VERTEX PHARMACEUTICALS INC / MA Form 10-K/A September 08, 2004

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# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

**WASHINGTON, D.C. 20549** 

# **FORM 10-K/A**

(Amendment No. 1)

(Mark One)

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

For the Fiscal Year Ended December 31, 2003

or

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

For the transition period from to Commission file number 000-19319

# **Vertex Pharmaceuticals Incorporated**

(Exact name of registrant as specified in its charter)

Massachusetts

04-3039129

(State of incorporation)

(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)

Securities registered pursuant to Section 12(b) of the Exchange Act: None

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

Common Stock, \$0.01 Par Value Per Share

(Title of class)

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 [X] No [ ]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [X]

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act). Yes [X] No [ ]

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate) based on the last reported sale price of the Common Stock on The Nasdaq Stock Market on June 30, 2003, was \$826,746,640.

As of August 4, 2004, the registrant had 80,113,087 shares of common stock outstanding.

#### DOCUMENTS INCORPORATED BY REFERENCE

	Portions of the definitive Proxy Statement for the 2004 Annual Meeting of Stockholders held on Ma	ay 6, 2004 are incorporated by reference
into I	nto Part III.	

#### **Explanatory Note**

This Annual Report on Form 10-K/A (Amendment No. 1) (the "Amendment") amends Item 7 (Management's Discussion and Analysis of Financial Condition and Results of Operations) of our Annual Report on Form 10-K for the year ended December 31, 2003, which was filed with the Securities and Exchange Commission on March 15, 2004 (the "Original Filing"), to add certain disclosure relating to our research and development expenses and to add certain disclosure relating to the drug discovery process. No other aspects of the Original Filing have been amended or modified. Pursuant to the applicable rules of the Securities and Exchange Commission, Item 7, as amended, is set forth in this Amendment in its entirety. We have also included, as Exhibit 10.35 to this Amendment, a more complete copy of the First Revised and Restated Research and Early Development Agreement between Vertex and Novartis Pharma AG, dated February 3, 2004 (the "Novartis Agreement"). The Novartis Agreement was previously filed as Exhibit 10.35 to the Original Filing. The copy of the Novartis Agreement included as an exhibit to this Amendment includes certain text that we had not previously publicly disclosed. We have withdrawn our request to the Securities and Exchange Commission for confidential treatment of some, but not all, of the redacted text set forth in the copy of the Novartis Agreement filed as an Exhibit to the Original Filing. Item 15 has also been amended (and reproduced in its entirety) to reflect the Sarbanes-Oxley Act of 2002 Section 302 Certifications submitted with this Amendment as well as the partially unredacted copy of the Novartis Agreement.

This Amendment has no impact on any reported amount or disclosure, nor does it modify any guidance previously provided by us (including but not limited to disclosure and guidance set forth in our Quarterly Report on Form 10-Q for the period ended June 30, 2004, which was filed with the Securities and Exchange Commission on August 9, 2004).

This Amendment continues to speak as of the date of the Original Filing, and we have not updated the disclosures contained therein to reflect any events that occurred at a date subsequent to the filing of the Original Filing. Accordingly, this Amendment should be read in conjunction with the Original Filing and our subsequent filings with the Securities and Exchange Commission, including but not limited to our Quarterly Reports on Form 10-Q for the periods ended March 31, 2004 and June 30, 2004.

#### **Forward-Looking Statements**

Our disclosure in this Amendment contains some forward-looking statements. Forward-looking statements give our current expectations or 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 terms of similar meaning in connection with any discussion of future operating or financial performance. In particular, these statements include, among other things, statements relating to:

our business strategy;
our predicted development and commercial timelines;
the selection, development and approval of our products;
the establishment, development and maintenance of collaborative partnerships;
our ability to identify and develop new potential products;
our ability to achieve commercial acceptance of our products;
our ability to scale up our manufacturing capabilities and facilities;
our estimates regarding liabilities associated with our Kendall Square lease;
the potential for the acquisition of new and complementary technologies, resources and products;

our projected capital expenditures; and	
our liquidity.	

Any or all of our forward-looking statements in this Amendment 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 Amendment will be important in determining future results. Consequently, no forward-looking statement can be guaranteed. Actual future results may vary materially. A more detailed reference to our forward-looking statements can be found under "Forward-looking Statements" in Item 7 of this Amendment.

#### ITEM 7. 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 marketing small molecule drugs for serious diseases including HIV infection, chronic hepatitis C virus infection, inflammatory and autoimmune disorders and cancer, independently and with collaborators. To date, we have discovered and advanced two products that have reached the market, Agenerase (amprenavir) and Lexiva (fosamprenavir calcium). Agenerase was approved and launched in the United States in early 1999, and Lexiva was approved and launched in the United States in late 2003. We earn a royalty on the sales of Agenerase and Lexiva and co-promote these products in collaboration with GlaxoSmithKline. Our drug candidate pipeline is principally focused on the development and commercialization of new treatments for viral and inflammatory diseases. We have built a drug discovery capability that integrates advanced biology, chemistry, biophysics, automation and information technologies, with a goal of making the drug discovery process more efficient and productive.

#### Drug Discovery and Development

Discovery and development of a single new pharmaceutical product is a lengthy and resource-intensive process which may take 10 to 15 years or more. During this process, potential drug candidates are subjected to rigorous evaluation, driven in part by stringent regulatory considerations, designed to generate information concerning toxicity profiles, efficacy, proper dosage levels and a variety of other characteristics which are important in determining whether a proposed drug candidate should be approved for marketing. Most chemical compounds which are investigated as potential drug candidates never progress into formal development, and most drug candidates which do advance into formal development never become commercial products.

We have a variety of drug candidates in clinical development and a broad-based drug discovery effort. Given the uncertainties of the research and development process, it is not possible to predict with confidence which, if any, of these efforts will result in a marketable pharmaceutical product. We constantly monitor the results of our discovery research and our nonclinical and clinical trials and regularly evaluate and re-evaluate our portfolio investments with the objective of balancing risk and potential return in view of new data and scientific, business and commercial insights. This process can result in relatively abrupt changes in focus and priority as new information comes to light and we gain new insights into ongoing 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 focus our efforts both on programs which we expect to control throughout the development and commercialization process, and programs which we expect will be conducted in the development and commercial phase principally by a collaborative partner. Since we have incurred losses from our inception and expect to incur losses for the forseeable future, our business strategy is dependent in large part on our continued ability to raise significant funding to finance our operations and 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 December 31, 2003 we had \$583 million of cash, cash equivalents and available for sale securities and \$315 million of 5% Convertible Subordinated Notes due 2007 (the "2007 Notes"). During 2003 and early 2004 we took a number of steps to address our cash position and investment requirements in support of our existing business strategy.

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Debt Exchange. On February 13, 2004, we exchanged approximately \$153.1 million in aggregate principal amount of our 2007 Notes for approximately \$153.1 million in aggregate principal amount of newly issued 5.75% Convertible Senior Subordinated Notes due 2011 (the "2011 Notes"). This transaction had an effect of significantly deferring the repayment date for almost half of our outstanding debt.

Sale of Business. In two independent transactions closed in March and December 2003, we sold the assets of our Discovery Tools and Services business for an aggregate of \$101 million of cash and the assumption of certain liabilities, to Invitrogen Corporation ("Invitrogen") and to a company organized by Telegraph Hill Partners, respectively. As a result of the disposition of the Discovery Tools and Services business, we now operate in a single operating segment: Pharmaceuticals.

Novartis Restructuring. In January 2004, we amended our existing collaboration agreement with Novartis. We will continue to receive research funding through April 2006, consistent with the original agreement, and up to \$35 million in pre-commercial payments for each preclinical drug candidate which we propose and Novartis accepts for preclinical development. We will no longer be responsible for the early development of drug candidates through proof-of-concept, as required under the original agreement, except that we may elect to develop VX-680 under the terms of the original agreement. We believe the restructured agreement remains financially attractive for us, and we are now free to devote our internal development resources to Vertex-controlled compounds in our areas of principal therapeutic interest.

#### Rebalancing of Research and Development

During 2003, we elected to focus our internal development and commercialization activity on two principal areas for the intermediate term: viral and inflammatory diseases. Our most advanced drug candidates in these areas are merimepodib (HCV), VX-950 (HCV) and VX-765 (inflammatory diseases). In preparation for advancing these and other Vertex-controlled drug candidates, we restructured our operations during the second half of the year to rebalance our relative investment in research, development and commercialization. This restructuring included a workforce reduction and a decision not to occupy our Kendall Square facility in Cambridge, Massachusetts. Of the terminated employees, 59% were from research, 30% were from sales, general and administrative functions primarily supporting research, and 11% were from development. Our investment in Company-sponsored research declined during 2003 approximately 22% from 2002 levels, while our investment in Company-sponsored development during 2003 increased over 2002 levels by approximately 57%. Collaborator-sponsored research increased approximately 14% while our Collaborator-sponsored development declined in 2003 by 44%. Overall we expect our total research and development investment in 2004 to be comparable to 2003, with any increases, if any, resulting principally from activities funded in whole or in part by new collaborators.

#### Collaborative Revenue

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

We currently have significant collaborations with Novartis, Aventis, GlaxoSmithKline, and Serono. In these collaborations, we have retained a share of downstream product revenue and may be entitled to significant pre-commercial milestone payments as drug candidates progress in development. We currently receive research funding from Novartis and Serono, and we currently have drug candidates in clinical development and commercialization under the collaborations with GlaxoSmithKline and Aventis and under a collaboration with Kissei. In 2003 we realized \$69.1 million in royalties and collaborative revenue, all of which was earned under our pharmaceutical partnerships. This represented a significant decline from the 2002 level of \$94.8 million and reflected the conclusion of funding from our collaborations with Lilly, Taisho and Schering AG and our lack of any new source of collaboration

revenue since 2000. Our collaborations with Novartis and GlaxoSmithKline accounted for 64% and 17%, respectively, of our total revenue in 2003.

A significant portion of our total research effort is being conducted under our collaboration with Novartis, which is scheduled to conclude, along with our research funding from Novartis, in April 2006. Under the terms of our agreement with Novartis, we will retain all rights to the intellectual property which we generate during that collaboration, except for rights licensed to Novartis in connection with the development and commercialization of specific preclinical drug candidates that Novartis accepts for development. Our access to these retained rights may help us initiate other collaborative opportunities in the kinase inhibitor field if our collaboration with Novartis is not extended beyond 2006. We will need to seek those opportunities or other financing alternatives in order to maintain our discovery effort at its existing level. It is not possible to predict at present whether any of those collaborations or other financing alternatives will be available in 2006 and beyond.

Based on the value that we believe we have built through research and development investments in certain of our drug discovery and development programs and our perception of the level of interest in certain of our programs among some potential collaborators, we believe that we could enter into additional collaborative agreements in 2004 which could be material to our business. Our business development priorities include new collaborations to support development and commercialization, in Europe and Japan, of our HCV clinical candidates and our oral cytokine inhibitor, VX-765. Our product development pipeline also includes drug candidates that are outside our core therapeutic areas of viral and inflammatory diseases, such as VX-702 (acute coronary syndromes), VX-944 (oncology) and VX-680 (oncology). In 2004 and future periods we expect to identify collaborative development and commercialization opportunities for these drug candidates in order to continue their clinical advancement, as we maintain focus on our Company-sponsored opportunities. We are also seeking collaborators for our ion channels and other discovery programs.

#### Lease Restructuring

For the twelve months ended December 31, 2003, we recorded restructuring and other related expenses of \$91.8 million, of which \$78.7 million relates to the potential restructuring of our Kendall Square lease. The restructuring accrual remaining at December 31, 2003 was \$69.5 million. The liability at December 31, 2003 represents our best judgment of the assumptions and estimates most appropriate in measuring the outcome of the potential lease restructuring. Although it is possible that this liability will be paid in full over the next 24 months, the actual amount and timing of any payments will depend on the actual terms of any lease restructuring transaction(s). If we are successful in restructuring the lease, we could potentially be relieved of a future lease obligation of approximately \$16 to \$18 million per year and a contractual construction obligation which could be in excess of \$30 million through 2006.

#### Financial Guidance

The key financial measures for which we have provided guidance in 2004 are as follows:

Our full year loss is expected to be between \$140 and \$150 million, before any gains or charges, including additional charges relating to the potential lease restructuring and the convertible note debt exchange.

Total revenue is expected to be in the range of \$90 to \$100 million in 2004. This is expected to be comprised of \$60 to \$65 million in committed funding and milestones from existing collaborative partners, and \$15 to \$18 million from HIV product royalties. In addition, we are currently in discussions with pharmaceutical companies regarding strategic research and product development agreements, and the successful conclusion of such discussions may result in additional revenue and cash flow in 2004.

As we prioritize our investment toward proprietary drug candidates and realize the benefits from the operational restructuring in drug discovery during 2003, we anticipate that research and development expenses will be in the range of \$190 to \$205 million for the full year of 2004.

We expect sales, general and administrative expenses to be between \$38 and \$43 million in 2004.

We expect cash, cash equivalents and available for sale securities to be in excess of \$350 million at the end of 2004.

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, as referenced in the section below entitled "Forward-Looking Statements."

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

The first part of the following table sets forth commitments and obligations that have been recorded on our consolidated balance sheet as of December 31, 2003. Certain other obligations and commitments, while not required under accounting principles generally accepted in the United States ("GAAP") to be included in the consolidated balance sheets, may have a material impact on liquidity. We have presented these items, all of which have been entered into in the ordinary course of business, in the table below in order to present a more complete picture of our financial position and liquidity.

December 31, 2003		Less than 1 year		1 to 3 years		to 5 years	5 years or more		Total
					(in t	housands)			
Commitments and Obligations Recorded on the Balance Sheet at December 31, 2003:									
Capital leases	\$	113	\$		\$		\$		\$ 113
Collaborator development loans		14,000				18,460			32,460
Convertible subordinated notes*						315,000			315,000
Off-Balance Sheet Commitments and Obligations at December 31, 2003:									
Operating leases		44,962		108,180		59,740		182,847	395,729
Purchase obligations		3,000		6,000					9,000
Research and development and other commitments		2,769		2,365	_				5,134
Total contractual obligations and commitments	\$	64,844	\$	116,545	\$	393,200	\$	182,847	\$ 757,436

See description below of our Note exchange, which closed on February 13, 2004, pursuant to which we have deferred approximately \$153.1 million of principal repayment obligations from 2007 to 2011.

Commitments and Obligations Recorded on the Balance Sheet at December 31, 2003:

Capital leases relate to equipment leases that expire at various dates though June 2004.

The collaborator development loans in the table above represent indebtedness to Novartis in the amount of \$32,460,000 that was advanced under a loan facility established pursuant to the original collaboration agreement with Novartis. Loans under the facility were intended to fund early clinical studies of kinase inhibitor compounds that we selected for early development. In February 2004, we amended the terms of the

Novartis collaboration agreement. We will continue to be responsible for drug discovery and Novartis will continue to provide research funding through the balance of the research term ending in April 2006, as provided in the original agreement. However, Novartis will now

be responsible for all nonclinical and clinical development of drug candidates which it accepts for development, and consequently the loan facility providing funding for development activities by Vertex has been terminated. We may either continue development of VX-680 under the terms of the original agreement using loan proceeds we have received under the Novartis loan facility, or elect to develop and commercialize VX-680 independent of Novartis. If we elect to develop and commercialize VX-680 independent of Novartis, loan amounts with respect to that drug candidate which are unspent and uncommitted at the time of our election will be repayable immediately. Outstanding loans which funded amounts either spent or committed to be spent on development activities relating to a particular compound will be forgiven if that compound is selected by Novartis for development. If not, the related loan will be repayable without interest in May 2008. At December 31, 2003, approximately \$14 million in development loans previously advanced to us were unspent and uncommitted. Please refer to Note P to our consolidated financial statements included in this Annual Report on Form 10-K.

At December 31, 2003 we had \$315,000,000 in 2007 Notes. On February 13, 2004, we concluded an exchange of approximately \$153.1 million in aggregate principal amount of 2007 Notes for approximately \$153.1 million in aggregate principal amount of newly issued 2011 Notes. As a result of this transaction, the Company has outstanding \$161.9 million in aggregate principal amount of 2007 Notes and \$153.1 million in aggregate principal amount of 2011 Notes. Our annual interest payment obligation increased by \$1.1 million to \$16.9 million, reflecting the slightly higher coupon rate on the 2011 Notes.

Off-Balance Sheet Commitments and Obligations at December 31, 2003:

At December 31, 2003, our future minimum commitments and contractual obligations included facilities operating leases, a purchase obligation and contractual commitments related to our research and development programs. These items are not required to be recorded on our consolidated balance sheets under GAAP. They are disclosed in the table presented above and described more fully in the following paragraphs in order to provide a more complete picture of our financial position and liquidity at December 31, 2003.

Our Kendall Square lease term began January 1, 2003 and lease payments commenced in May 2003. We have an obligation, staged over a number of years, to build out the space into finished laboratory and office space. The lease will expire in 2018 with options to extend the lease for two consecutive terms of ten years each, ultimately expiring in 2038. In June 2003, we decided not to occupy the space under this lease and to attempt to restructure the lease. See Note E to our consolidated financial statements included in this Annual Report on Form 10-K. The Company's future minimum commitments under this lease including lease payments and a construction obligation are \$29.2 million for less than 1 year, \$68.4 million for 1 to 3 years, \$38.7 million for 3 to 5 years and \$176.2 million for 5 years or more and are included in the table above.

Commitments under research and development programs represent contractual commitments entered into for materials and services in the normal course of business.

The purchase obligations referred to above include an agreement to purchase a minimum of \$3 million of certain specified products from Invitrogen annually for three years after the completion of the sale of certain assets of the Discovery Tools and Services business on March 28, 2003.

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

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

At December 31, 2003 we had cash, cash equivalents and marketable securities of \$583,164,000, which is a decrease of \$51,820,000 from \$634,984,000 at December 31, 2002. The decrease of \$51,820,000 is primarily the result of cash used by operations of \$167,623,000 offset by the net cash consideration received from the sale of the assets of the Discovery Tools and Services business of approximately \$96,561,000. Additionally, expenditures for property and equipment were \$17,351,000, cash receipts from the issuance of common stock under our employee benefit programs were approximately \$11,959,000 and we drew down \$27,460,000 under the Novartis loan facility in 2003, bringing the balance outstanding under the loan facility to \$32,460,000 at December 31, 2003.

As part of our strategy to manage our long term operational cash needs, in early 2004 we exchanged approximately \$153.1 million in aggregate principal amount of our 2007 Notes for approximately \$153.1 million in aggregate principal amount of newly issued 2011 Notes. The 2011 Notes were issued through a private offering to qualified institutional buyers. The 2011 Notes are convertible, at the option of the holder, into common stock at a price equal to \$14.94, subject to adjustment under certain circumstances. The 2007 Notes are convertible, at the option of the holder, into common stock at a price equal to \$92.26.

The restructuring accrual remaining at December 31, 2003 of \$69.5 million, relating to the potential Kendall Square lease restructuring, could possibly be paid in full over the next 24 months. However, the actual amount and timing of such payments will be dependent upon the ultimate terms of any lease restructuring. We review our estimates underlying the restructuring accrual on at least a quarterly basis, and the accrual could change with any future change in our estimates.

We expect to continue to invest significantly in our pipeline, particularly in clinical trials of merimepodib, VX-950 and VX-765, and in our ion channel and kinase discovery efforts. Consequently, we expect to incur losses on a quarterly and annual basis for the foreseeable future as we continue to develop and commercialize existing and future drug candidates. We also expect to incur substantial administrative expenditures in the future and expenses related to filing, prosecution, defense and enforcement of patent and other intellectual property rights. We expect our capital expenditures to remain at levels consistent with 2003, and we expect to complete 2004 with cash, cash equivalents and marketable securities in excess of \$350 million.

Beyond 2004, the adequacy of our available funds to meet our future operating and capital requirements, including repayment of the 2007 Notes and the 2011 Notes, will depend on many factors, including the number, breadth and prospects of our discovery and development programs and the costs and timing of obtaining regulatory approvals for any of our product candidates. Collaborations have been and will continue to be an important component of our business strategy. We will continue to rely on cash receipts from our existing research and development collaborations, including research funding, development reimbursements and potential milestone payments, and from new collaborations we may enter, in order to help fund our research and development efforts.

From time to time during 2004, we may repurchase our existing 2007 Notes in privately negotiated transactions, or market purchases or otherwise, depending on market conditions. Any such repurchases may be material.

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 securities or other methods of financing. We will continue to manage our capital structure and consider financing opportunities to strengthen our long term liquidity profile. There can be no assurance that such financing will be available on acceptable terms, if at all.

#### **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 generally accepted accounting principles in the United States of America. 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 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 expenses, research and development expenses, and revenue recognition, all of which are important to our financial position and results of operations, require significant judgments and estimates on the part of management. Our accounting polices, including the ones discussed below, are more fully described in Note B to our consolidated financial statements included in this Annual Report on Form 10-K.

#### Restructuring and Other Expense

We record liabilities associated with restructuring activities based on estimates of fair value in the period the liabilities are incurred, in accordance with SFAS 146 "Accounting for Costs Associated with Exit or Disposal Activities" ("SFAS 146"). These 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, the impact of which is measured using the credit-adjusted risk-free rate applied in the initial period.

On June 10, 2003, we announced a plan to restructure our operations in preparation for increased investment in the clinical development and commercialization of our drug candidates. We designed the restructuring to rebalance our relative investment in research, development and commercialization, to better support our long-term objective of becoming an integrated drug company. The restructuring included a workforce reduction, write-offs of certain assets and a decision not to occupy the Kendall Square facility. We are actively trying to restructure the lease obligation.

As a result of the Company's restructuring plan and in accordance with SFAS 146, we recorded an initial estimate of the fair value of the estimated liability in the second quarter of 2003. We have reviewed our assumptions and estimates quarterly and updated the liability as changes in circumstances have required. For the twelve months ended December 31, 2003, we recorded restructuring and other related expenses of \$91.8 million. The \$91.8 million includes \$78.7 million of potential lease restructuring expense (of which \$34.9 million, \$42.4 million and \$1.4 million was recorded in the second, third and fourth quarters of 2003, respectively). In addition to the \$78.7 million, other costs included in the \$91.8 million charge include \$6.0 million of lease operating expense incurred prior to the decision not to occupy the Kendall Square facility, \$2.6 million for severance and related employee transition benefits and \$4.5 million for a write-off of leasehold improvements and other assets.

The charge for the potential lease restructuring is the most significant component of the total restructuring charge and requires us to make significant judgments and assumptions. We use probability weighted discounted cash flows in order to calculate the amount of the liability associated with the potential lease restructuring. In accordance with SFAS 146, we used a credit-adjusted risk-free rate of approximately 10% in discounting our estimated cash flows. The probability weighted cash flows are based on management's assumptions and estimates regarding the possible outcomes of the potential lease restructuring. In estimating the liability we considered several possible outcomes of the potential lease restructuring, including a sublease of the entire space, a buy-out of our obligation, partial subleases by multiple parties, and other variations of these same outcomes. We also included in these potential outcomes the contractually required commitment for build-out of the leased space. We validate our estimates and assumptions through consultations with independent third parties having relevant expertise. We increased our estimated lease restructuring expense from the second quarter to the third quarter by \$42.4 million, based on our judgment that a significant decline in the real estate

market in Cambridge, Massachusetts had occurred. We believe an increase in available laboratory and office space in Cambridge, Massachusetts and certain other factors led to a corresponding overall decline in real estate market fundamentals from the previous quarter. Accordingly, we revised our expectations of attainable sublease terms, assuming lower sublease rental rates and a delay in occupancy by potential subtenants.

It is possible that our estimates and assumptions will change in the future resulting in additional adjustments to the amount of the liability, and the effect of such adjustments could be material. For example, if sublease rental rates differ from our assumption by approximately 10% in either direction, our recorded liability will be negatively or positively adjusted by approximately \$8 million. If the time to finalize the restructuring is delayed by six months from our estimated completion date, the impact could be as high as approximately \$10 million in additional liability, or more if there is further delay. We will review our assumptions and judgments related to the potential lease restructuring on at least a quarterly basis, until the outcome is finalized, and make whatever modifications we believe are necessary, based on our best judgment, to reflect any changed circumstances.

#### Revenue Recognition

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

Our collaborative and other research and development revenue is generated primarily through collaborative research and development agreements with strategic partners. The terms of these agreements typically include non-refundable up-front license fees, funding of research and development efforts, payments based upon achievement of certain milestones and royalties on product sales.

We recognize revenue from non-refundable, up-front license fees and milestones, not specifically tied to a separate earnings process, ratably over the contracted or estimated period of performance. Changes in estimates could impact revenue in the period the estimate is changed. If our estimate of the period of performance shortens or lengthens, the amount of revenue we recognize from non-refundable, up-front license fees and milestones could increase or decrease in the period the change in estimate becomes known. Future related revenues would be adjusted accordingly. To date, changes to our estimates have not had a material impact on our financial position or results of operations. Research funding is recognized ratably over the period of effort, as earned. Milestones that are based on designated achievement points and that are considered at risk and substantive at the inception of the collaborative contract, are recognized as earned when the corresponding payment is considered reasonably assured. We evaluate whether milestones are at risk and substantive based on the contingent nature of the milestone, specifically reviewing factors such as the technological and commercial risk that must be overcome and the level of investment required.

Under EITF 00-21, in multiple element arrangements, license payments are recognized together with any up-front payment and the research and development funding as a single unit of accounting, unless the delivered technology has stand-alone value to the customer and we have objective and reliable evidence of fair value of the undelivered elements in the arrangement. License payments received during the course of a collaboration that do not meet the separation criteria above are recognized, when earned, in proportion to the period of time completed on the contract relative to the total contracted or estimated period of performance on the underlying research and development collaboration, with the remaining amount deferred and recognized ratably over the remaining period of performance. Payments received after performance obligations are complete are recognized when earned. We did not receive any license payments in 2003.

Royalty revenue is recognized based upon actual and estimated net sales of licensed products in licensed territories, as provided by our collaborative partner, and is recognized in the period the sales

occur. Differences between actual royalty revenues and estimated royalty revenues, which have not been historically 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, facilities costs, overhead costs, clinical trial costs, contract services and other outside costs. Clinical trial, contract services and other outside costs require that we make estimates of the costs incurred in a given accounting period and record accruals at period end as 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.

#### **Results of Operations**

The following discussion of revenues and expenses is based only on the results of our continuing operations. We sold the assets of the Discovery Tools and Services business in two independent transactions in March and December 2003. In accordance with SFAS No. 144, "Accounting for the Impairment of Long-Lived Assets" ("SFAS No. 144"), the results of operations associated with the assets sold have been reclassified on the consolidated financial statements under the heading "discontinued operations" for all periods presented. The reclassification of the amounts to discontinued operations have been prepared using estimates and assumptions we have deemed appropriate based upon the information currently available. Prior to 2002, the Discovery Tools and Services business was not separately managed operationally or financially and therefore, we have estimated certain operating expenses, based on certain assumptions, including relative costs of the business being sold compared to historical site costs. Amounts reclassified to discontinued operations are not necessarily indicative of the results that would have been achieved had the Discovery Tools and Services business operated on a stand-alone basis during the periods presented.

As a result of the disposition of these assets, we now operate in a single operating segment: Pharmaceuticals.

Year Ended December 31, 2003 Compared with Year Ended December 31, 2002

Our net loss for 2003 was \$196,767,000 or \$2.56 per basic and diluted common share, compared to a net loss for 2002 of \$108,621,000 or \$1.43 per basic and diluted common share. Our loss in 2003 includes restructuring and other expense of \$91,824,000 and income from discontinued operations of \$69,646,000. Included in the income from discontinued operations is a gain from the sale of assets of \$70,339,000. Included in our net loss for 2002 was income from discontinued operations of \$28,337,000.

In addition to restructuring and other expense, offset by income from discontinued operations, our net loss for 2003 as compared with our net loss for 2002 increased primarily as a result of decreased revenue and interest income.

Total revenues decreased to \$69,141,000 in 2003 compared to \$94,770,000 in 2002. In 2003, revenue was comprised of \$9,002,000 in royalties and \$60,139,000 in collaborative and other research and development revenue, as compared with \$10,054,000 in royalties and \$84,716,000 in collaborative research and development revenue in 2002.

Royalties consist primarily of Agenerase royalty revenue. Agenerase royalty revenue is based on actual and estimated worldwide net sales of Agenerase. We began earning royalties on sales of Lexiva in the United States in November 2003. We expect to receive marketing approval for Lexiva in the European Union in 2004. We pay a royalty to a third party on sales of Agenerase and Lexiva.

Collaborative and other research and development revenue decreased \$24,577,000 or 29% in 2003 as compared with 2002. The decrease in collaborative and other research and development revenue is due to the conclusion of certain of our collaborative research and development arrangements, mainly in late 2002, partially offset by additional revenue recognized under our Novartis collaboration and a milestone payment received from GlaxoSmithKline in connection with FDA approval of Lexiva. The table presented below is a summary of significant revenue arrangements for the year ended 2003 as compared with the year ended 2002.

	Y	Year Ended December 31,					
		2003	2002				
		(In thousands)					
Collaborative and other research and development revenue:							
Summary of significant collaborative revenue arrangements:							
Novartis	\$	44,502	\$	41,894			
Serono		5,280		5,280			
GlaxoSmithKline		2,500		1,500			
Eli Lilly				12,054			
Schering				5,000			
Kissei		267		4,574			
Taisho				4,187			
Other		7,590		10,227			
			_				
Total collaborative and other research and development revenue	\$	60,139	\$	84,716			

We have not entered into any significant collaborative research and development agreements since 2000. Additionally as shown in the table above, research funding under our partnerships with Eli Lilly, Schering and Taisho concluded in 2002.

We expect that collaborative and other research and development revenues will continue to be a significant source of our total revenues and we believe we could enter into additional collaborative agreements in 2004 which could be material to our business.

Research and development expenses remained relatively consistent at \$199,636,000 in 2003 compared to \$198,338,000 in 2002.

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 years ended December 31, 2003 and 2002 into these major categories (in thousands):

	Year Ended December 31,						
		2003		2002	\$	Change	% Change
Research Expenses:							
Salary and benefits	\$	38,140	\$	35,724	\$	2,416	6.8%
Laboratory supplies and other direct expenses		20,025		20,046		(21)	
Contractual services		6,390		14,718		(8,328)	(56.6)%
Infrastructure costs		48,880		49,918		(1,038)	(2.1)%
			_				
Total research expenses	\$	113,435	\$	120,406			
			_				
Development Expenses:							
Salary and benefits	\$	19,796	\$	16,300	\$	3,496	21.4%
Laboratory supplies and other direct expenses		5,307		6,976		(1,669)	(23.9)%
Contractual services		42,594		39,697		2,897	7.3%
Infrastructure costs		18,504		14,959		3,545	23.7%
			_				
Total development expenses	\$	86,201	\$	77,932			
			_				
Total Research and Development Expenses:							
Salary and benefits	\$	57,936	\$	52,024	\$	5,912	11.4%
Laboratory supplies and other direct expenses		25,332		27,022		(1,690)	(6.3)%
Contractual services		48,984		54,415		(5,431)	(10.0)%
Infrastructure costs		67,384		64,877		2,507	3.9%
			_				
Total research and development expenses	\$	199,636	\$	198,338			

- (a) In order to show comparative information, certain research costs in 2002 have been allocated among the categories of expense, based on certain estimates and assumptions. These estimates and assumptions include allocations based upon ratios of actual expenses in comparative periods.
- (b)

  Aurora Biosciences Corporation, which we acquired in July 2001, did not track research and development expenses in a manner consistent with Vertex and, as a result, we are unable to provide this reconciliation for 2001.

Our investment in research has decreased due to the operational restructuring in June 2003 while our investment in development has increased as a result of our proprietary drug candidates entering and advancing through clinical development. In 2003 our clinical trials focused on multiple drug candidates. The results of these trials enabled us to focus our clinical pipeline on two core therapeutic areas viral and inflammatory diseases. Our lead drug candidates in these areas are merimepodib (HCV), VX-950 (HCV) and VX-765 (inflammatory diseases). In 2003 our development investment also focused on drug candidates with potential therapeutic indications outside our current core therapeutic areas, such as VX-702 (acute coronary syndromes), VX-148 (autoimmune diseases), VX-944 (oncology) and VX-680 (oncology). In 2004 and future periods we will seek to identify licensing opportunities for these drug candidates in order to continue their clinical development. We continue to focus our main drug discovery efforts on the protein kinase and ion channel gene families as well as other targeted areas.

Our collaborative partners have agreed to fund portions of our research and development programs related to specified drug candidates. Our research and development expenses for 2003, 2002 and 2001 were as follows:

	2003									2002		2001						
	R	Research	Deve	elopment		Total	I	Research	D	evelopment	Total	R	esearch	De	evelopment		Total	
Collaborator-Sponsored Company-Sponsored	\$	62,162 51,273	\$	19,935 66,266	\$	82,097 117,539	\$	54,509 65,897	\$	35,675 42,257	\$ 90,184 108,154	\$	49,490 43,427	\$	20,262 28,809	\$	69,752 72,236	
Total	\$	113,435	\$	86,201	\$	199,636	\$	120,406	\$	77,932	\$ 198,338	\$	92,917	\$	49,071	\$	141,988	

Company With

Our product pipeline is principally focused on viral diseases, inflammatory and autoimmune diseases, and cancer.

Therapeutic Area and Product Candidate	Clinical Indications	Development Phase	Company With Marketing Rights (Region)				
Antivirals Agenerase (amprenavir)	HIV infection	Mktd	GlaxoSmithKline				
Lexiva (fosamprenavir calcium)**	HIV infection	Mktd/MAA filed	(Worldwide)* GlaxoSmithKline (Worldwide)*				
VX-385	HIV infection	Phase I	GlaxoSmithKline (Worldwide)*				
Merimepodib (VX-497)	Chronic hepatitis C	Phase II	Vertex (Worldwide)				
VX-950	Chronic hepatitis C	Preclin	Vertex (Worldwide)				
Inflammation and Autoimmune Disease							
VX-765	Inflammatory/autoimmune diseases	Phase I	Vertex (Worldwide)				
VX-702	Acute coronary syndromes; inflammatory diseases	Phase II	Kissei (Japan); Vertex (R.O.W.)				
Pralnacasan (VX-740)	Rheumatoid arthritis (RA); osteoarthritis (OA); other inflammatory/autoimmune diseases	Phase II	Aventis (Worldwide)*				
Cancer							
VX-680	Oncology	Preclin	Novartis (Worldwide)				
VX-944	Oncology	Phase I	Vertex (Worldwide)				

Vertex has co-promotion rights in the U.S. and the E.U. Kissei has marketing rights to amprenavir (Prozei ) in Japan.

GlaxoSmithKline is seeking marketing approval in the E.U. under the name "Telzir".

Vertex may elect by June 30, 2004 to continue the development of VX-680 under the original terms of the Novartis agreement, in which event Novartis will hold an option on worldwide commercial rights.

To date we have incurred in excess of \$1 billion in research and development costs associated with drug discovery and development. We expect research and development expenses in 2004 to remain comparable with 2003. However, our anticipated 2004 research and development expenses could vary materially, depending on the occurrence and timing of clinical trials. We anticipate that research and development expenses will increase in future periods as we add personnel and capabilities to support the advancement of our lead drug candidates. However, we do not

expect that our research expenses will increase significantly unless we obtain a significant amount of funding from new collaborations.

We estimate that it takes 10 to 15 years (the industry average is 12 years) to discover, develop and bring to market a new pharmaceutical product in the U.S. as outlined below:

Phase:	Objective:	Estimated Duration:
Discovery	Lead identification and target validation	2 to 4 years
Pre-Clinical	Initial toxicology for preliminary identification of risks for humans; gather early pharmacokinetic data	1 to 2 years
Phase I	Evaluate safety in humans; study how the drug works, metabolizes and interacts with other drugs	1 to 2 years
Phase II	Establish effectiveness of the drug and its optimal dosage; continue safety evaluation	2 to 4 years
Phase III	Confirm efficacy, dosage regime and safety profile of the drug	2 to 4 years
FDA approval Animal and other	Approval by the FDA to sell and market the drug under approved labeling nonclinical studies are typically conducted during each phase of human clinical studies	6 months to 2 years es.

The successful development of our products is highly uncertain and subject to a number of risk factors. The duration of clinical trials may vary substantially according to the type, complexity and novelty of the pharmaceutical product. The FDA and comparable agencies in foreign countries impose substantial requirements on the introduction of therapeutic pharmaceutical products through lengthy and detailed laboratory and clinical testing procedures, sampling activities and other costly and time-consuming procedures. Data obtained from preclinical, nonclinical and clinical activities at any step in the testing process may be adverse and lead to discontinuation of development. Data obtained from these activities also are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The duration and cost of discovery, preclinical, nonclinical and clinical activities may vary significantly over the life of a project and are difficult to predict. Therefore, we are unable to generate accurate and meaningful estimates of the ultimate costs and anticipated completion dates of our pharmaceutical research and development and commercialization efforts. The most significant costs associated with drug discovery and development are those costs associated with Phase II and Phase III clinical trials. Given the uncertainties related to development, we are currently unable to reliably estimate when, if ever, our drug candidates will generate revenue and cash flows. We do not expect to receive net cash inflows from any major discovery and development products until a drug candidate becomes a profitable commercial product.

Sales, general and administrative expenses decreased \$1,974,000, or 5%, to \$39,082,000 in 2003 from \$41,056,000 in 2002, due primarily to a reduction in personnel resulting from our consolidation of certain general and administration functions to our corporate office location in Cambridge, Massachusetts, and from our restructuring in the second quarter of 2003.

Restructuring and other expense for the twelve months ended December 31, 2003 was \$91.8 million. The activity related to restructuring and other expense for the twelve months ended December 31, 2003, is presented below (in thousands):

		Charge for the Twelve Months Ended December 31, 2003		Cash Payments in 2003		Non-cash Write-off in 2003		Accrual as of December 31, 2003
Lease restructuring expense and other								
operating lease expense	\$	84,726	\$	15,200	\$		\$	69,526
Employee severance, benefits and								
related costs		2,616		2,616				
Leasehold improvements and asset								
impairments		4,482				4,482		
	_		_		_		_	
Total	\$	91,824	\$	17,816	\$	4,482	\$	69,526
		13				_		

In accordance with SFAS 146, we review on a quarterly basis the estimates and assumptions underlying our determination of the anticipated liability associated with the potential lease restructuring and adjust the liability as changes in circumstances require. It is possible that those estimates and assumptions could change in the future resulting in incremental expense or, alternatively, in reversal of expense, and the effect of any such adjustments could be material.

Interest income decreased approximately \$13,310,000 to \$15,412,000 in 2003 from \$28,722,000 in 2002. The decrease is mainly the result of both a lower level of invested funds and lower portfolio yields due to a reduced interest rate environment.

Income from discontinued operations increased \$69,646,000 in 2003 from \$28,337,000 in 2002, due to our sale of the assets of our Discovery Tools and Services business in 2003. Included in the income from discontinued operations in 2003 is a gain on the sale of those assets of \$70,339,000.

Year Ended December 31, 2002 Compared with Year Ended December 31, 2001

Our net loss for 2002 was \$108,621,000 or \$1.43 per basic and diluted common share compared to a net loss of \$66,233,000 or \$0.89 per basic and diluted common share for 2001. The net loss for 2002 includes income from discontinued operations of \$28,337,000. The net loss for 2001 includes income from discontinued operations of \$22,148,000, a charge of \$25,901,000 representing a cumulative change in accounting principle related to revenue recognition and a gain of \$17,749,000 representing a cumulative change in accounting related to derivative instruments.

Total revenues increased to \$94,770,000 in 2002 compared to \$85,297,000 in 2001. In 2002, revenue was comprised of \$10,054,000 in royalties and \$84,716,000 in collaborative and other research and development revenue, as compared with \$10,783,000 in royalties and \$74,514,000 in collaborative and other research and development revenue in 2001.

Collaborative and other research and development revenue increased \$10,202,000 or 14% in 2002 as compared with 2001. The table presented below is a summary of significant revenue arrangements for the year ended 2002 as compared with the year ended 2001. As illustrated in the table below the overall increase in collaborative and other research and development revenue in 2002 is due to an increase in revenue recorded in connection with certan collaborations, such as Novartis and Eli Lilly, offset by a decrease in revenue earned under our arrangements with Kissei and Taisho. In 2002 we recognized an increased amount of revenue under our Novartis collaboration as a result of increased effort allocated to our kinase research program. In the fourth quarter of 2002, our research and development agreement with Lilly was restructured; the original contractual research term was to conclude in June 2003. In connection with the restructuring of the agreement and termination of the research term, we recognized approximately \$1,637,000 in revenue that had been previously deferred. This deferred revenue related to the development milestone paid in December 2001 and the up-front payment received in June 1997 at the commencement of the collaboration. Additionally, in the fourth quarter of 2002 we received and recognized a milestone payment of \$1,500,000 from GlaxoSmithKline in connection with the submission of a new drug application for market approval of Lexiva in the U.S.

We have not entered into any significant collaborative research and development agreements since 2000. Funding under our partnerships with Lilly, Schering and Taisho concluded in 2002.

	Y	Year Ended December 31,					
		2002	2001				
		(In thousands)					
Collaborative and other research and development revenue:							
Summary of significant collaborative revenue arrangements:							
Novartis	\$	41,894	\$	36,723			
Serono		5,280		4,802			
GlaxoSmithKline		1,500					
Eli Lilly		12,054		6,686			
Schering		5,000		5,000			
Kissei		4,574		7,405			
Taisho		4,187		5,583			
Other		10,227		8,315			
Total collaborative and other research and development revenue	\$	84,716	\$	74,514			

Research and development expenses increased to \$198,338,000 in 2002 from \$141,988,000 in 2001, primarily due to investment in advancing our clinical pipeline and broadening our research efforts. Our clinical investment was directed primarily toward advancing our second generation p38 MAP kinase inhibitor (VX-702), our IMPDH inhibitors (VX-148 and merimepodib), our HCV protease inhibitor (VX-950) and ICE inhibitor (VX-765). Development investment increased from \$49,071,000 in 2001 to \$77,932,000 in 2002. Investment in research increased from \$92,917,000 in 2001 to \$120,406,000 in 2002, resulting principally from the expansion of our multi-target gene family research programs, including our kinase program and ion channel program. As a result of our continued expansion, personnel and facilities expenses also increased.

Sales, general and administrative expenses increased \$9,200,000, or 29%, to \$41,056,000 in 2002 from \$31,856,000 in 2001. The increase is primarily attributable to increased personnel and professional expenses. Included in the increase in personnel and professional expenses is an increase in expenses relating to the addition of certain key executives, certain process consulting costs and legal and patent expenses related to continued protection of our intellectual property, including expenses associated with contesting a suit filed by Oregon Health Sciences University.

Merger related costs of \$22,960,000 in 2001 consisted of investment banking, legal and accounting fees associated with the acquisition of Aurora Biosciences Corporation completed on July 18, 2001.

Interest income decreased approximately \$16,411,000 to \$28,722,000 in 2002 from \$45,133,000 in 2001. The decrease is a result of both a lower level of invested funds, and lower portfolio yields due to a reduced interest rate environment.

Interest expense decreased to approximately \$17,684,000 in 2002 from \$19,318,000 in 2001. The decrease is a result of the reduction in principal amount of the 2007 Notes. In October 2001, we repurchased \$30,000,0000 in principal amount of our 2007 Notes and recorded a gain of \$10,340,000 on the retirement of the notes in the fourth quarter of 2001.

In April 2002, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standard ("SFAS") 145, "Recission of FASB Statements No. 4, 44 and 64, Amendment of FASB Statement No. 13, and Technical Corrections." FAS 145 recinds FAS 4 and FAS 64, which addressed the accounting for gains and losses from extinguishment of debt. Under FAS 145 the gain on retirement of convertible subordinated notes is considered an ordinary item. The gain on retirement of convertible subordinated notes was originally classified in 2001 as an extraordinary item but has been reclassified as part of loss from continuing operations. At December 31, 2002 and 2001, \$315,000,000 of the 2007 Notes was outstanding.

Using the equity method of accounting, we recorded \$662,000 as our share of loss in Altus Biologics Inc. (Altus), for the year ended December 31, 2001. The loss is included in other expense on the Statement of Operations. Effective September 28, 2001, coincident with a financial restructuring of Altus, we changed our method of accounting for Altus from the equity method to the cost method. See Note I to our consolidated financial statements included in this Annual Report on Form 10-K.

In the third quarter of 2001, in connection with our overall review of accounting policies concurrent with our merger with Aurora, we elected to change our revenue recognition policy for collaborative and other research and development revenues from the Emerging Issues Task Force No. 91-6 ("EITF 91-6") method to the Substantive Milestone Method, adopted retroactive to January 1, 2001. We believe this method is preferable because it is reflective of the Company's on-going business operations and is more consistent with industry practices following the implementation of SAB 101 throughout the biotechnology industry in 2000.

Pursuant to the 2001 change, we recorded a one-time, non-cash charge of \$25,901,000, representing a cumulative change in accounting principle for periods prior to 2001. The amount of revenue recognized in 2003, 2002 and 2001 which was included in the one-time, non-cash charge was \$2,809,000, \$6,979,000 and \$7,748,000, respectively. Additionally, \$3,684,000, \$3,628,000 and \$1,053,000 will be recognized as revenue in 2004, 2005 and thereafter, respectively, which amounts were included in the January 2001 charge to income.

Effective July 1, 2001, we adopted Derivative Implementation Group Issue No. A17, "Contracts that Provide for Net Share Settlement" (DIG A17). Pursuant to the adoption of DIG A17, we recorded a \$17,749,000 cumulative effect of a change in accounting principle to reflect the value of warrants held in Altus. This amount is included in investments in the December 31, 2001 balance sheet. As of September 30, 2001, the warrants no longer qualified as derivatives under DIG A17 due to changes in the terms of the warrants coincident with a financial restructuring of Altus.

#### **Forward-looking Statements**

This reports contains forward-looking statements about our business, including our expectation that (i) we are positioned to commercialize multiple products in the coming years that we expect will generate increased revenues; (ii) our losses will continue; (iii) research and development expenses will continue to increase, but research expenses will not increase without new funding from collaborations; (iv) we will enter into additional strategic collaborations for the development of our drug candidates which are outside our focus areas of viral and inflammatory diseases; (v) our financial results for 2004 will be as set forth in this Annual Report on Form 10-K; (vi) we will continue to collaborate with existing and new partners to develop and market Vertex-discovered products for selected major therapeutic areas; (vii) we and our partners will begin clinical trials on a number of our development stage drug candidates during 2004; (viii) Lexiva will be approved and launched in the E.U. in 2004; (ix) we will initiate expanded clinical trials of merimepodib in 2004, and believe we may be able to file an NDA for merimepodib as early as 2007; (x) development of pralnacasan will be delayed by at least 12-24 months, if the adverse toxicology finding is satisfactorily addressed; (xi) our Phase II clinical trial of VX-702 will be complete in 2004; (xii) our research programs will produce additional development candidates, including numerous kinase inhibitors, in the next several years; and (xiii) our liability to restructure the Kendall Square lease will be as we have estimated and we may pay the full amount in the next 24 months. 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, our inability to further identify, develop and achieve commercial success for new products and technologies, the possibility of delays in the research and development necessary to select drug development candidates, the possibility of delays in the commencement or completion of clinical trials, the risk that clinical activities planned for 2004 may not commence as scheduled, the risk that clinical trials may not result in marketable products, the risk that we may be unable to successfully finance and secure regulatory approval of and market our drug candidates, including Lexiva, our dependence upon existing and new pharmaceutical

and biotechnology collaborations, the levels and timing of payments under our collaborative agreements, uncertainties about our ability to obtain new corporate collaborations on satisfactory terms, if at all, the development of competing systems, our ability to protect our proprietary technologies, patent-infringement claims, risks of new, changing and competitive technologies, the risk that there may be changing and new regulations in the U.S. and internationally and uncertainty about our ability to restructure our obligation under the Kendall Square facility lease. Please see the "Risk Factors" appearing elsewhere in this report for more details regarding these and other risks. 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.

#### **Recent Accounting Pronouncements**

In May 2003, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards No. 150 ("SFAS 150"), Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity. SFAS 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. The adoption of SFAS 150 in the third quarter of 2003 did not have a material impact on our results of operations or financial position.

In April 2003, the FASB issued Statement of Financial Accounting Standards No. 149 ("SFAS 149"), Amendment of Statement 133 on Derivative Instruments and Hedging Activities. SFAS 149 amends and clarifies financial accounting and reporting for derivative instruments and for hedging activities under Statement of Financial Accounting Standards No. 133, *Accounting for Derivative Instruments and Hedging Activities* (SFAS 133). The adoption of SFAS 149 in the third quarter of 2003 did not have a material impact on our results of operations or financial position.

In November 2002, the FASB issued Interpretation No. 45, "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others" ("FIN 45"). FIN 45 elaborates on the disclosures the Company must make about obligations under certain guarantees that the company has issued. It also requires the Company to recognize, at the inception of a guarantee, a liability for the fair value of the obligations undertaken in issuing the guarantee. The initial recognition and initial measurement provisions are to be applied only to guarantees issued or modified after December 31, 2002. The adoption of FIN 45 did not have a material impact on our results of operations or financial position. We have provided additional disclosure with respect to guarantees in Note U to the Consolidated Financial Statements.

In January 2003, the FASB issued FASB Interpretation No. 46 ("FIN 46"), "Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51" and in December 2003 issued a revised FIN 46 ("FIN 46R") which addresses the period of adoption of FIN 46 for entities created before January 31, 2003. FIN 46 provides a new consolidation model which determines control and consolidation based on potential variability in gains and losses. The provisions of FIN 46 are effective for enterprises with variable interest entities created after January 31, 2003. We must adopt the provisions of FIN 46 in the first quarter of 2004 and do not expect the adoption to have a material impact on our financial position or results of operations.

#### PART IV

#### ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K

(a)(1) Financial Statements. The Financial Statements required to be filed by Item 8 of this Annual Report on Form 10-K (as filed with the Original Filing) are as follows:

Dogo Number in

	Original Filing
Report of Independent Auditors	F-2
Consolidated Balance Sheets as of December 31, 2003 and 2002	F-3
Consolidated Statements of Operations for the years ended December 31, 2003, 2002 and	
2001	F-4
Consolidated Statements of Stockholders' Equity and Comprehensive Loss for the years	
ended December 31, 2003, 2002 and 2001	F-5
Consolidated Statements of Cash Flows for the years ended December 31, 2003, 2002 and	
2001	F-6
Notes to Consolidated Financial Statements	F-7 to F-37

(a)(2) Financial Statement Schedules. Financial Statement Schedules have been omitted because they are either not applicable or the required information is included in the consolidated financial statements or notes thereto.

(a)(3) Exhibits.

Exhibit
Number

#### **Exhibit Description**

- 2.1 Agreement and Plan of Merger dated as of April 29, 2001, by and among Vertex, Aurora and Ahab Acquisition Sub Inc. (filed as Exhibit 2 to Vertex's Current Report on Form 8-K dated April 29, 2001 [File No. 000-19319] and incorporated herein by reference).
- 2.2 Asset Purchase Agreement among Vertex, PanVera LLC and Invitrogen Corporation dated February 4, 2003 (filed as Exhibit 2.2 to Vertex's 2002 Annual Report on Form 10-K [file No. 000-19319] and incorporated herein by reference).
- 3.1 Restated Articles of Organization filed with The Commonwealth of Massachusetts on July 31, 1991 (filed as Exhibit 3.1 to Vertex's 1997 Annual Report on Form 10-K [File No. 000-19319] and incorporated herein by reference).
- 3.2 Articles of Amendment filed with The Commonwealth of Massachusetts on June 4, 1997 (filed as Exhibit 3.2 to Vertex's 1997 Annual Report on Form 10-K [File No. 000-19319] and incorporated herein by reference).
- 3.3 Certificate of Vote of Directors Establishing a Series of a Class of Stock, as filed with the Secretary of The Commonwealth of Massachusetts on July 31, 1991 (filed as Exhibit 3.3 to Vertex's 1997 Annual Report on Form 10-K [File No. 000-19319] and incorporated herein by reference).
- 3.4 Articles of Amendment filed with The Commonwealth of Massachusetts on May 21, 2001 (filed as Exhibit 3.4 to Vertex's registration statement on Form S-4 [Registration Number 333-61480] and incorporated herein by reference.)
- 3.5 By-laws of Vertex as amended and restated as of March 12, 2001 (filed as Exhibit 3.4 to Vertex's 2000 Annual Report on Form 10-K [File No. 000-19319] and incorporated herein by reference).
- 4.1 Specimen stock certificate (filed as Exhibit 4.1 to Vertex's Registration Statement on Form S-1 [Registration No. 33-40966] or amendments thereto and incorporated herein by reference).

- 4.2 Stockholder Rights Plan (filed as Exhibit 4.2 to Vertex's Registration Statement on Form S-1 [Registration No. 33-40966] or amendments thereto and incorporated herein by reference).
- 4.3 First Amendment to Rights Agreement dated as of February 21, 1997 (filed as Exhibit 4.3 to Vertex's 1996 Annual Report on Form 10-K [File No. 000-19319] and incorporated herein by reference).
- 4.4 Indenture dated as of September 19, 2000 between Vertex and State Street Bank and Trust Company (filed as Exhibit 4.1 to Vertex's Quarterly Report on Form 10-Q for the quarter ended September 30, 2000 [File No. 000-19319] and incorporated herein by reference).
- 4.5 Supplemental Indenture dated as of December 12, 2000 between Vertex and State Street Bank and Trust Company (filed as Exhibit 4.2 to Pre-Effective Amendment No. 1 to the Form S-3 filed by Vertex [Registration No. 333-49844] and incorporated herein by reference)
- 4.6 Second Amendment to Rights Agreement dated as of June 30, 2001 (filed as Exhibit 4.4 to Vertex's Quarterly Report on Form 10-Q for the quarter ended June 30, 2001 [File No. 000-19319] and incorporated herein by reference).
- 4.7 Indenture dated February 13, 2004 between Vertex and U.S. Bank National Association (filed as Exhibit 4.1 to Vertex's Current Report on Form 8-K dated February 23, 2004 [File No. 000-19319] and incorporated herein by reference).
- 10.1 1991 Stock Option Plan, as amended and restated as of September 14, 1999 (filed as Exhibit 10.1 to Vertex 1999 Annual Report on Form 10-K [File No. 000-19319] and incorporated herein by reference).\*
- 10.2 1994 Stock and Option Plan, as amended and restated as of September 14, 1999 (filed as Exhibit 10.1 to Vertex 1999 Annual Report on Form 10-K [File No. 000-19319] and incorporated herein by reference).\*
- 10.3 1996 Stock and Option Plan, Amended and Restated as of July 17, 2002 (filed as Exhibit 10.3 to Vertex's 2002 Annual Report on Form 10-K [file No. 000-19319] and incorporated herein by reference).\*
- 10.4 Non-Competition and Stock Repurchase Agreement between Vertex and Joshua Boger, dated April 20, 1989 (filed as Exhibit 10.2 to Vertex's Registration Statement on Form S-1 [Registration No. 33-40966] or amendments thereto and incorporated herein by reference).\*
- 10.5 Form of Employee Stock Purchase Agreement (filed as Exhibit 10.3 to Vertex's Registration Statement on Form S-1 [Registration No. 33-40966] or amendments thereto and incorporated herein by reference).\*
- 10.6 Form of Employee Non-Disclosure and Inventions Agreement (filed as Exhibit 10.4 to Vertex's Registration Statement on Form S-1 [Registration No. 33-40966] or amendments thereto and incorporated herein by reference).
- 10.7 Form of Executive Employment Agreement executed by Joshua S. Boger and Vicki L. Sato (filed as Exhibit 10.6 to Vertex's 1994 Annual Report on Form 10-K [File No. 000-19319] and incorporated herein by reference).\*
- 10.8 Form of Amendment to Employment Agreement executed by Joshua S. Boger and Vicki L. Sato (filed as Exhibit 10.1 to Vertex's Quarterly Report on Form 10-Q for the quarter ended June 30, 1995 [File No. 000-19319] and incorporated herein by reference).\*
- 10.9 Executive Employment Agreement between Vertex and Iain P.M. Buchanan (filed as Exhibit 10.9 to Vertex's 2001 Annual Report on Form 10-K [File No. 000-19319] and incorporated herein by reference).\*

- 10.10 Agreement dated December 21, 2000 between Vertex and Richard H. Aldrich (filed as Exhibit 10.10 to Vertex's 2000 Annual Report on Form 10-K [File No. 000-19319] and incorporated herein by reference).\*
- 10.11 Lease dated March 3, 1995, between Fort Washington Realty Trust and Vertex, relating to the premises at 130 Waverly Street, Cambridge, MA (filed as Exhibit 10.15 to Vertex's 1994 Annual Report on Form 10-K [File No. 000-19319] and incorporated herein by reference).
- 10.12 First Amendment to Lease dated December 29, 1995 between Fort Washington Realty Trust and Vertex (filed as Exhibit 10.15 to Vertex's 1995 Annual Report on Form 10-K [File No. 000-19319] and incorporated herein by reference).
- 10.13 Second Amendment to Lease and Option Agreement dated June 12, 1997 between Fort Washington Realty Trust and Vertex (filed as Exhibit 10.17 to Vertex 1999 Annual Report on Form 10-K [File No. 000-19319] and incorporated herein by reference).
- 10.14 Third, Fourth and Fifth Amendments to Lease between Fort Washington Realty Trust and Vertex (with certain confidential information deleted) (filed as Exhibit 10.14 to Vertex's 2001 Annual Report on Form 10-K [File No. 000-19319] and incorporated herein by reference).
- 10.15 Lease by and between Trustees of Fort Washington Realty Trust, Landlord, and Vertex, executed September 17, 1999 (filed, with certain confidential information deleted, as Exhibit 10.27 to Vertex's Quarterly Report on Form 10-Q for the quarter ended September 30, 1999 [File No. 000-19319], and incorporated herein by reference).
- 10.16 Lease by and between Kendall Square, LLC, Landlord, and Vertex, executed January 18, 2001 (filed, with certain confidential information deleted, as Exhibit 10.16 to Vertex's 2000 Annual Report on Form 10-K [File No. 000-19319] and incorporated herein by reference).
- 10.17 Agreement for Lease of Premises at 88 Milton Park, Abingdon, Oxfordshire between Milton Park Limited and Vertex Pharmaceuticals (Europe) Limited and Vertex Pharmaceuticals Incorporated (filed as Exhibit 10.18 to Vertex 1999 Annual Report on Form 10-K [File No. 000-19319] and incorporated herein by reference).
- 10.18 Research and Development Agreement dated April 13, 1993 between Vertex and Kissei Pharmaceutical Co., Ltd. (filed, with certain confidential information redacted, as Exhibit 10.1 to Vertex's Quarterly Report on Form 10-Q for the quarter ended March 31, 1993 [File No. 000-19319] and incorporated herein by reference).
- 10.19 Research Agreement and License Agreement, both dated December 16, 1993, between Vertex and Burroughs Wellcome Co. (filed, with certain confidential information redacted, as Exhibit 10.16 to Vertex's 1993 Annual Report on Form 10-K [File No. 000-19319] and incorporated herein by reference).
- 10.20 Research and Development Agreement between Vertex and Eli Lilly and Company effective June 11, 1997 (filed, with certain confidential information redacted, as Exhibit 10.1 to Vertex's Quarterly Report on Form 10-Q for the quarter ended June 30, 1997 [File No. 000-19319] and incorporated herein by reference).
- 10.21 Research and Development Agreement between Vertex and Kissei Pharmaceutical Co. Ltd. effective September 10, 1997 (filed, with certain confidential information redacted, as Exhibit 10.1 to Vertex's Quarterly Report on Form 10-Q for the quarter ended September 30, 1997 [File No. 000-19319] and incorporated herein by reference).
- 10.22 Research Agreement between Vertex and Schering AG dated as of August 24, 1998 (filed, with certain confidential information redacted, as Exhibit 10.1 to Vertex's Quarterly Report on Form 10-Q for the quarter ended September 30, 1998 [File No. 000-19319] and incorporated herein by reference).

- 10.23 License, Development and Commercialization Agreement between Vertex and Hoechst Marion Roussel Deutschland GmbH dated September 1, 1999 (filed, with certain confidential information redacted, as Exhibit 10.27 to Vertex's Quarterly Report on Form 10-Q for the quarter ended September 30, 1999 [File No. 000-19319], and incorporated herein by reference).
- 10.24 Collaboration and Option Agreement between Vertex and Taisho Pharmaceutical Co., Ltd. dated November 30, 1999 (filed, with certain confidential information redacted, as Exhibit 10.27 to Vertex's 1999 Form 10-K [File No. 000-19319] and incorporated herein by reference).
- 10.25 Research and Early Development Agreement between Vertex and Novartis Pharma AG dated May 8, 2000 (filed, with certain confidential information redacted, as Exhibit 10.1 to Vertex's Quarterly Report on Form 10-Q for the quarter ended March 31, 2000 [File No. 000-19319] and incorporated herein by reference).
- 10.26 Research Agreement between Vertex and Laboratoires Serono S.A. dated December 11, 2000 (filed, with certain confidential information redacted, as Exhibit 10.26 to Vertex's 2000 Annual Report on Form 10-K [File No. 000-19319] and incorporated herein by reference).
- 10.27 Letter Agreement between Aurora and Stuart J. Collinson (filed as Exhibit 10.26 to Vertex's registration statement on Form S-4 [Registration No. 333-61480] and incorporated herein by reference).\*
- 10.28 Executive Employment Agreement between Vertex and Kenneth S. Boger (filed as Exhibit 10.28 to Vertex's 2001 Annual Report on Form 10-K [File No. 000-19319] and incorporated herein by reference).\*
- 10.29 Executive Employment Agreement between Vertex and Ian F. Smith (filed as Exhibit 10.29 to Vertex's 2001 Annual Report on Form 10-K [File No. 000-19319] and incorporated herein by reference).\*
- 10.30 Letter Agreement between Vertex and N. Anthony Coles, M.D. (filed as Exhibit 10.30 to Vertex's 2001 Annual Report on Form 10-K [File No. 000-19319] and incorporated herein by reference).\*
- 10.31 Form of Non-Competition Agreement between Vertex and Invitrogen Corporation dated March 28, 2003 (filed as Exhibit 10.31 to Vertex's 2002 Annual Report on Form 10-K [File No. 000-19319] and incorporated herein by reference).
- 10.32 Form of letter agreement with John J. Alam, Senior Vice President of Drug Evaluation and Approval; Lynne H. Brum, Vice President of Corporate Communications and Financial Planning; Pamela Fritz, Vice President, Human Resources; Peter Mueller, Chief Scientific Officer and Senior Vice President, Drug Discovery and Innovation; Mark Murcko, Vice President and Chief Technology Officer; Steven Schmidt, Vice President, Information Systems; John A. Thomson, Vice President, Research; and Jeffrey D. Wilson, Vice President, Pharmaceutical Operations, covering special rights upon a change of control transaction (filed as Exhibit 10.32 to Vertex's 2002 Annual Report on Form 10-K [File No. 000-19319] and incorporated herein by reference).\*
- 10.33 Dealer Manager Agreement dated February 10, 2004 between Vertex and UBS Securities LLC, (filed as Exhibit 10.1 to Vertex's Current Report on Form 8-K dated February 23, 2004 [File No. 000-19319] and incorporated herein by reference.
- 10.34 Resale Registration Rights Agreement dated as of February 13, 2004 between Vertex and UBS Securities LLC (filed as Exhibit 10.2 to Vertex's Current Report on Form 8-K dated February 23, 2004 [File No. 000-19319] and incorporated herein by reference).
- 10.35 First Revised and Restated Research and Early Development Agreement between Vertex and Novartis Pharma AG dated February 3, 2004 (filed, with certain confidential information redacted, as Exhibit 10.35 to the Original Filing [File No. 000-19319] and incorporated herein by reference).

- 18.1 Letter from PricewaterhouseCoopers LLP dated November 14, 2001 re: Change in Accounting Principle (filed as Exhibit 18.1 to Vertex's Quarterly Report on Form 10-Q for the quarter ended September 30, 2001 [File No. 000-19319] and incorporated herein by reference).
- 21 Subsidiaries of Vertex (filed as Exhibit 21 to the Original Filing [File No. 000-19319] and incorporated herein by reference).
- 23.1 Consent of Independent Accountants, PricewaterhouseCoopers LLP (filed as Exhibit 23.1 to the Original Filing [File No. 000-19319] and incorporated herein by reference)
- 31.1 Certification of the Chief Executive Officer under Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
- 31.2 Certification of the Chief Financial Officer under Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
- 32.1 Certification of the Chief Executive Officer and the Chief Financial Officer under Section 906 of the Sarbanes-Oxley Act of 2002 (filed as Exhibit 32.1 to the Original Filing [File No. 000-19319] and incorporated herein by reference).

Compensatory plan or agreement applicable to management and employees.

Confidential portions of these documents have been filed separately with the Commission pursuant to a request for confidential treatment.

#### (b) Reports on Form 8-K.

On November 10, 2003, we furnished a report on Form 8-K-Item 9-Regulation FD Disclosure Item 12-Disclosure of Results of Operations and Financial Condition, reporting that the Company had issued two press releases, one regarding the development status of certain of its drug candidates and the second reporting that the Company had issued a press release to report the Company's financial results for the quarter ended September 30, 2003.

On December 5, 2003, we filed a report on Form 8-K-Item 5-Other Events, reporting that Joshua S. Boger, the Company's Chairman and CEO, entered into a plan with Goldman, Sachs & Co., pursuant to which Goldman will undertake to sell, subject to a limit order, an aggregate of 370,000 shares of the Company's stock issuable upon exercise of options held by Dr. Boger.

On December 5, 2003, we furnished a report on Form 8-K-Item 9-Regulation FD Disclosure, reporting that the Company had issued a press release on December 4, 2003 to announce the sale of certain instrumentation assets of Vertex's subsidiary Aurora Instruments LLC to Aurora Discovery, Inc., and updating our 2003 full-year financial guidance.

On December 16, 2003, we filed a report on Form 8-K-Item 5-Other Events, reporting that on November 17, 2003, Iain P.M. Buchanan, the Company's Vice President of European Operations, entered into a plan with Lehman Brothers Inc., pursuant to which Lehman will undertake to sell, subject to a limit order, an aggregate of 50,000 shares of the Company's stock issuable upon exercise of options held by Mr. Buchanan.

On December 19, 2003, we filed a report on Form 8-K-Item 5-Other Events, reporting that Vicki L. Sato, the Company's President, entered into a plan with Goldman, Sachs & Co., pursuant to which Goldman will undertake to sell, subject to a limit order, an aggregate of 344,509 shares of the Company's stock issuable upon exercise of options held by Dr. Sato.

# **SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

	VERTEX PHARMACEUTICALS INCORPORATED	
September 8, 2004	Ву:	/s/ JOSHUA S. BOGER
		Joshua S. Boger Chief Executive Officer
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QuickLinks

 $\underline{\mathsf{ITEM}\,\mathsf{7}.\,\mathsf{MANAGEMENT'S\,DISCUSSION\,AND\,ANALYSIS\,OF\,FINANCIAL\,CONDITION\,AND\,RESULTS\,OF\,OPERATIONS}\\ \underline{\mathsf{PART\,IV}}$ 

 $\underline{\mathsf{ITEM}\ 15}. \ \underline{\mathsf{EXHIBITS}}, \underline{\mathsf{FINANCIAL}\ \mathsf{STATEMENT}\ \mathsf{SCHEDULES}}, \underline{\mathsf{AND}\ \mathsf{REPORTS}\ \mathsf{ON}\ \mathsf{FORM}\ 8\text{-}\mathsf{K}}$