssen shall be entitled to complete access to any such intellectual property and all embodiments of such intellectual property in the Territory.

**13.5 Effect of Termination by Vertex For Cause or by Janssen Without Cause.**

If Vertex terminates this Agreement under Section 13.3 or Janssen terminates this Agreement under Section 13.2:

**13.5.1** The license granted to Janssen and its Affiliates under Article 7, and any sublicense granted by Janssen with respect to any [\*\*\*] under Section 7.7, shall terminate as of the effective date of termination, except to the extent necessary to enable Janssen to perform its obligations under this section 13.5, and Janssen shall, within [\*\*\*] after such termination, return or cause to be returned to Vertex at Vertex's request all Vertex

Information in tangible form, and all substances or compositions delivered or provided by Vertex, as well as any other material provided by Vertex in any medium, except that Janssen may retain one copy in its confidential files for records purposes.

**13.5.2** The license granted to Vertex by Janssen under Section 7.4 hereof shall continue in effect notwithstanding termination of this Agreement and shall be extended in geographic scope to cover the right to Develop, Manufacture and Commercialize Product Candidates and Products in the Territory. During the period commencing with notice of termination and ending [\*\*\*] following the effective date of termination, Janssen will provide Vertex and its sublicensees, at Janssen's expense and in accordance with procedures to be agreed by the Parties, with reasonable access to information and know-how necessary for Vertex to apply the licensed technology.

**13.5.3** If Vertex terminates this Agreement pursuant to subsection 13.3.2, all licenses and rights to licenses granted under or pursuant to this Agreement by Janssen to Vertex are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the United States Bankruptcy Code (the "Code"), licenses of rights to "intellectual property" as

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defined under Section 101(35A) of the Code. The Parties agree that Vertex, as a licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Code, and that upon commencement of a bankruptcy proceeding by Janssen under the Code, or against Janssen if such proceeding is not dismissed within [\*\*\*] of its initial filing, Vertex shall be entitled to complete access to any such intellectual property and all embodiments of such intellectual property in the Territory.

**13.5.4** Upon termination by Janssen under Section 13.2, (a) all filings and approvals with Regulatory Authorities and Regulatory Approvals concerning Product Candidates or Products and Marketing Authorizations relating to any Product will be assigned or otherwise transferred to or at the direction of Vertex as soon as practicable and at Janssen's expense, and any reports required to be made to any Regulatory Authority covering any periods prior to the effective date of termination of the Agreement will be prepared promptly and filed at Vertex's direction with the appropriate Regulatory Authority or, at Vertex's discretion, made available to or at the direction of Vertex for filing by Vertex. Janssen will also promptly deliver to or at the direction of Vertex (i) all governmental and regulatory correspondence and conversation logs relating to the Development, Manufacture or Commercialization of Product Candidates and Products in the Territory, (ii) copies of all data, reports, records and materials in Janssen's possession or Control relating to the Development, Manufacture or Commercialization of Product Candidates and Products in the Territory, including all non-clinical and clinical data relating to Product Candidates and Products, and (iii) all records and materials in Janssen's possession or Control containing Confidential Information of Vertex.

(b) Janssen will appoint Vertex as Janssen's and/or its Affiliates' agent for all Product-related matters involving Regulatory Authorities in the Territory.

(c) if Vertex so requests, Janssen and its Affiliates will assign to Vertex any agreements with Third Parties relating solely to the Development, Manufacture or Commercialization of the Product to which Janssen is a party to the extent permitted by the applicable law and the terms of such agreements, and Janssen will use best efforts not to enter into any agreement that restricts its ability to comply with this provision.

(d) Janssen will, upon request by Vertex, appoint Vertex or its designee as its exclusive distributor of the Product in the Territory, and grant Vertex or its designee the right to appoint sub-distributors.

(e) Janssen will, at its cost, return to Vertex or its designee all inventory of Intermediates and Product in its possession as of the date of termination and, at Vertex's election, make payment to Vertex for any Intermediates and Product ordered by Janssen pursuant to the Supply Agreement but not yet paid for.

(f) Notwithstanding the provisions of Section 11.1, Vertex shall be able to disclose any such data and information as is necessary to exercise its rights with respect to a Compound, Product Candidate or Product.

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(g) Notwithstanding termination of this Agreement, this Section 13.5.4 shall remain in effect until the completion by Janssen of all actions which are required by it to enable a full transfer to Vertex of all filings for Regulatory Approvals and all Marketing Authorizations relating to any Product.

**13.5.5** If Janssen or any of its Affiliates at the time of termination is performing any Manufacturing activities with respect to a Product Candidate or Product, then at Vertex's request Janssen or its Affiliates, as applicable, shall continue to perform those Manufacturing activities with respect to a Product on the same terms in accordance with forecasts under the most recent and mutually agreed forecast for commercial supply, as applicable, until [\*\*\*] During that period Janssen shall use [\*\*\*] at Janssen cost to cooperate with Vertex in the transition of manufacturing capacity to other sources as early as practicable.

### **13.6 [\*\*\*]**

This section 13.6 is not a termination provision under section 13.7 of this Agreement.

**13.6.1 [\*\*\*]**

**13.6.2 [\*\*\*]**

### **13.7 Survival.**

Any expiration or termination of this Agreement shall be without prejudice to the rights of either Party against the other accrued or accruing under this Agreement prior to expiration or termination, including without limitation the obligation to pay royalties for Product(s) sold prior to such expiration or termination or make other payments under this Agreement. In addition to any other provisions which by their terms specifically survive expiration or termination of this Agreement, the following provisions shall indefinitely survive any expiration or termination of this Agreement: Section 7.4, provided that any and all licenses granted under Section 7.4 shall be non-exclusive, Sections 9.6, 9.7, 9.9, and 9.11, Article 11, Section 12.3, Article 13, sections 14.1, 14.2, 14.3, and 14.5, sections 15.1, 15.3, 15.4, 15.5, 15.6, 15.7, 15.8, 15.9, 15.10, 15.11, 15.12, 15.13, 15.14, and 15.15, and the definitions of terms from Article 1 that are part of the recitation of any of the sections listed in this section 13.7.

**13.8 Non-exclusive Remedies.** The remedies provided to either Party in this Article 13 shall not be deemed the exclusive remedies available to that Party, and in particular shall not limit any legal or equitable remedies otherwise available to that Party.

#### Article 14 -Governing Law and Dispute Resolution

**14.1 Governing Law.** This Agreement shall be governed by and construed in accordance with the laws of The Commonwealth of Massachusetts without reference to any rules of conflict of laws. The United Nations Convention on the Sale of Goods shall not apply.

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**14.2 Referral to Executive Officers.** If for any reason the JSC cannot resolve any matter properly referred to it for resolution, either Party may refer the matter to the Executive Officers for resolution. If, after discussing the matter in good faith and attempting to find a mutually satisfactory resolution to the issue, the Executive Officers fail to come to consensus within [\*\*\*] after the date on which the matter is referred to the Executive Officers (unless a longer period is agreed to in writing by the Parties) the provisions of Section 14.3 shall apply and resolutions reached through such provisions shall be binding on the Parties; provided that [\*\*\*]

**14.3 Final Decision-Making Authority.** If the Executive Officers fail to come to consensus on any matter properly referred to the Executive Officers within the period for resolution set forth in Section 14.2 (an “Unresolved Matter”) then the following provisions shall apply:

**14.3.1** Subject to the provisions of subsections 14.3.2 through 14.3.3, Vertex shall have final decision-making authority over all Unresolved Matters;

**14.3.2** Janssen shall have final decision-making authority with respect to the following:

**14.3.2.1** [\*\*\*]

**14.3.2.2** [\*\*\*]

**14.3.2.3** [\*\*\*]

**14.3.2.4** [\*\*\*]

**14.3.3** Notwithstanding the foregoing provisions of this Section 14.3, neither Party shall have final decision-making authority pursuant to this Section 14.3 with respect to matters over which one or the other of the Parties is expressly allocated decision-making authority elsewhere in this Agreement.

**14.4 Decision to Terminate or Suspend a Study Based on Safety Concerns.** The Party sponsoring or controlling any clinical study of a Product Candidate may terminate or suspend such clinical study if (a) a Regulatory Authority or safety data review board for such clinical study has required such termination or suspension, or (b) if such Party believes in good faith that such termination or suspension is warranted because of safety or tolerability risks to the study subjects. In either case, such Party shall promptly notify the other Party of such termination or suspension, and shall use all reasonable efforts to notify and consult with the other Party prior to taking such action.

**14.5 Dispute Resolution.**

**14.5.1** The Parties shall negotiate in good faith and use reasonable efforts to settle any dispute, controversy or claim arising from or related to this Agreement or the breach thereof. If the Parties are unable to resolve a dispute other than a dispute properly referred to the Executive Officers under Sections 14.2 and 14.3 above, despite using reasonable efforts to do so, either Party may, by written notice to the other, pursue any matter through binding arbitration in accordance with the Rules for Non-Administered

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Arbitration then pertaining of the International Institute for Conflict Prevention and Resolution (available at <http://www.cpradr.org/arb-intro.asp?M=9.3>) or its successor (“CPR”), except where those rules conflict with these provisions, in which case these provisions control. This dispute resolution provision will be binding on any corporate parent, subsidiary, affiliate under common control, director or officer of the Parties hereto. All proceedings will be conducted in the English language.

**14.5.2** The arbitration will be held in Boston, MA.

**14.5.3** The panel shall consist of [\*\*\*] arbitrators chosen from the CPR Panels of Distinguished Neutrals (or, by agreement, from another provider of arbitrators) each of whom is either a lawyer [\*\*\*] In the event the aggregate damages sought by the claimant are stated to be less than [\*\*\*], and the aggregate damages sought by the counterclaimant are stated to be less than [\*\*\*] then a [\*\*\*] shall be chosen, having the same qualifications and experience specified above. Each arbitrator shall be impartial and independent of the Parties and shall abide by the Code of Ethics for Arbitrators in Commercial Disputes then pertaining (available at <http://www.adr.org/EthicsAndStandards>).

**14.5.4** The Parties agree to cooperate (1) to attempt to select the arbitrator(s) by agreement within [\*\*\*] of initiation of the arbitration, including jointly interviewing the final candidates, (2) to meet with the arbitrator(s) within [\*\*\*] of selection and (3) to agree at that meeting or before upon procedures for discovery and as to the conduct of the hearing which will result in the hearing being concluded within no more than [\*\*\*] after selection of the arbitrator(s) and in the award being rendered within [\*\*\*] of the conclusion of the hearings, or of any post-hearing briefing, which briefing will be completed by both sides within [\*\*\*] after the conclusion of the hearings.

**14.5.5** In the event the Parties cannot agree upon selection of the arbitrator(s), the CPR will select arbitrator(s) as follows: CPR shall provide the Parties with a list of no less than [\*\*\*] proposed arbitrators ([\*\*\*] if a single arbitrator is to be selected) having the credentials referenced above. Within [\*\*\*] of receiving such list, the Parties shall rank at least [\*\*\*] of the proposed arbitrators on the initial CPR list, after exercising cause challenges. The Parties may then interview the [\*\*\*] candidates ([\*\*\*] if a [\*\*\*] arbitrator is to be selected) with the highest combined rankings for no more than [\*\*\*] each and, following the interviews, may exercise [\*\*\*] each. The panel will consist of the remaining [\*\*\*] candidates (or [\*\*\*], if [\*\*\*] is to be selected) with the highest combined rankings. In the event these procedures fail to result in selection of the required number of arbitrators, CPR shall select the appropriate number of arbitrators from among the members of the various CPR Panels of Distinguished Neutrals, allowing each side [\*\*\*] each.

**14.5.6** In the event the Parties cannot agree upon procedures for discovery and hearing, then the arbitrator(s) shall set dates for a hearing, any post-hearing briefing, and the issuance of the award. The arbitrator(s) shall provide for discovery, giving recognition to the understanding of the Parties that they contemplate reasonable discovery, including

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document demands and depositions. Multiple hearing days will be scheduled consecutively to the greatest extent possible.

**14.5.7** The arbitrator(s) are expressly empowered to decide dispositive motions, including but not limited to pre-hearing motions to dismiss and summary judgment motions, and shall endeavor to decide such motions as would a U.S. District Judge of the District where the hearings are to be held.

**14.5.8** The arbitrator(s) must render their award by application of the substantive law of the Commonwealth of Massachusetts and are not free to apply “amiable compositeur” or “natural justice and equity.” The arbitrator(s) shall render a written opinion setting forth findings of fact and conclusions of law with the reasons therefor stated. A transcript of the evidence adduced at the hearing shall be made and shall, upon request, be made available to either Party. The arbitrator(s) shall have power to exclude evidence on grounds of hearsay, prejudice beyond its probative value, redundancy, or irrelevance and no award shall be overturned by reason of such ruling on evidence. To the extent possible, the arbitration hearings and award will be maintained confidential.

**14.5.9** In the event the panel’s award exceeds [\*\*\*] in monetary damages or includes or consists of equitable relief, or rejects a claim in excess of that amount or for that relief, then the losing Party may obtain review of the arbitrators’ award or decision pursuant to the CPR Arbitration Appeal Procedure then pertaining by a single appellate arbitrator (the “Appeal Arbitrator”) selected from the CPR Panels of Distinguished Neutrals by agreement or, failing agreement within [\*\*\*] working days, pursuant to the selection procedures specified in Section 14.5.5. If CPR cannot provide such services, the Parties will together select another provider of arbitration services that can do so. No Appeal Arbitrator shall be selected unless he or she can commit to rendering a decision within [\*\*\*] following oral argument; any such review must be initiated within [\*\*\*] following the rendering of the award referenced in Section 14.5.8.

**14.5.10** The Appeal Arbitrator will make the same review of the arbitration panel’s ruling and its bases that the U.S. Court of Appeals of the Circuit where the arbitration hearings are held would make of findings of fact and conclusions of law rendered by a district court after a bench trial and then reverse, modify, vacate or affirm the arbitration panel’s award or decision accordingly, or remand to the panel for further proceedings. The Appeal Arbitrator will consider only the arbitration panel’s findings of fact and conclusions of law, pertinent portions of the hearing transcript and evidentiary record as submitted by the Parties, opening and reply briefs of the Party pursuing the review, and the answering brief of the opposing Party, plus a total of no more than [\*\*\*] or oral argument evenly divided between the Parties. The Party seeking review must submit its opening brief and any reply brief within [\*\*\*] respectively, following the date of the

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award under review, whereas the opposing Party must submit its responsive brief within [\*\*\*] of that date. Oral argument shall take place within [\*\*\*] after the date of the award under review, and the Appeal Arbitrator shall render a decision within [\*\*\*] following oral argument. That decision will be final and not subject to further review, except pursuant to the Federal Arbitration Act.

**14.5.11** The Parties irrevocably consent to and submit their person to the jurisdiction of the U. S. District Court for the District in which the arbitration is held for the enforcement of these provisions and the entry of judgment on any award rendered hereunder (including after review by the Appeal Arbitrator where such an appeal is pursued). Should such court for any reason lack jurisdiction, any court with jurisdiction shall act in the same fashion.





or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice shall be deemed to have been given: (a) when delivered if personally delivered or sent by facsimile on a business day; (b) on the next business day after dispatch if sent by internationally-recognized overnight courier; and/or (c) on the fifth (5<sup>th</sup>) business day following the date of mailing if sent by other internationally-recognized courier or by mail. Notices hereunder will not be deemed sufficient if provided only between or among each Party's representatives on any committee established in accordance with this Agreement.

- 15.5 Entire Agreement; Amendments.** This Agreement, together with the Exhibits and Schedules hereto, contains the entire understanding of the Parties with respect to the subject matter hereof and supercedes and cancels all previous express or implied agreements and understandings, negotiations, writings and commitments, either oral or written, in respect to the subject matter hereof. The Schedules to this Agreement are incorporated herein by reference and shall be deemed a part of this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representatives of both Parties.
- 15.6 Headings.** The captions to the several articles, sections and subsections hereof are not a part of this Agreement, and shall not be interpreted as having any substantive meaning, but are merely for convenience to assist in locating and reading the several Articles and Sections hereof.
- 15.7 Independent Contractors.** It is expressly agreed that Vertex and Janssen shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither Vertex nor Janssen shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party. Neither Party shall have any responsibility for the hiring, firing or compensation of the other Party's employees or for any employee benefits. No employee or representative of a Party shall have any authority to bind or obligate the other Party to

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this Agreement for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said Party's written approval.

- 15.8 Waiver.** The waiver by either Party hereto of any right hereunder, or the failure of the other Party to perform, or a breach by the other Party, shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise.
- 15.9 Cumulative Remedies.** No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.
- 15.10 Waiver of Rule of Construction.** Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.
- 15.11 Certain Conventions.** Any reference in this Agreement to an Article, Section, subsection, paragraph, clause, Schedule or Exhibit shall be deemed to be a reference to an Article, Section, subsection, paragraph, clause, Schedule or Exhibit, of or to, as the case may be, this Agreement, unless otherwise indicated. Unless the context of this Agreement otherwise requires, (a) words of any gender include each other gender, (b) words such as "herein", "hereof", and "hereunder" refer to this Agreement as a whole and not merely to the particular provision in which such words appear, and (c) words using the singular shall include the plural, and vice versa.
- 15.12 Counterparts.** This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.
- 15.13 Performance by Affiliates.** To the extent that this Agreement imposes obligations on Affiliates of a Party, such Party agrees to cause its Affiliates to perform such obligations. Either Party may use one or more of its Affiliates to perform its obligations and duties hereunder, provided that the Parties shall remain liable hereunder for the prompt payment and performance of all their respective obligations hereunder. Each of Vertex and Janssen guarantees performance of this Agreement by any of its Affiliates. Any Affiliate of Vertex or Janssen to which rights are extended or which performs any of the obligations required of the respective Party hereunder shall be deemed to have accepted and be bound by the relevant terms and conditions of this Agreement including, without limitation, the jurisdiction and binding effect of the arbitration proceeding carried out pursuant to Section 14.5.
- 15.14 Standstill.** Janssen agrees that during the period beginning on the Effective Date and ending on [\*\*\*] neither Janssen nor any of its Affiliates will, without the prior written consent of Vertex (i) acquire, or participate as part of a group which in the aggregate acquires, securities representing [\*\*\*] of the voting power of the outstanding voting securities of Vertex, or (ii) make, or in any way participate in, directly or indirectly, any

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"solicitation" of "proxies" (as such terms are used in the rules of the United States Securities and Exchange Commission). The foregoing provisions of this Section 15.14 shall no longer apply (i) if Vertex announces publicly that (a) it is seeking, or considering seeking, purchasers for Vertex or (b) it is otherwise exploring, or considering exploring, strategic options in this regard; (ii) upon the commencement by a Third Party of a tender or exchange offer for shares of Vertex voting stock which, when added to shares then owned by the Third Party, would result in ownership by the Third Party of [\*\*\*] of the voting power of the outstanding voting securities of Vertex; (iii) if a Third Party acquires or seeks to acquire beneficial ownership of [\*\*\*] of the outstanding common stock of Vertex; (iv) if Vertex publicly announces a transaction, or an intention to effect any transaction which would result in (a) the sale by Vertex or one or more of its subsidiaries of assets representing [\*\*\*] of the consolidated earning power or assets of Vertex; (b) the common stockholders of Vertex (other than stockholders who are Affiliates of the acquiring entity) immediately prior to such transaction owning [\*\*\*] of the outstanding common stock of the acquiring entity or, in the case of a merger transaction, the surviving corporation (or, if the surviving

corporation is a subsidiary of a parent company, the parent company); or (c) a Third Party acquiring beneficial ownership of [\*\*\*] or more of the outstanding common stock of Vertex.

**15.15 Export Control.** This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States of America or other countries that may be applicable to Janssen or Vertex from time to time. Neither Party will export, directly or indirectly, any technical information acquired from the other Party under this Agreement, or any products using that technical information, to a location or in a manner that at the time of export requires an export license or other governmental approval, without first obtaining necessary and sufficient consents to do so from the appropriate agency or other governmental authority.

**IN WITNESS WHEREOF**, the Parties have executed this Agreement as of the date first set forth above.

<p><b>JANSSEN PHARMACEUTICA, N.V.</b></p> <p>By: <u>/s/Dirk Collier</u>  Name: Dirk Collier  Title: Board Member</p>	<p><b>VERTEX PHARMACEUTICALS INCORPORATED</b></p> <p>By: <u>/s/Kenneth S. Boger</u>  Name: Kenneth S. Boger  Title: Senior Vice President and General Counsel</p>
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Date: 30/6/06 Date: June 30, 2006

By: /s/Didier de Chaffoy de Courcelles  
Name: Didier de Chaffoy de Courcelles  
Title: Senior Vice President, Research and Early Development Europe

Date: 30/6/06

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**Schedule 1.7**

**Janssen 2006 Universal Calendar**

	<b>M</b>	<b>T</b>	<b>W</b>	<b>T</b>	<b>F</b>	<b>S</b>	<b>S</b>
<b>JAN</b>							
(4 Weeks)	2	3	4	5	6	7	8
	9	10	11	12	13	14	15
	16	17	18	19	20	21	22
	23	24	25	26	27	28	29
	30	31					
<b>FEB</b>			1	2	3	4	5
(4 Weeks)	6	7	8	9	10	11	12
	13	14	15	16	17	18	19
	20	21	22	23	24	25	26
	27	28					
<b>MAR</b>			1	2	3	4	5
(5 Weeks)	6	7	8	9	10	11	12
	13	14	15	16	17	18	19
	20	21	22	23	24	25	26
	27	28	29	30	31		
<b>APR</b>						1	2
(4 Weeks)	3	4	5	6	7	8	9
	10	11	12	13	14	15	16
	17	18	19	20	21	22	23
	24	25	26	27	28	29	30
<b>MAY</b>	1	2	3	4	5	6	7
(4 Weeks)	8	9	10	11	12	13	14
	15	16	17	18	19	20	21
	22	23	24	25	26	27	28
	29	30	31				
<b>JUN</b>				1	2	3	4
(5 Weeks)	5	6	7	8	9	10	11
	12	13	14	15	16	17	18
	19	20	21	22	23	24	25
	26	27	28	29	30		

JUL						1	2
(4 Weeks)	3	4	5	6	7	8	9
	10	11	12	13	14	15	16
	17	18	19	20	21	22	23
	24	25	26	27	28	29	30
	31						
AUG		1	2	3	4	5	6
(4 Weeks)	7	8	9	10	11	12	13
	14	15	16	17	18	19	20
	21	22	23	24	25	26	27
	28	29	30	31			
SEP					1	2	3
(5 Weeks)	4	5	6	7	8	9	10
	11	12	13	14	15	16	17
	18	19	20	21	22	23	24
	25	26	27	28	29	30	
OCT							1
(4 Weeks)	2	3	4	5	6	7	8
	9	10	11	12	13	14	15
	16	17	18	19	20	21	22
	23	24	25	26	27	28	29
	30	31					
NOV			1	2	3	4	5
(4 Weeks)	6	7	8	9	10	11	12
	13	14	15	16	17	18	19
	20	21	22	23	24	25	26
	27	28	29	30			
DEC					1	2	3
(5 Weeks)	4	5	6	7	8	9	10
	11	12	13	14	15	16	17
	18	19	20	21	22	23	24
	25	26	27	28	29	30	31

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**Schedule 1.19**

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Information redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.

**Schedule 1.31  
Existing Third Party Agreements**

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Information redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.

**Schedule 1.32  
Far East**

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Information redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.

**Schedule 1.55  
Janssen Patent Rights**

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Information redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.

**Schedule 1.116**  
**Vertex Patent Rights**

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Docket No.	Serial No.	Patent No.	Publication No.	Status	Filed
[**]	[**]			[**]	[**]
[**]	[**]			[**]	[**]
VPI/00-131 BR	0113666-6			PUBLISHED	08/31/2001
[**]	[**]			[**]	[**]
[**]	[**]			[**]	[**]
VPI/00-131 CN	01815055			PUBLISHED	08/31/2001
VPI/00-131 CO	03016961			PUBLISHED	08/31/2001
[**]	[**]			[**]	[**]
[**]	[**]			[**]	[**]
VPI/00-131 EA	200300318			PUBLISHED	08/31/2001
[**]	[**]			[**]	[**]
[**]	[**]			[**]	[**]
VPI/00-131 EP	01968040.4		1320540	PUBLISHED	08/31/2001
VPI/00-131 HK	03108422.8			PUBLISHED	01/20/2003
VPI/00-131 HR	20030139		02/2005	PUBLISHED	08/31/2001
[**]	[**]			[**]	[**]
[**]	[**]			[**]	[**]
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[**]	[**]			[**]	[**]

Information redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.

Docket No.	Serial No.	Patent No.	Publication No.	Status	Filed
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Information redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.

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Docket No.	Serial No.	Patent No.	Publication No.	Status	Filed
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Information redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.

Docket No.	Serial No.	Patent No.	Publication No.	Status	Filed
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***	***			***	***
VPI/04-139 US	11/264,746		US 2006/0105978	PUBLISHED	10/31/2005
VPI/04-139 WO	PCT/US2005/039240		WO 2006/050250	PUBLISHED	10/31/2005

Information redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.

Docket No.	Serial No.	Patent No.	Publication No.	Status	Filed
***	***			***	***
***	***			***	***
***	***			***	***
***	***			***	***
***	***			***	***
VPI/04-136 WO	PCT/US2005/035191		WO 2006/039488	PUBLISHED	09/30/2005
***	***			***	***
***	***			***	***
***	***			***	***
VPI/04-114 US	11/147,524		US 2006/0089385	PUBLISHED	06/08/2005
VPI/04-114 WO	PCT/US2005/019929		WO 2005/123076	PUBLISHED	06/08/2005
***	***			***	***
***	***			***	***
***	***			***	***

Information redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.

VPI/03-172 US	10/974,558		US 2005/0136400	PUBLISHED	10/27/2004
VPI/03-172 WO	PCT/US2004/035839		WO 2005/042570	PUBLISHED	10/27/2004

Information redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.

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Docket No.	Serial No.	Patent No.	Publication No.	Status	Filed
***	***			***	***
VPI/03-171 US	10/974,538		US 2006/0003942	PUBLISHED	10/27/2004
VPI/03-171 WO	PCT/US2004/035549		WO 2005/042020	PUBLISHED	10/27/2004

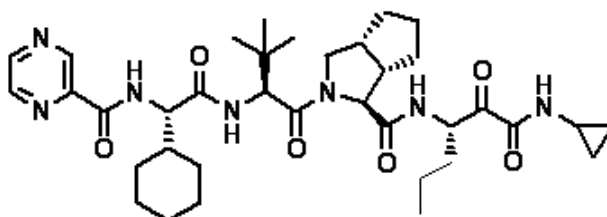
Docket No.	Serial No.	Patent No.	Publication No.	Status	Filed
VPI/03-149 TW	093127683		200518669	PUBLISHED	09/13/2004
***	***			***	***
***	***			***	***
***	***			***	***
***	***			***	***
VPI/03-149 US	10/939,958		US 2005/0120398	PUBLISHED	09/13/2004
VPI/03-149 WO	PCT/US2004/29961		WO 2005/025517	PUBLISHED	09/13/2004

Information redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.

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#### Schedule 1.117

#### VX-950



Information redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.

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Information redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.

#### Exhibit 4.5(a) Supply Agreement Key Elements

The Parties agree to negotiate the terms of a supply agreement in good faith, subject to the terms of this Agreement, which will include the following:

1. Vertex will supply Product that meets the Specifications (unless otherwise agreed by Vertex) to Janssen [\*\*\*] the Effective Date of the Agreement.
2. Janssen will forecast and place orders with Vertex for its Product requirements and its requirement of Intermediates for Commercialization in the Territory, commencing [\*\*\*] of the first requested delivery of Tablets. Based on the current Development Program, the first forecast to be provided under the Supply Agreement will be due [\*\*\*] Based on the forecast, Vertex will make commitments to Third Party Manufacturers for Territory supplies, in accordance with lead-time or contractual obligations with Third Party Manufacturers, that will be binding on Janssen.
3. Vertex will supply Janssen through its Third Party Manufacturers in accordance with the terms of the Third Party Manufacturer agreements.

4. Vertex will supply the Product to Janssen at [\*\*\*]. All [\*\*\*] directly related to supply of Product to the Territory will be borne by Janssen. Vertex will provide financial transparency for all [\*\*\*] associated with supply of Product for the Territory.

5. Delivery will be FCA facility (see INCOTERMS 2000).

6. Janssen will be responsible for shipping and handling charges arising in connection with Product delivered to Janssen, and for defining the method of shipment and for undertaking, at its expense, any validation that may be required.

7. Rights with respect to non-conforming product, shortage of supply and late delivery will be consistent with comparable rights that Vertex has with the relevant Third Party Manufacturers. [\*\*\*]

8. [\*\*\*]

9. Representations, warranties, insurance and indemnification will be no more extensive than those which Vertex has in the relevant Third Party Agreements.

10. Vertex's liability will be limited to its own negligence. [\*\*\*] In the event product delivered to Janssen is non-conforming, Janssen's remedy will be that Vertex will [\*\*\*] to seek remedies available pursuant to the relevant Third Party Manufacturing Agreements and pass those remedies on to Janssen.

11. The agreement will include provisions that address continuity of supply concerns for Janssen.

*Information redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

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12. The Parties will execute a Quality Agreement.

*Information redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

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## CERTIFICATION

I, Joshua S. Boger, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Vertex Pharmaceuticals Incorporated;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 9, 2006

/s/ JOSHUA S. BOGER

Joshua S. Boger

*President and Chief Executive Officer*

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## CERTIFICATION

I, Ian F. Smith, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Vertex Pharmaceuticals Incorporated;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 9, 2006

/s/ IAN F. SMITH

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Ian F. Smith

*Executive Vice President and Chief Financial Officer*

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**Certification**  
**Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**  
**(Subsections (a) and (b) of Section 1350,**  
**Chapter 63 of Title 18, United States Code)**

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code), each of the undersigned officers of Vertex Pharmaceuticals Incorporated, a Massachusetts corporation (the "Company"), does hereby certify, to such officer's knowledge, that the Quarterly Report on Form 10-Q for the quarter ended June 30, 2006 (the "Form 10-Q") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 9, 2006

/s/ JOSHUA S. BOGER

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Joshua S. Boger  
*President and Chief Executive Officer*  
*(principal executive officer)*

Dated: August 9, 2006

/s/ IAN F. SMITH

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

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