

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)

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

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 of incorporation)

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)

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

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subject to such filing requirements for the past 90 days. Yes 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.

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act). Yes 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 May 6, 2004 are incorporated by reference into 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 foreseeable 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.

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.

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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	3 to 5 years	5 years or more	Total
(in thousands)					
<i>Commitments and Obligations Recorded on the Balance Sheet at December 31, 2003:</i>					
Capital leases	\$ 113	\$	\$	\$	\$ 113
Collaborator development loans	14,000		18,460		32,460
Convertible subordinated notes*			315,000		315,000
<i>Off-Balance Sheet Commitments and Obligations at December 31, 2003:</i>					
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 through 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

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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 policies, 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.

	Year Ended December 31,	
	2003	2002
(In thousands)		
Collaborative and other research and development revenue:		
<i>Summary of significant collaborative revenue arrangements:</i>		
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
	<u>60,139</u>	<u>84,716</u>
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,		\$ Change	% Change
	2003	2002		
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.

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

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 (Worldwide)*
Lexiva (fosamprenavir calcium)**	HIV infection	Mktd/MAA filed	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.

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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	Approval by the FDA to sell and market the drug under approved labeling	6 months to 2 years

Animal and other nonclinical studies are typically conducted during each phase of human clinical studies.

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

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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 certain 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.