

CHIRON CORP  
Form 10-Q  
May 06, 2005

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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FORM 10-Q

(Mark one)

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

For the quarterly period ended March 31, 2005

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: 0-12798

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CHIRON CORPORATION

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)  
**4560 Horton Street, Emeryville, California**  
(Address of principal executive offices)

**94-2754624**  
(I.R.S. Employer  
Identification No.)  
**94608**  
(Zip code)

(510) 655-8730

(Registrant's telephone number, including area code)

**Not Applicable**

(Former name, former address and former fiscal year, if changed since last report)

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Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

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Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Title of Class	Outstanding at April 28, 2005
Common Stock, \$0.01 par value	187,458,623

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## Item 1. Financial Statements

**CHIRON CORPORATION**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
(Unaudited)  
(In thousands, except share data)

	March 31, 2005	December 31, 2004
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 198,770	\$ 209,509
Short-term investments in marketable debt securities	430,668	394,112
Total cash and short-term investments	629,438	603,621
Accounts receivable, net of allowances	378,790	402,094
Inventories, net of reserves	233,257	221,154
Assets held for sale	1,275	
Current net deferred income tax asset	65,342	71,287
Derivative financial instruments	7,833	4,969
Other current assets	92,709	90,898
Total current assets	1,408,644	1,394,023
Non-current investments in marketable debt securities	402,841	409,421
Property, plant, equipment and leasehold improvements, at cost:		
Land and buildings	381,014	379,861
Laboratory, production and office equipment	668,221	637,394
Leasehold improvements	132,850	125,858
Construction-in-progress	206,630	225,482
	1,388,715	1,368,595
Less accumulated depreciation and amortization	(583,698 )	(569,180 )
Property, plant, equipment and leasehold improvements, net	805,017	799,415
Purchased technologies, net	210,960	216,037
Goodwill	845,825	861,394
Other intangible assets, net	432,906	457,707
Investments in equity securities and affiliated companies	76,512	100,951
Non-current notes receivable	7,500	7,500
Other non-current assets	58,368	59,055
	\$ 4,248,573	\$ 4,305,503

The accompanying Notes to Condensed Consolidated Financial Statements are integral to this statement.

**CHIRON CORPORATION**  
**CONDENSED CONSOLIDATED BALANCE SHEETS (Continued)**  
(Unaudited)  
(In thousands, except share data)

	March 31, 2005	December 31, 2004
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 122,878	\$ 129,942
Accrued compensation and related expenses	73,889	79,113
Derivative financial instruments		10,395
Current portion of long-term debt and capital lease	1,137	2,687
Current portion of unearned revenue	59,745	35,651
Income taxes payable	23,689	16,363
Other current liabilities	169,420	160,293
Total current liabilities	450,758	434,444
Long-term debt	938,112	936,652
Long-term portion of capital lease	156,890	156,952
Non-current derivative financial instruments		156
Non-current net deferred income tax liability	35,929	60,427
Non-current unearned revenue	41,074	26,175
Other non-current liabilities	73,410	79,643
Minority interest	10,000	9,350
Total liabilities	1,706,173	1,703,799
Commitments and contingencies		
Stockholders equity:		
Common stock	1,917	1,917
Additional paid-in capital	2,533,597	2,527,709
Deferred stock compensation	(17,515 )	(13,825 )
Accumulated deficit	(34,420 )	(11,843 )
Accumulated other comprehensive income	267,751	330,491
Treasury stock, at cost (4,370,000 shares at March 31, 2005 and 4,804,000 shares at December 31, 2004)	(208,930 )	(232,745 )
Total stockholders equity	2,542,400	2,601,704
	\$ 4,248,573	\$ 4,305,503

The accompanying Notes to Condensed Consolidated Financial Statements are integral to this statement.

**CHIRON CORPORATION**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
(Unaudited)  
(In thousands, except per share data)

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2005</b>	<b>2004</b>
<b>Revenues:</b>		
Product sales, net	\$ 277,163	\$ 281,066
Revenues from joint business arrangement	36,058	30,361
Collaborative agreement revenues	4,527	6,515
Royalty and license fee revenues	80,061	54,792
Other revenues	9,547	6,938
<b>Total revenues</b>	<b>407,356</b>	<b>379,672</b>
<b>Operating expenses:</b>		
Cost of sales (excludes amortization expense related to acquired developed products)	162,960	126,701
Research and development	109,839	98,410
Selling, general and administrative	131,908	104,740
Amortization expense of intangible assets acquired in business combinations and asset purchases	21,263	21,332
Other operating expenses	7,146	2,116
<b>Total operating expenses</b>	<b>433,116</b>	<b>353,299</b>
(Loss) income from operations	(25,760 )	26,373
Interest expense	(7,079 )	(5,925 )
Interest and other income, net	21,447	16,074
Minority interest	(530 )	(620 )
(Loss) income from continuing operations before income taxes	(11,922 )	35,902
Provision for (benefit of) income taxes	(2,980 )	8,975
(Loss) income from continuing operations	(8,942 )	26,927
Gain from discontinued operations, net of taxes		12,845
<b>Net (loss) income</b>	<b>\$ (8,942 )</b>	<b>\$ 39,772</b>
<b>Basic (loss) earnings per share:</b>		
(Loss) income from continuing operations	\$ (0.05 )	\$ 0.14
Net (loss) income	\$ (0.05 )	\$ 0.21
<b>Diluted (loss) earnings per share:</b>		
(Loss) income from continuing operations	\$ (0.05 )	\$ 0.14
Net (loss) income	\$ (0.05 )	\$ 0.21

The accompanying Notes to Condensed Consolidated Financial Statements are integral to this statement.

**CHIRON CORPORATION**  
**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)**  
**(Unaudited)**  
**(In thousands)**

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2005</b>	<b>2004</b>
Net (loss) income	\$ (8,942 )	\$ 39,772
Other comprehensive (loss) income:		
Change in foreign currency translation adjustment during the period	(50,562 )	(21,628 )
Unrealized (losses) gains from investments:		
Net unrealized holding (losses) gains arising during the period, net of tax benefit (provision) of \$2,046 and (\$2,498) for the three months ended March 31, 2005 and 2004, respectively	(3,191 )	1,277
Reclassification adjustment for net gains included in net (loss) income, net of tax provision of \$5,553 and \$6,388 for the three months ended March 31, 2005 and 2004, respectively	(8,987 )	(3,268 )
Net unrealized losses from investments	(12,178 )	(1,991 )
Other comprehensive loss	(62,740 )	(23,619 )
Comprehensive (loss) income	\$ (71,682 )	\$ 16,153

The accompanying Notes to Condensed Consolidated Financial Statements are integral to this statement.

**CHIRON CORPORATION**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(Unaudited)  
(In thousands)

	<b>Three Months Ended</b>	
	<b>March 31,</b>	<b>2004</b>
	<b>2005</b>	<b>2004</b>
Net cash provided by operating activities	\$ 57,226	\$ 11,080
Cash flows from investing activities:		
Purchases of investments in marketable debt securities	(321,571 )	(202,899 )
Proceeds from sales of investments in marketable debt securities	37,548	30,634
Proceeds from maturities of investments in marketable debt securities	249,657	78,908
Capital expenditures	(48,447 )	(44,600 )
Purchases of equity securities and interests in affiliated companies	(1,559 )	(2,390 )
Proceeds from sale of equity securities and interests in affiliated companies	8,274	3,537
Cash paid for acquisitions, net of cash acquired	(1,292 )	(1,006 )
Other, net	(1,809 )	(766 )
Net cash used in investing activities	(79,199 )	(138,582 )
Cash flows from financing activities:		
Repayment of debt and capital leases	(64 )	(84 )
Payments to acquire treasury stock		(8,459 )
Proceeds from re-issuance of treasury stock	9,970	35,603
Proceeds from issuance of debt		973
Net cash provided by financing activities	9,906	28,033
Effect of exchange rate changes on cash and cash equivalents	1,328	(5,722 )
Net decrease in cash and cash equivalents	(10,739 )	(105,191 )
Cash and cash equivalents at beginning of the period	209,509	364,270
Cash and cash equivalents at end of the period	\$ 198,770	\$ 259,079

The accompanying Notes to Condensed Consolidated Financial Statements are integral to this statement.



**CHIRON CORPORATION**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**March 31, 2005**  
**(Unaudited)**

**Note 1 Basis of Presentation**

The information presented in the Condensed Consolidated Financial Statements at March 31, 2005, and for the three months ended March 31, 2005 and 2004, is unaudited but includes adjustments, consisting only of all normal recurring adjustments, which Chiron Corporation believes to be necessary for fair presentation of the periods presented.

The Condensed Consolidated Balance Sheet amounts at December 31, 2004, have been derived from audited financial statements. Historically, Chiron's operating results have varied considerably from period to period due to the nature of Chiron's collaborative, royalty and license arrangements and the seasonality of certain vaccine products. In addition, the mix of products sold and the introduction of new products will affect comparability from quarter to quarter. As a consequence, Chiron's interim results in any one quarter are not necessarily indicative of results to be expected for a full year. This information should be read in conjunction with Chiron's audited Consolidated Financial Statements as of and for the year ended December 31, 2004, which are included in the Annual Report on Form 10-K filed by Chiron with the Securities and Exchange Commission.

*Principles of Consolidation*

The Condensed Consolidated Financial Statements include the accounts of Chiron and its majority-owned subsidiaries. For consolidated majority-owned subsidiaries in which Chiron owns less than 100%, Chiron records minority interest in the Condensed Consolidated Financial Statements to account for the ownership interest of the minority owner. Investments in limited partnerships and interests in which Chiron has an equity interest of 50% or less are accounted for using either the equity or cost method. All significant intercompany accounts and transactions have been eliminated in consolidation.

*Use of Estimates and Reclassifications*

The preparation of financial statements requires management to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures of contingent assets and liabilities. On an on-going basis, management evaluates its estimates, including those related to investments; inventories; derivatives; capital leases; intangible assets; goodwill; purchased in-process research and development; product discounts, rebates and returns; bad debts; collaborative, royalty and license arrangements; restructuring; pension and other post-retirement benefits; income taxes; and litigation and other contingencies. Chiron bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from those estimates under different assumptions or conditions.

Chiron, prior to filing its financial statements on Form 10-Q, publicly releases an unaudited condensed balance sheet and statement of operations. Between the date of Chiron's earnings release and the filing of Form 10-Q, reclassifications may be required. These reclassifications, when made, have no effect on income from continuing operations, net income or earnings per share. There has been no such reclassification in the first quarter of 2005.

**CHIRON CORPORATION**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**March 31, 2005**  
**(Unaudited)**

**Note 1 Basis of Presentation (Continued)**

Chiron currently owns certain manufacturing and inspection equipment which are no longer useful and became available for sale in the first quarter of 2005. Chiron has committed to a plan to sell these assets and is actively marketing these assets. These assets are classified as Assets held for sale in the Condensed Consolidated Balance Sheet at March 31, 2005.

Certain previously reported amounts have been reclassified to conform to the current year presentation.

*Stock-Based Compensation*

Chiron measures compensation expense for its stock-based employee compensation using the intrinsic value method. Compensation expense is based on the difference, if any, between the fair value of Chiron's common stock and the exercise price of the option or share right on the measurement date, which is typically the date of grant. This amount is recorded as Deferred stock compensation in the Condensed Consolidated Balance Sheets and amortized as a charge to operations over the vesting period of the applicable options or share rights.

The following table illustrates the effect on net income (loss) and related net income (loss) per share, had compensation cost for the stock-based employee compensation been determined based upon the fair value method:

		<b>Three Months Ended March 31, 2005                      2004 (in thousands, except per share data)</b>	
Net income (loss):			
As reported		\$ (8,942 )	\$ 39,772
Add:	Stock-based employee compensation expense included in reported net income (loss), net of related tax effects	1,061	1,340
Less:	Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	16,674	21,507
	Proforma	\$ (24,555 )	\$ 19,605
Basic net income (loss) per share:			
As reported		\$ (0.05 )	\$ 0.21
Proforma		\$ (0.13 )	\$ 0.10
Diluted net income (loss) per share:			
As reported		\$ (0.05 )	\$ 0.21
Proforma		\$ (0.13 )	\$ 0.10

**CHIRON CORPORATION**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**March 31, 2005**

**(Unaudited)**

**Note 2 New Accounting Standards**

In December 2004, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment* (SFAS 123(R)), which requires the cost resulting from all share-based payment transactions to be recognized in the consolidated financial statements. That cost will be measured based on the fair value of the equity instruments issued or on the fair value of liabilities incurred. Under SFAS 123(R), the fair-value-based method for recognition or disclosure of compensation expense will be applied using the modified prospective application transition method or the modified retrospective application transition method. Chiron currently measures compensation expense for its stock-based employee compensation under the intrinsic method. We are currently evaluating transition methods, option valuation methodologies and assumptions in light of SFAS 123(R), and therefore cannot estimate the impact of our adoption at this time, although we expect that its adoption will have a material impact on Chiron's consolidated financial statements. Current option values determined using the Black-Scholes-Merton formula, used for purposes of proforma disclosure, may not be indicative of results from the valuation methodologies Chiron finally adopts. The effective date of SFAS 123(R) is the first reporting period beginning after June 15, 2005. However, on April 14, 2005, the Securities and Exchange Commission (SEC) announced the adoption of a new rule that amends the compliance date of SFAS 123(R). The SEC's new rule allows calendar year companies to implement SFAS 123(R) at the beginning of 2006, which makes SFAS 123(R) effective for Chiron in the first quarter of 2006.

On October 22, 2004, the American Jobs Creation Act of 2004 (the Act) was signed into law. The Act includes a temporary incentive for U.S. multinationals to repatriate accumulated income earned outside the U.S. at an effective tax rate of 5.25%. On December 21, 2004, the FASB issued Staff Position 109-2, *Accounting and Disclosure Guidance for the Foreign Earnings Repatriation Provisions within the American Jobs Creation Act of 2004* (FSP 109-2). FSP 109-2 allows companies additional time to evaluate the effect of the law on whether unrepatriated foreign earnings continue to qualify for SFAS No. 109's exception to recognizing deferred tax liabilities and would require explanatory disclosures from those who need the additional time. Through March 31, 2005, Chiron has not provided deferred taxes on foreign earnings because such earnings were intended to be indefinitely reinvested outside the U.S. Whether Chiron will ultimately take advantage of this provision depends on a number of factors including reviewing future Congressional and regulatory guidance before a decision can be made. Until that time, Chiron will make no change in its current intention to indefinitely reinvest accumulated earnings of its foreign subsidiaries. If Chiron repatriates these earnings, a one-time tax charge to Chiron's consolidated results of operations could occur. Chiron will continue to evaluate the impact of this provision in 2005.

**Note 3 Inventories**

Inventories, net of reserves, are stated at the lower of cost or market using the moving weighted-average cost method. Chiron maintains inventory reserves primarily for product failures, expiration and obsolescence. Inventory that is obsolete (inventory that will no longer be used in the manufacturing process), expired, or in excess of forecasted usage is written down to its market value, if lower than cost.

**CHIRON CORPORATION**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**March 31, 2005**  
**(Unaudited)**

**Note 3 Inventories (Continued)**

Inventories, net of reserves consisted of the following:

	<b>March 31, 2005</b>	<b>December 31, 2004</b>
	<b>(in thousands)</b>	
Finished goods	\$ 57,046	\$ 59,206
Work-in-process	107,518	116,660
Raw materials	68,693	45,288
	\$ 233,257	\$ 221,154

**Note 4 Income Taxes**

The effective tax rate for the three months ended March 31, 2005 and 2004 was 25% of pretax income (loss) from continuing operations. The effective tax rate may be affected in future periods by changes in management's estimates with respect to our deferred tax assets and other items affecting the overall tax rate.

**Note 5 Comprehensive Income (Loss)**

For the three months ended March 31, 2005 and 2004, the foreign currency translation component of comprehensive income (loss) relates to permanent investments in non-U.S. subsidiaries, and accordingly, was not adjusted for income taxes.

**Note 6 Treasury Stock**

Treasury stock is stated at cost. Gains on reissuance of treasury stock are credited to Additional paid-in capital. Losses on reissuance of treasury stock are charged to Additional paid-in capital to the extent of available net gains on reissuance of treasury stock. Otherwise, losses are charged to Accumulated deficit. Chiron charged losses of \$13.6 million and \$25.4 million for the three months ended March 31, 2005 and 2004, respectively, to Accumulated deficit in the Condensed Consolidated Balance Sheets.

**Note 7 Earnings (Loss) Per Share**

Basic earnings per share is based upon the weighted-average number of common shares outstanding. Diluted earnings per share is based upon the weighted-average number of common shares and dilutive potential common shares outstanding. Dilutive potential common shares could result from (i) the assumed exercise of outstanding stock options and equivalents, which are included under the treasury-stock method; (ii) performance based share rights awards to the extent that dilutive shares are assumed issuable; (iii) the assumed exercise of outstanding put options, which are included under the reverse treasury-stock method; and (iv) convertible notes and debentures, which are included under the if-converted method, if applicable. Due to rounding, quarterly amounts may not sum to full year amounts.

**CHIRON CORPORATION**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**March 31, 2005**  
**(Unaudited)**

**Note 7 Earnings (Loss) Per Share (Continued)**

Contingently convertible debt instruments ( CoCos ) are included in diluted earnings per share, if dilutive. For the three months ended March 31, 2005, Chiron s \$500.0 million contingently convertible debentures due 2033 ( 2033 Debentures ) and Chiron s \$385.0 million contingently convertible debentures due 2034 ( 2034 Debentures ) were excluded from the computations of diluted earnings per share as the inclusion of each of these CoCos would be antidilutive.

The following table sets forth the computations for basic and diluted earnings (loss) per share on income (loss) from continuing operations (in thousands, except per share data):

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2005</b>	<b>2004</b>
(Loss) income (Numerator):		
(Loss) income from continuing operations	\$ (8,942 )	\$ 26,927
Shares (Denominator):		
Weighted-average common shares outstanding	187,108	187,809
Effect of dilutive securities:		
Stock options and equivalents		4,190
Weighted-average common shares outstanding, plus impact from assumed conversions	187,108	191,999
Basic (loss) earnings per share	\$ (0.05 )	\$ 0.14
Diluted (loss) earnings per share	\$ (0.05 )	\$ 0.14

The following table sets forth the computations for basic and diluted earnings (loss) per share on net income (loss) (in thousands, except per share data):

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2005</b>	<b>2004</b>
(Loss) income (Numerator):		
Net (loss) income	\$ (8,942 )	\$ 39,772
Shares (Denominator):		
Weighted-average common shares outstanding	187,108	187,809
Effect of dilutive securities:		
Stock options and equivalents		4,190
Weighted-average common shares outstanding, plus impact from assumed conversions	187,108	191,999
Basic (loss) earnings per share	\$ (0.05 )	\$ 0.21
Diluted (loss) earnings per share	\$ (0.05 )	\$ 0.21

**CHIRON CORPORATION**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**March 31, 2005**  
**(Unaudited)**

**Note 7 Earnings (Loss) Per Share (Continued)**

Stock options to purchase 22.4 million shares and 7.0 million shares with exercise prices greater than the average market prices of common stock were outstanding during the three months ended March 31, 2005 and 2004, respectively. These options were excluded from the respective computations of diluted earnings per share, as their inclusion would be antidilutive.

The dilutive effect of CoCos must be included in diluted earnings per share regardless of whether the triggering contingency has been satisfied, if dilutive. For the three months ended March 31, 2005 and 2004, 7.3 million shares of common stock issuable upon conversion of the 2033 Debentures were excluded from the computations of diluted earnings per share as their inclusion would be antidilutive.

If the 2034 Debentures are tendered for conversion, the value ( Conversion Value ) of cash and shares of Chiron's common stock, if any, to be received by a holder converting \$1,000 principal amount of the debentures will be determined by multiplying the applicable conversion rate by a weighted average price. Chiron will deliver the Conversion Value to debenture holders as follows: (1) an amount in cash ( Principal Return ) equal to the lesser of (a) the aggregate Conversion Value of the debentures to be converted and (b) the aggregate principal amount of the debentures to be converted and (2) if the aggregate Conversion Value of the debentures to be converted is greater than the Principal Return, an amount in shares ( Net Shares ) equal to the aggregate Conversion Value less the Principal Return ( Net Share Amount ). The number of Net Shares to be paid will be determined by dividing the Net Share Amount by a weighted average price. If dilutive, common shares to be added to the diluted shares outstanding would be determined by the net share settlement of the 2034 Debentures. For the three months ended March 31, 2005, the assumed conversion of the 2034 Debentures was not dilutive.

In addition, for the three months ended March 31, 2005 and 2004, 0.6 million shares and 8.5 million shares of common stock issuable upon conversion of the Liquid Yield Option Notes were excluded from the computations of diluted earnings per share as their inclusion would be antidilutive.

All potential common shares have been excluded from the computation of diluted loss per share for the three months ended March 31, 2005, as their inclusion would be antidilutive. These potential common shares included stock options to purchase 1.2 million shares of common stock, 0.6 million shares of common stock issuable upon conversion of the Liquid Yield Option Notes and 7.3 million shares issuable upon conversion of the Convertible Debentures.

**Note 8 Discontinued Operations**

In a strategic effort to focus on its core businesses of blood-testing, vaccines and biopharmaceuticals, Chiron completed the sale of Chiron Diagnostics to Bayer in 1998.

**CHIRON CORPORATION****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****March 31, 2005****(Unaudited)****Note 8 Discontinued Operations (Continued)**

Chiron and Bayer Corporation, or Bayer, were involved in a dispute with respect to their respective rights to certain royalty refunds receivable for which a settlement was reached in 2004. Under this settlement agreement, Chiron made a settlement payment to Bayer in 2004. This settlement includes an agreement that all outstanding items with Bayer related to the sale of Chiron Diagnostics are resolved and no future indemnity obligations are required. Chiron released previously established reserves deemed to be in excess following this settlement. This settlement resulted in a net gain of \$12.8 million for the three months ended March 31, 2004. This net gain primarily relates to a tax benefit as a result of the settlement payment to Bayer.

**Note 9 Intangible Assets**

Intangible assets subject to amortization consisted of the following (in thousands):

	March 31, 2005			December 31, 2004		
	Gross Carrying Value	Accumulated Amortization	Net Carrying Value	Gross Carrying Value	Accumulated Amortization	Net Carrying Value
Purchased technologies	\$ 332,746	\$ 121,786	\$ 210,960	\$ 333,085	\$ 117,048	\$ 216,037
Patents	\$ 135,375	\$ 73,684	\$ 61,691	\$ 132,385	\$ 71,616	\$ 60,769
Trademarks	63,401	25,427	37,974	65,609	25,450	40,159
Licenses and technology rights	46,190	33,439	12,751	47,745	34,079	13,666
Developed product technologies	366,122	89,087	277,035	374,025	77,253	296,772
Customer relationships	29,729	12,211	17,518	31,234	12,421	18,813
Know how(1)	13,501	7,427	6,074	14,185	7,548	6,637
Databases	7,100	2,130	4,970	7,100	2,012	5,088
Other	24,785	9,892	14,893	34,893	19,090	15,803
Total other intangible assets	\$ 686,203	\$ 253,297	\$ 432,906	\$ 707,176	\$ 249,469	\$ 457,707
Total intangible assets subject to amortization	\$ 1,018,949	\$ 375,083	\$ 643,866	\$ 1,040,261	\$ 366,517	\$ 673,744

(1) Upon acquisition of a 100% interest in Chiron Behring by the second quarter 1998, Chiron acquired a portfolio of products that were created by Behring and are currently being sold internationally. These products embody Chiron Behring's proprietary know-how consisting of unpatented technology and trade secrets. Since the unpatented technology and trade secrets meet the separability criterion, Chiron has recognized them collectively as a separate intangible asset apart from goodwill in accordance with SFAS No. 141, Business Combinations.

**CHIRON CORPORATION**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**March 31, 2005**  
**(Unaudited)**

**Note 9 Intangible Assets (Continued)**

Aggregate future amortization expense is expected to be as follows (in thousands):

For the three months ended March 31, 2005	\$24,414
For the remaining nine months in the year ended December 31, 2005	\$73,402
For the year ended December 31, 2005	\$97,816
For the year ended December 31, 2006	\$107,204
For the year ended December 31, 2007	\$105,398
For the year ended December 31, 2008	\$79,862
For the year ended December 31, 2009	\$54,832
For the year ended December 31, 2010	\$53,329

The changes in the carrying value of goodwill by reporting unit consisted of the following (in thousands):

	Biopharmaceuticals	Vaccines	Total
Balance as of December 31, 2004	\$ 192,186	\$ 669,208	\$ 861,394
Effect of exchange rate changes		(15,569)	(15,569)
Balance as of March 31, 2005	\$ 192,186	\$ 653,639	\$ 845,825

**Note 10 Segment Information**

Chiron is organized based on the products and services that it offers. Under this organizational structure, there are three reportable segments: (i) blood-testing, (ii) vaccines and (iii) biopharmaceuticals. The blood-testing segment consists of an alliance with Gen-Probe and Chiron's one-half share in the pretax operating earnings generated by the joint business contractual arrangement with Ortho-Clinical Diagnostics. Chiron's alliance with Gen-Probe is focused on developing and commercializing nucleic acid testing products using Transcription-Mediated Amplification technology to screen donated blood and plasma products for viral infection. Chiron's joint business arrangement with Ortho-Clinical Diagnostics is operated under a contractual arrangement and is not a separate and distinct legal entity. Through Chiron's joint business contractual arrangement with Ortho-Clinical Diagnostics, Chiron sells a line of immunodiagnostic tests to detect hepatitis viruses and retroviruses and provides supplemental tests and microplate and chemiluminescent instrument systems to automate test performance and data collection. The blood-testing segment also earns royalties from third parties based on their sales of immunodiagnostic and nucleic acid testing probe diagnostic products utilizing Chiron's hepatitis C virus and HIV-related patents, for use in blood screening and plasma fractionation markets. The vaccines segment consists principally of adult and pediatric vaccines for viral and bacterial infections. Chiron sells these vaccines primarily in the U.S., Germany, Italy, and the United Kingdom, as well as in other international markets. The vaccines segment is also involved in the development of novel vaccines and vaccination technology. The biopharmaceuticals segment consists of therapeutic products and services, with an emphasis on the treatment of cancer and infectious and pulmonary diseases, using the development and acquisition of technologies related to therapeutic proteins, antibodies and small molecules. The biopharmaceuticals segment earns royalties on third party sales of several products, including BETAFERON® interferon



**CHIRON CORPORATION**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**March 31, 2005**  
**(Unaudited)**

**Note 10 Segment Information (Continued)**

beta-1b and earns license fees for technologies, such as hepatitis C virus-related patents, used by third parties to develop therapeutic products.

Revenues and expenses associated with Chiron's research and development activities specifically benefit each of the reportable segments and as such, have been included in the results of operations of the respective reportable segment.

Chiron views certain other revenues and expenses, particularly certain royalty and license fee revenues primarily related to HIV and hepatitis C virus related patents, and unallocated corporate expenses, as not belonging to any one reportable segment. As a result, Chiron has aggregated these items into an Other segment.

The accounting policies of Chiron's reportable segments are the same as those described in Chiron's Annual Report on Form 10-K for the year ended December 31, 2004. Chiron evaluates the performance of its segments based on each segment's income (loss) from continuing operations.

**CHIRON CORPORATION**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**March 31, 2005**  
**(Unaudited)**

**Note 10 Segment Information (Continued)**

The following segment information excludes all significant intersegment transactions as these transactions are eliminated for management reporting purposes (in thousands):

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2005</b>	<b>2004</b>
<i>Revenues</i>		
Blood-testing:		
Product sales, net:		
PROCLEIX® products	\$ 64,431	\$ 61,886
Ortho-Clinical Diagnostics	6,462	6,234
Total product sales, net	70,893	68,120
Revenues from joint business arrangement	36,058	30,361
Collaborative agreement revenues	1,882	2,064
Royalty and license fee revenues	25,204	16,434
Other revenues	76	195
Total blood-testing revenues	134,113	117,174
Vaccines:		
Product sales, net:		
Influenza vaccines	3,571	7,705
Meningococcus vaccines	9,153	4,549
Travel vaccines	43,759	23,010
Pediatric and other vaccines	30,493	51,182
Total product sales, net	86,976	86,446
Collaborative agreement revenues	2,242	3,966
Royalty and license fee revenues	1,416	2,650
Other revenues	3,276	3,643
Total vaccines revenues	93,910	96,705
Biopharmaceuticals:		
Product sales, net:		
BETASERON® interferon beta-1b	26,634	30,136
TOBI® tobramycin	52,935	52,524
PROLEUKIN® aldesleukin	29,535	31,868
Other	10,190	11,972
Total product sales, net	119,294	126,500
Collaborative agreement revenues	403	485
Royalty and license fee revenues	18,626	17,297
Other revenues	6,195	3,100
Total biopharmaceuticals revenues	144,518	147,382
Other:		
Royalty and license fee revenues	34,815	18,411
Total revenues	\$ 407,356	\$ 379,672
<i>Income (loss) from continuing operations</i>		
Blood-testing	\$ 74,359	\$ 63,640
Vaccines	(85,399 )	(50,039 )
Biopharmaceuticals	(6,108 )	19,249
Other	(8,612 )	(6,477 )
Segment (loss) income from operations	(25,760 )	26,373
Interest expense	(7,079 )	(5,925 )
Interest and other income, net	21,447	16,074
Minority interest	(530 )	(620 )
(Loss) income from continuing operations before income taxes	\$ (11,922 )	\$ 35,902



**CHIRON CORPORATION**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**March 31, 2005**

**(Unaudited)**

**Note 11 Commitments and Contingencies**

On October 5, 2004, the U.K. regulatory body, the Medicines and Healthcare products Regulatory Agency, or MHRA, sent Chiron a letter prohibiting us from releasing any FLUVIRIN<sup>®</sup> influenza vaccine doses manufactured at our Liverpool facility since March 2, 2004 and suspending our license to manufacture influenza virus vaccine in our Liverpool facility for three months (later extended for an additional three months). In that letter, the MHRA asserted that our manufacturing process did not comply with U.K. good manufacturing practices regulations. Following the MHRA's decision and an inspection by the Food and Drug Administration, or FDA, the FDA sent Chiron a warning letter citing violations of good manufacturing practices. Chiron provided the FDA with a written response to the warning letter on January 7, 2005. As a result of the suspension of Chiron's license, Chiron did not release any FLUVIRIN product during the 2004-2005 influenza season.

On March 2, 2005, the MHRA notified us that it had lifted the license suspension, giving Chiron clearance to initiate full production of FLUVIRIN<sup>®</sup> vaccine, conditioned on the understanding that Chiron's commitment to remediation will continue and will be subject to further inspections by the MHRA. The FDA is still expected to conduct a full inspection to determine whether deficiencies noted in the warning letter the FDA issued in December 2004 have been resolved. If Chiron fails to adequately address the matters discussed in the warning letter, the FDA may modify Chiron's U.S. license in an adverse manner, take action that could result in imposition of fines, require temporary or permanent cessation of future selling of FLUVIRIN vaccine or take other action that could reduce Chiron's ability to market FLUVIRIN vaccine.

Chiron received a grand jury subpoena issued by the U.S. Attorney's Office for the Southern District of New York in October 2004 requesting production of certain documents relating to FLUVIRIN vaccine and the suspension by the MHRA of our license. In February 2005, after having previously commenced an informal inquiry, the Securities and Exchange Commission, or SEC, notified Chiron that it would commence a formal investigation into whether Chiron or its employees have violated any federal securities laws in connection with these developments regarding FLUVIRIN vaccine, and in April 2005, Chiron received a subpoena from the SEC requesting production of certain documents relating to its Liverpool facility and FLUVIRIN vaccine. Chiron also received a voluntary request for information from the United States House of Representatives Committee on Energy and Commerce requesting production of certain documents. Numerous documents have been collected and produced in response to these requests, and several witnesses have been interviewed by the U.S. Attorney's Office and the SEC staff and additional interviews are anticipated. Additional investigations regarding these matters may arise. In addition, Chiron and certain of our officers and directors have also been named as defendants in several putative shareholder class action and derivative lawsuits alleging various claims arising out of or relating to these developments regarding FLUVIRIN vaccine. Chiron has been contacted by certain parties who may bring claims against us as a result of Chiron's inability to supply FLUVIRIN vaccine in the 2004-2005 season, including the U.S. Centers for Disease Control and Prevention and certain distributors of FLUVIRIN vaccine who have suggested that they are entitled to compensation under their contracts for the 2004-2005 season. It is not possible to predict whether any of these claims will be pursued and, if so, whether those claims will be upheld. Investigations, litigation and disputes have caused Chiron to incur substantial

**CHIRON CORPORATION**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**March 31, 2005**  
**(Unaudited)**

**Note 11 Commitments and Contingencies (Continued)**

expense, and have required significant time and attention from Chiron's management and will continue to do so in the future and could result in civil and/or criminal penalties against Chiron. The results of any such investigations, proceedings or disputes could have a material adverse effect on Chiron's consolidated financial position and results of operations and/or cash flow.

In addition to the investigations, inquiry and lawsuits related to the recent FLUVIRIN vaccine developments, Chiron is party to various claims, investigations and legal proceedings arising in the ordinary course of business. These claims, investigations and legal proceedings related to intellectual property rights, contractual rights and obligations, employment matters, claims of product liability and other issues. While it is possible that an adverse determination of any of such ordinary course matters could have a material adverse impact in any future period, management does not believe, based upon information known to it, that the final resolution of any these ordinary course matters will have a material adverse effect upon Chiron's consolidated financial position and results of operations or cash flows.

Chiron's tax filings are presently under examination in several domestic and international tax jurisdictions. While there is no assurance that Chiron will prevail in all tax examinations in the event the taxing authorities disagree with Chiron's interpretation of the tax law, Chiron's management does not believe, based upon information known to it, that the final resolution of any of these audits will have a material adverse effect upon Chiron's consolidated financial position and results of operations or cash flows. Adequate provisions have been made for these tax examinations.

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

***Forward-Looking Statements***

This Form 10-Q contains forward-looking statements regarding our expectations, hopes or intentions regarding the future, including statements relating to sales growth, product development initiatives, new product marketing, acquisitions, competition, and licensing activities that involve risks and uncertainties and are subject to change. The forward-looking statements contained in this Form 10-Q reflect our current expectations on the date of this Form 10-Q. Actual results, performance or outcomes may differ materially from current expectations. Our actual performance may differ from current expectations due to many factors, including additional adverse developments resulting from the suspension from October 5, 2004 through March 2, 2005 of Chiron's UK license to manufacture FLUVIRIN<sup>®</sup> influenza virus vaccine, the announcement of such suspension and the litigation and investigations relating to these matters, the outcome of clinical trials, regulatory review and approvals, manufacturing capabilities, intellectual property protections and defenses, stock price and marketing effectiveness. In particular, there can be no assurance that we will increase sales of existing products, successfully develop and receive approval to market new products, or achieve market acceptance for such new products. No assurances can be given that additional issues with respect to FLUVIRIN<sup>®</sup> vaccine or Chiron's manufacturing generally will not arise in the future, or that we will successfully address matters raised in a warning letter from the U.S. Food and Drug Administration with respect to our FLUVIRIN vaccine manufacturing facilities. There can be no assurance that our out-licensing activity will generate significant revenue, or that our in-licensing activities will fully protect us from claims of infringement by third parties. In addition, we may engage in business opportunities, the successful completion of which is subject to certain risks, including approval by Novartis, regulatory approvals and the integration of operations. We have discussed the important factors, which we believe could cause actual results to differ from what is expressed in the forward-looking statements, under the caption "Factors That May Affect Future Results" in this Form 10-Q. We do not undertake an obligation to update the forward-looking information contained in this Form 10-Q.

***Introduction***

We are a global biopharmaceutical company that participates in three healthcare markets: blood-testing, vaccines, and biopharmaceuticals. Our revenues consist of product sales, revenues from a joint business contractual arrangement, collaborative agreement revenues, royalty and license fee revenues, and other revenues, primarily consisting of contract manufacturing and grant revenues. Our research and development efforts are focused on developing products for cancer and infectious and pulmonary disease.

The blood-testing segment consists of an alliance with Gen-Probe and our one-half share in the pretax operating earnings generated by the joint business contractual arrangement with Ortho-Clinical Diagnostics. Our alliance with Gen-Probe is focused on developing and commercializing nucleic acid testing products using transcription-mediated amplification technology to screen donated blood and plasma products for viral infection. Our joint business arrangement with Ortho-Clinical Diagnostics is operated under a contractual arrangement and is not a separate and distinct legal entity. Through our joint business contractual arrangement with Ortho-Clinical Diagnostics, we sell a line of immunodiagnostic tests to detect hepatitis viruses and retroviruses and provide supplemental tests and microplate and chemiluminescent instrument systems to automate test performance and data collection. The blood-testing segment also earns royalties from third parties based on their sales of immunodiagnostic and nucleic acid testing probe diagnostic products utilizing our hepatitis C virus and HIV-related patents, for use in blood screening and plasma fractionation markets.

The vaccines segment consists of more than 20 pediatric and adult vaccines including influenza, meningococcal, travel and pediatric vaccines. We sell these vaccines primarily in the U.S., Germany, Italy and the United Kingdom, as well as in other international markets. Our vaccines segment is also involved

in the development of other novel vaccines and vaccination technology. We acquired a number of vaccines including FLUVIRIN® influenza virus vaccine as part of our July 8, 2003 acquisition of PowderJect.

The biopharmaceuticals segment consists of therapeutic products and services, with an emphasis on the treatment of cancer, infectious and pulmonary diseases. Our in-house capabilities span three types of therapeutics, including small molecules, therapeutic proteins and monoclonal antibodies. Our products include TOBI® (tobramycin solution for inhalation) for pseudomonal lung infections in cystic fibrosis patients, PROLEUKIN® (aldesleukin) for cancer (metastatic melanoma and renal cell carcinoma) and BETASERON® (interferon beta-1b) for multiple sclerosis. The biopharmaceuticals segment also includes collaborations with Berlex Laboratories, Inc. and its parent company, Schering AG of Germany, related to BETASERON® interferon beta-1b. The biopharmaceuticals segment earns royalties on third party sales of several products, including BETA FERON® interferon beta-1b, and earns license fees for technologies, such as hepatitis C virus-related patents, used by third parties to develop therapeutic products.

We view certain other revenues and expenses as not belonging to any one segment. As a result, we have aggregated these items into an Other segment.

#### ***FLUVIRIN® Influenza Virus Vaccine Recent Events***

During the third quarter of 2004, in conducting final internal release procedures for our FLUVIRIN influenza virus vaccine, our quality systems identified lots that did not meet product sterility specifications. As a result, we determined at that time to delay releasing any FLUVIRIN vaccine doses pending completion of internal investigations. On October 5, 2004, the U.K. regulatory body, the Medicines and Healthcare products Regulatory Agency, or MHRA, sent us a letter prohibiting us from releasing any FLUVIRIN® influenza vaccine doses manufactured at our Liverpool facility since March 2, 2004 and suspending our license to manufacture influenza virus vaccine in our Liverpool facility for three months (later extended for an additional three months). In that letter, the MHRA asserted that our manufacturing process did not comply with U.K. good manufacturing practices regulations. Following the MHRA's decision and an inspection by the Food and Drug Administration, or FDA, the FDA sent us a warning letter citing violations of good manufacturing practices. We provided the FDA with a written response to the warning letter on January 7, 2005. As a result of the suspension of our license, we did not release any FLUVIRIN product during the 2004-2005 influenza season.

On March 2, 2005, the MHRA notified us that it had lifted the license suspension, giving Chiron clearance to initiate full production of FLUVIRIN® vaccine, conditioned on the understanding that Chiron's commitment to its remediation plan will continue and will be subject to further inspections by the MHRA. The FDA is still expected to conduct a full inspection to determine whether deficiencies noted in the warning letter the FDA issued in December 2004 have been resolved. If we fail to adequately address the matters discussed in the warning letter, the FDA may modify our U.S. license in an adverse manner, take action that could result in imposition of fines, require temporary or permanent cessation of future selling of FLUVIRIN vaccine or take other action that could reduce our ability to market FLUVIRIN vaccine.

We received a grand jury subpoena issued by the U.S. Attorney's Office for the Southern District of New York in October 2004 requesting production of certain documents relating to FLUVIRIN vaccine and the suspension by the MHRA of our license. In February 2005, after having previously commenced an informal inquiry, the Securities and Exchange Commission, or SEC, notified us that it would commence a formal investigation into whether we or our employees have violated any federal securities laws in connection with these developments regarding FLUVIRIN vaccine, and in April 2005, we received a subpoena from the SEC requesting production of certain documents relating to our Liverpool facility and FLUVIRIN vaccine. We also received a voluntary request for information from the United States House of Representatives Committee on Energy and Commerce requesting production of certain documents.

Numerous documents have been collected and produced in response to these requests, and several witnesses have been interviewed by the U.S. Attorney's Office and the SEC staff and additional interviews are anticipated. Additional investigations regarding these matters may arise.

In addition, we and certain of our officers and directors have also been named as defendants in several putative shareholder class action and derivative lawsuits alleging various claims arising out of or relating to these developments regarding FLUVIRIN vaccine, including the U.S. Centers for Disease Control and Prevention and certain distributors of FLUVIRIN vaccine who have suggested that they are entitled to compensation under their contracts for the 2004-2005 season. It is not possible to predict whether any of these claims will be pursued and, if so, whether those claims will be upheld. Investigations, litigation and disputes have caused us to incur substantial expense and have required significant time and attention from our management and will continue to do so in the future and could result in civil and/or criminal penalties against Chiron. The results of any such investigations, proceedings or disputes could have a material adverse effect on our consolidated financial position and results of operations and/or cash flow.

Our inability to supply FLUVIRIN vaccine during the 2004-2005 influenza season may also lead to loss of market share in the 2005-2006 season and future seasons. Following the announcement of our license suspension, competitors announced plans to introduce influenza vaccine products in the United States and are seeking expedited regulatory approval to do so. Even though the license suspension has been lifted, some of our customers may choose to purchase flu vaccine from other providers as their products become available in the United States. Loss of market share could have a material adverse effect on our business and results of operations. We also expect to incur expenses in connection with ongoing FLUVIRIN vaccine matters, which could be material, including in connection with (1) our continuing remediation efforts at our Liverpool facility; and (2) responding to the U.S. Attorney for the Southern District of New York, the SEC, the United States House of Representatives Committee on Energy and Commerce and the private lawsuits and other claims and investigations that may arise.

For additional information concerning the risks we face as a result of these FLUVIRIN vaccine developments, see *Factors That May Affect Future Results*. The recent developments with respect to FLUVIRIN vaccine will harm our business and results of operations. For additional information on the U.S. Attorney's investigation, SEC investigation and private lawsuits and other claims, see Part II, Item 1. *Legal Proceedings* of this report on Form 10-Q.

#### ***Restated Second-Quarter and Third-Quarter 2004 Financial Statements***

During our 2004 year-end financial statement review and Section 404 Sarbanes-Oxley review, we determined that certain sales of the travel vaccine recorded as revenues in the second quarter of 2004 should not have been recorded as revenue at that time, and that portions of those sales should have been recorded as revenues in the third and fourth quarters of 2004 and possibly in later quarters. As a result, we restated the financial statements included in our Quarterly Reports on Form 10-Q for such quarters and filed amended Form 10-Q's for such quarters on April 6, 2005.

In light of the fact that we were already in contact with the SEC in relation to their investigation described above under *FLUVIRIN<sup>®</sup> Influenza Virus Vaccine Recent Events*, we informed the SEC of these matters, and adjustments we made after January 26, 2005 to the fourth quarter and full-year 2004 financial information we released on January 26, 2005, and have been providing the SEC information.



**Summary Consolidated Financial Data**

Following is an analysis and discussion of our operating results on a consolidated basis, which is followed by a description of our most critical accounting policies and use of estimates and more detailed analysis and discussion of our operating results by segment and our liquidity and capital resources.

	Three Months Ended March 31,		\$ Change Three Months	% Change Three Months
	2005	2004		
	(\$ in 000 s, except per share data)			
Product sales, net	\$ 277,163	\$ 281,066	\$ (3,903 )	(1.4 )%
Revenues from joint business arrangement	36,058	30,361	5,697	18.8 %
Royalty and license fee revenues	80,061	54,792	25,269	46.1 %
Total revenues	407,356	379,672	27,684	7.3 %
Gross profit margin	41 %	55 %		
Research and development expenses	109,839	98,410	11,429	11.6 %
Selling, general and administrative expenses	131,908	104,740	27,168	25.9 %
Income (loss) from continuing operations	(8,942 )	26,927	(35,869 )	(133.2 )%
Diluted earnings (loss) per share:				
Income (loss) from continuing operations	\$ (0.05 )	\$ 0.14	\$ (0.19 )	(135.7 )%

Loss from continuing operations was \$8.9 million or \$0.05 per diluted share for the three months ended March 31, 2005. Income from continuing operations was \$26.9 million or \$0.14 per diluted share for the three months ended March 31, 2004. For the first quarter 2005, we incurred \$16.0 million of FLUVIRIN vaccine remediation costs and \$10.0 million of legal costs associated with the FLUVIRIN vaccine-related developments. In addition, our Liverpool facility was not in flu production during the first quarter 2005, therefore idle facility costs increased by \$13.0 million as compared with the first quarter 2004. Total revenues were \$407.4 million and \$379.7 million for the three months ended March 31, 2005 and 2004, respectively. Revenues increased primarily due to increased royalty and license fee revenues and higher revenues from the joint business arrangement with Ortho-Clinical Diagnostics. The increase in total revenues was attributable in part to the movement in exchange rates, in particular the movements in the Euro and British Pound against the U.S. dollar. The movement in exchange rates added approximately 1.0% to our total revenues for the three months ended March 31, 2005. However, since our Euro and British Pound denominated expenses have also increased due to the movement in exchange rates, our loss per share from continuing operations increased \$0.01 per diluted share for the three months ended March 31, 2005, due to higher expenses compared to revenues denominated in Euros and British Pounds.

For the three months ended March 31, 2005, product sales decreased compared with the three months ended March 31, 2004 primarily due to declines in sales of pediatric and other vaccines, BETASERON<sup>®</sup> interferon beta-1b and PROLEUKIN<sup>®</sup> aldesleukin, offset by increases in sales of travel vaccines, Meningococcus vaccines and PROCLEIX<sup>®</sup> assays and systems, as discussed below.

Revenues from the joint business arrangement increased primarily due to higher profits from Ortho's foreign affiliates. Royalty and license fee revenues increased, primarily due to our September 2004 settlement agreement with Roche regarding our HIV patent in the US.

The decline in gross profit margins for the three months ended March 31, 2005 as compared with the three months ended March 31, 2004 was primarily due to \$13.0 million of increased idle facility costs as a result of the delay in commercial production of FLUVIRIN vaccine for the 2005-2006 season and \$16.0 million of FLUVIRIN vaccine remediation costs included in cost of sales for the three months ended March 31, 2005. Also, contributing to the decrease was planned idle facility time for Biopharmaceuticals manufacturing. Gross profit margins do not include amortization expense of intangible assets from acquired developed products related to business combinations.

The main components of the increase in research and development expenses for the three months ended March 31, 2005 as compared with the three months ended March 31, 2004 relate to development efforts in our oncology franchise, development of new processes and procedures in existing manufacturing facilities for BETAFERON interferon beta-1b, and development efforts for CUBICIN<sup>®</sup> (daptomycin for injection), tifacogin and blood-testing programs. This increase was partially offset by research and development programs that have been discontinued or disposed of prior to the first quarter of 2005.

The increase in selling, general and administrative expenses for the three months ended March 31, 2005 as compared with the three months ended March 31, 2004 was due partially to approximately \$10.0 million in legal expenses associated with the FLUVIRIN developments discussed above under "FLUVIRIN<sup>®</sup> Influenza Virus Vaccine Recent Events". The increase also reflects \$3.0 million due to the movement in the Euro and British Pound exchange rates. The remaining increase in selling, general and administrative expenses reflects a broad range of activities, significant among them on-going marketing and pre-launch programs to support the continued growth of our business, investment in geographic penetration and corporate governance costs.

The effective tax rate for the three months ended March 31, 2005 and 2004 was 25% of pretax income (loss) from continuing operations. The effective tax rate may be affected in future periods by changes in management's estimates with respect to our deferred tax assets and other items affecting the overall tax rate.

#### *Critical Accounting Policies and the Use of Estimates*

Our critical accounting policies, which incorporate our more significant judgments and estimates used in the preparation of our Condensed Consolidated Financial Statements are the same as those described in Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2004.

The preparation of financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, including those related to investments; inventories; derivatives; capital leases; intangible assets; goodwill; purchased in-process research and development; product discounts, rebates and returns; bad debts; collaborative, royalty and license arrangements; restructuring; pension and other post-retirement benefits; income taxes; and litigation and other contingencies. We base our estimates on historical experience and various other assumptions that we believe to be reasonable under the circumstances, the results of which form our basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from those estimates under different assumptions or conditions.

**Results of Operations****Blood-testing**

	Three Months Ended March 31,		\$ Change	% Change
	2005	2004	Three Months	Three Months
	(\$ in 000 s, except percentages)			
Product sales, net:				
PROCLEIX® products	\$ 64,431	\$ 61,886	\$ 2,545	4.1 %
Ortho-Clinical Diagnostics	6,462	6,234	228	3.7 %
	70,893	68,120	2,773	4.1 %
Revenue from joint business arrangement	36,058	30,361	5,697	18.8 %
Collaborative agreement revenues	1,882	2,064	(182 )	(8.8 )%
Royalty and license fee revenues	25,204	16,434	8,770	53.4 %
Other revenues	76	195	(119 )	(61.0 )%
Total blood-testing revenues	\$ 134,113	\$ 117,174	\$ 16,939	14.5 %
Gross profit margin	44 %	43 %		
Research and development expenses	\$ 7,804	\$ 5,109	\$ 2,695	52.8 %
Selling, general and administrative expenses	\$ 11,775	\$ 9,257	\$ 2,518	27.2 %

**Product sales**

**PROCLEIX® Products** On February 27, 2002, the U.S. Food and Drug Administration approved the PROCLEIX® HIV-1/ HCV Assay. We have marketed the PROCLEIX® HIV-1/HCV Assay in Europe since 1999. On January 15, 2004, the PROCLEIX® ULTRIO HIV-1/HCV/HBV Assay received European CE marking for use on the semi-automated PROCLEIX System, and on December 14, 2004 the PROCLEIX ULTRIO Assay received European CE marking for use on the fully automated, high throughput PROCLEIX®TIGRIS® System. Under a collaboration agreement with Gen-Probe, we market and sell the PROCLEIX® HIV-1/ HCV Assay, the PROCLEIX ULTRIO Assay and the related instrument system. In addition to selling directly in the U.S., we also sell in various international markets, directly and through distributors. We record revenue based upon the reported results obtained from the customer from the use of assays to screen donations or upon sale and delivery of the assays, depending on the underlying contract. In the case of equipment sales or leases, we record revenue upon the sale and transfer of the title of the instrument or ratably over the life of the lease term, respectively. For provision of service on the instruments, we recognize revenue ratably over the life of the service agreement.

The increase in product sales for the three months ended March 31, 2005 as compared with the three months ended March 31, 2004 was primarily due to \$3.9 million from price increases from the conversion to the PROCLEIX® ULTRIO HIV-1/HCV/HBV Assay from the PROCLEIX® HIV-1/HCV Assay and continued penetration into several markets abroad. This increase was offset by a decline of \$1.3 million from the U.S. market primarily due to decreased donations resulting in lower sales in the U.S. of the PROCLEIX® HIV-1/HCV Assay.

**Revenue from joint business arrangement** The increase in revenue from joint business arrangement for the three months ended March 31, 2005 as compared with the three months ended March 31, 2004 was primarily due to (i) \$8.5 million from an increase in profitability from Ortho-Clinical Diagnostics foreign affiliates and (ii) \$1.2 million from an increase in royalties. These increases were partially offset by \$4.0 million lower profits from Ortho-Clinical Diagnostics U.S. operations.

**Collaborative agreement revenues** Collaborative agreement revenues tend to fluctuate based on the amount and timing of research services performed, the status of projects under collaboration and the achievement of milestones. Due to the nature of our collaborative agreement revenues, results in any one period are not necessarily indicative of results to be achieved in the future. Our ability to generate



additional collaborative agreement revenues may depend, in part, on our ability to initiate and maintain relationships with potential and current collaborative partners.

**Royalty and license fee revenues** Our blood-testing segment earns royalties from third parties based on their sales of immunodiagnostic and nucleic acid testing probe diagnostic products utilizing our hepatitis C virus (HCV) and HIV-related (HIV) patents, for use in the blood screening and plasma fractionation markets. Our blood-testing segment also earns license fees related to our HCV and HIV patents for technologies used by third parties to develop products for use in the blood screening and plasma fractionation markets. The increase in royalty and license fee revenues for the three months ended March 31, 2005 as compared with the three months ended March 31, 2004 was primarily due to (i) \$5.3 million from the Roche settlement reached in September 2004 as discussed below under

Other Royalty and license fee revenues Roche Settlement , (ii) \$2.0 million for the remainder of the fee under our licensing agreement reached in 2004 with Laboratory Corporation of America Holdings (LabCorp) for our HCV intellectual property for nucleic acid testing (NAT) and (iii) \$0.7 million in royalty fees from the blood transfusion centers of the German Red Cross.

Royalty and license fee revenues may fluctuate based on the nature of the related agreements, the timing of receipt of license fees and the expiration of patents. Results in any one period are not necessarily indicative of results to be achieved in the future. Also, the license agreements typically provide for certain milestone payments and various royalties on future product sales if the licensee commercializes a product using our technology. However, we have no assurance that the licensee will meet their development objectives or commercialize a product using our technology. In addition, our ability to generate additional royalty and license fee revenues may depend, in part, on our ability to market and capitalize on our technologies.

**Gross profit margin** Gross profit margin was consistent for the three months ended March 31, 2005 as compared with the three months ended March 31, 2004.

Blood-testing gross profit margin may fluctuate in future periods as the blood-testing product and customer mix changes.

**Research and development** The increase in research and development expenses for the three months ended March 31, 2005 as compared with the three months ended March 31, 2004 was primarily due to \$2.6 million for research activities focused primarily on variant Creutzfeldt-Jakob disease (vCJD).

Research and development expenses may fluctuate from period to period depending upon the stage of certain projects and the level of pre-clinical and clinical trial-related activities.

**Selling, general, and administrative** The increase in selling, general and administrative expenses for the three months ended March 31, 2005 as compared with the three months ended March 31, 2004 was primarily due to (i) \$1.7 million from the geographic expansion of our customer base for the PROCLEIX<sup>®</sup> HIV-1/HCV Assay particularly in Latin America and Asia markets and (ii) \$0.7 million for the increase in technical training.

We expect continued growth in selling, general and administrative expenses related to nucleic acid testing technology and products as our sales opportunities expand in new markets through anticipated additional nucleic acid testing adoption.

*Vaccines*

	Three Months Ended March 31, 2005 2004 (\$ in 000 s, except percentages)		\$ Change Three Months	% Change Three Months
Product sales, net:				
Influenza vaccines:				
Other Influenza vaccines	\$ 3,571	\$ 5,260	\$ (1,689 )	(32.1 )%
FLUVIRIN vaccine		2,445	(2,445 )	(100.0 )%
Influenza vaccines	3,571	7,705	(4,134 )	(53.7 )%
Meningococcus vaccines	9,153	4,549	4,604	101.2 %
Travel vaccines	43,759	23,010	20,749	90.2 %
Pediatric and other vaccines	30,493	51,182	(20,689 )	(40.4 )%
	86,976	86,446	530	0.6 %
Collaborative agreement revenues	2,242	3,966	(1,724 )	(43.5 )%
Royalty and license fee revenues	1,416	2,650	(1,234 )	(46.6 )%
Other revenues	3,276	3,643	(367 )	(10.1 )%
Total vaccines revenues	\$ 93,910	\$ 96,705	\$ (2,795 )	(2.9 )%
Gross profit margin	(3 )%	33 %		
Research and development expenses	\$ 33,556	\$ 34,409	\$ (853 )	(2.5 )%
Selling, general and administrative expenses	\$ 39,462	\$ 39,003	\$ 459	1.2 %
Amortization expense	\$ 14,999	\$ 15,084	\$ (85 )	(0.6 )%

**Product sales** We sell influenza, meningococcal, travel, pediatric and other vaccines in the U.S., Germany, Italy, and the United Kingdom, as well as in other international markets.

*Influenza vaccines* As described above under FLUVIRIN® Influenza Virus Vaccine Recent Events, as a result of recent developments with respect to FLUVIRIN vaccine, we had no FLUVIRIN vaccine sales in the three months ended March 31, 2005. Sales of FLUVIRIN influenza vaccine were \$2.4 million for the three months ended March 31, 2004 from the 2003-2004 influenza season. Our other influenza vaccines decreased by \$1.7 million due to lack of sales for the southern hemisphere.

*Meningococcus vaccines* The increase in meningococcus vaccines sales for the three months ended March 31, 2005 as compared with the three months ended March 31, 2004 was primarily due to (i) \$4.8 million of MENZB meningococcal B vaccine sales to the Ministry of Health in New Zealand and (ii) \$1.8 million increase in tender sales of MENJUGATE® meningococcus C conjugate vaccine to Canada. This increase is partially offset by (i) a \$1.2 million decline in MENJUGATE® vaccine tender sales in Australia and (ii) \$0.8 million from a decline in MENJUGATE® vaccine sales to other countries.

*Travel vaccines* The increase in travel vaccines sales for the three months ended March 31, 2005 as compared with the three months ended March 31, 2004 was primarily due to (i) \$12.0 million increase in tick-borne encephalitis (TBE) vaccine sales in the first quarter of 2005; sales in the first quarter of 2004 were lower due to \$15.1 million of sales in the fourth quarter of 2003; TBE vaccines are typically sold in the first half of the year, (ii) \$7.9 million from increased demand for our rabies vaccines in the U.S., primarily due to a product recall from a competitor, and increased sales to Canada and (iii) \$3.7 million from increased demand for our rabies vaccines in Asia. These increases were offset by a decline of \$3.0 million in sales of Dukoral vaccine due to the divestiture in the second quarter of 2004 of certain vaccines operations in Sweden acquired in our acquisition of PowderJect.

*Pediatric and other vaccines* Sales of our pediatric and other vaccines decreased for the three months ended March 31, 2005 as compared with the three months ended March 31, 2004 primarily due to (i) \$8.7 million decline in Polio vaccine sales due to a lack of product availability as a result of



manufacturing upgrades that have delayed manufacturing, (ii) \$5.3 million decline due to the planned divestiture of certain vaccines operations in Sweden in the second quarter of 2004 acquired from our acquisition of PowderJect and (iii) \$2.3 million decline in measles, mumps and rubella vaccines sales due to a lack of product availability as a result of manufacturing upgrades that have delayed manufacturing.

Certain of our vaccine products are seasonal, particularly our influenza vaccines, which have higher sales primarily in the second half of the year. Our tick-borne encephalitis vaccine is also seasonal with higher sales typically in the first half of the year. Certain of our vaccines require regulatory approval for production or sale of the product and sales may fluctuate depending on these regulatory approvals. We expect increased competition for our influenza vaccines business in the future as a result of the recent FLUVIRIN vaccine developments. For more information on this, see *FLUVIRIN Influenza Virus Vaccine Recent Events* above. In addition, we expect MENJUGATE meningococcus C conjugate vaccine sales to continue to fluctuate as public health authorities consider adoption of broad vaccination programs and competitive pressures continue to increase.

**Collaborative agreement revenues** We recognize collaborative agreement revenues for fees received as we perform research services and achieve specified milestones. Collaborative agreement revenues for the three months ended March 31, 2005 as compared with the three months ended March 31, 2004 decreased primarily due to \$1.0 million in lower milestone payments related to an agreement to supply MENZB meningococcal B vaccine to the Ministry of Health in New Zealand.

Collaborative agreement revenues tend to fluctuate based on the amount and timing of research services performed, the status of projects under collaboration and the achievement of milestones. Due to the nature of our collaborative agreement revenues, results in any one period are not necessarily indicative of results to be achieved in the future. In addition, the collaboration agreements typically provide for certain milestone payments and various royalties on future product sales if the collaborative partners commercialize a product using our technology. Also, our ability to generate additional collaborative agreement revenues may depend, in part, on our ability to initiate and maintain relationships with potential and current collaborative partners.

**Royalty and license fee revenues** Our vaccines segment earns royalties on third party sales of, and license fees on, several products.

*GlaxoSmithKline* An agreement with GlaxoSmithKline plc provides for royalties on sales of certain vaccine products. Under this agreement, royalties were \$0.9 million and \$1.9 million for the three months ended March 31, 2005 and 2004, respectively. This decrease was primarily due to lower sales and royalty rates.

The balance of royalty and license fee revenues recognized in our vaccines segment consisted of various other arrangements, which individually were not material.

Royalty and license fee revenues may fluctuate based on the nature of the related agreements, the timing of receipt of license fees and the expiration of patents. Results in any one period are not necessarily indicative of results to be achieved in the future. Also, the license agreements typically provide for certain milestone payments and various royalties on future product sales if the licensees commercialize a product using our technology. However, we have no assurance that the licensee will meet their development objectives or commercialize a product using our technology. In addition, our ability to generate additional royalty and license fee revenues may depend, in part, on our ability to market and capitalize on our technologies.

#### **Other revenues**

Other revenues recognized in our vaccines segment did not fluctuate significantly for the three months ended March 31, 2005 as compared with the three months ended March 31, 2004. Other revenues



recognized in our vaccines segment primarily consist of grant revenues and contract manufacturing revenues and may fluctuate due to the nature of the revenues recognized and the timing of events giving rise to these revenues.

**Gross profit margin** Gross profit margin decreased for the three months ended March 31, 2005 as compared with the three months ended March 31, 2004 primarily due to \$16.0 million of FLUVIRIN vaccine remediation costs charged to cost of sales and \$13.0 million increase in idle facility costs charged to cost of sales as our Liverpool facility was not in FLUVIRIN vaccine production during the first quarter of 2005 due to FLUVIRIN vaccine remediation activities.

Vaccines gross profit margin does not include amortization expense of intangible assets from acquired developed products related to business combinations. Such amortization expense is included in the caption amortization expense of intangible assets acquired in business combinations and asset purchases .

Vaccines gross profit margin may fluctuate significantly in future periods due to product and customer mix, seasonality and ordering patterns, production yields, regulatory approvals and competitive pressures.

**Research and development** The decrease in research and development expenses for the three months ended March 31, 2005 as compared with the three months ended March 31, 2004 was primarily due to the second quarter 2004 divestiture of certain research and development operations, acquired in the acquisition of PowderJect. The divested operations included \$4.2 million in research and development expenses for the three months ended March 31, 2004. This decrease was partially offset by an increase of \$1.7 million from our flu cell culture development program.

Research and development expenses may fluctuate from period to period depending upon the stage of certain projects and the level of pre-clinical and clinical trial-related activities.

**Selling, general, and administrative** The increase in selling, general and administrative expenses for the three months ended March 31, 2005 as compared with the three months ended March 31, 2004 was due to (i) an additional \$2.3 million from the establishment of sales and marketing operations in the U.S., (ii) \$1.7 million for executive severance and (iii) \$2.0 million due to the movement in the Euro and British pound to U.S. Dollar exchange rate. These increases were partially offset by a reduction of \$2.0 million as a result of the planned divestiture of certain PowderJect operations in the second quarter 2004 and (iii) \$1.5 million from the recovery of bad debt.

**Biopharmaceuticals**

	Three Months Ended March 31, 2005		2004		\$ Change Three Months	% Change Three Months
	(\$ in 000 s, except percentages)					
<b>Product sales, net:</b>						
BETASERON <sup>®</sup> interferon beta-1b	\$	26,634	\$	30,136	\$ (3,502 )	(11.6 )%
TOBI <sup>®</sup> tobramycin		52,935		52,524	411	0.8 %
PROLEUKIN <sup>®</sup> aldesleukin		29,535		31,868	(2,333 )	(7.3 )%
Other		10,190		11,972	(1,782 )	(14.9 )%
		119,294		126,500	(7,206 )	(5.7 )%
Collaborative agreement revenues		403		485	(82 )	(16.9 )%
Royalty and license fee revenues		18,626		17,297	1,329	7.7 %
Other revenues		6,195		3,100	3,095	99.8 %
Total biopharmaceutical revenues	\$	144,518	\$	147,382	\$ (2,864 )	(1.9 )%
Gross profit margin		72 %		76 %		
Research and development expenses	\$	67,729	\$	58,567	\$ 9,162	15.6 %
Selling, general and administrative expenses	\$	37,897	\$	31,926	\$ 5,971	18.7 %
Amortization expense	\$	6,264	\$	6,248	\$ 16	0.3 %

**Product sales** Biopharmaceutical product sales in 2005 and 2004 consisted principally of BETASERON<sup>®</sup> interferon beta-1b, TOBI<sup>®</sup> tobramycin and PROLEUKIN<sup>®</sup> aldesleukin products.

*BETASERON<sup>®</sup> interferon beta-1b* We manufacture interferon beta-1b, which is marketed by Schering AG and its affiliates, including Berlex Laboratories, Inc. (collectively, Schering), under the trade names BETASERON<sup>®</sup> (in the U.S and other non-European markets) and BETAFERON<sup>®</sup> (in Europe). Boehringer Ingelheim also supplies BETAFERON<sup>®</sup> interferon beta-1b to Schering for sale in Europe. For product we manufacture, we recognize a portion of revenue for product sales upon shipment to Schering and the remainder based on a contractual percentage of sales by Schering, both of which we record as product sales. For product manufactured by Boehringer Ingelheim and marketed by Schering in Europe under the trade name BETAFERON<sup>®</sup>, we receive royalties calculated at the same percentage of sales less the amount paid or incurred by Schering for supply costs, which we record in royalty and license fee revenues.

The decrease in BETASERON<sup>®</sup> product sales for the three months ended March 31, 2005 as compared with the three months ended March 31, 2004 primarily related to (i) \$3.6 million from reduced shipments to Berlex and (ii) \$1.0 million from inventory ordering patterns. These decreases were partially offset by (i) \$0.6 million from price increases and (ii) \$0.6 million from the change in foreign exchange rates.

*TOBI<sup>®</sup> tobramycin solution for inhalation* We sell TOBI<sup>®</sup> solution directly in the U.S. and certain international markets. The increase in sales for the three months ended March 31, 2005 as compared with the three months ended March 31, 2004 was primarily due to (i) \$2.9 million due to price increases, (ii) \$1.3 million due to increased patient demand in the U.S. and (iii) \$0.8 million due to the benefit of the movement in the Euro to U.S. Dollar exchange rate. These increases were partially offset by \$4.6 million reduction due to wholesaler ordering patterns.

*PROLEUKIN<sup>®</sup> (aldesleukin)* The decrease in sales for PROLEUKIN (aldesleukin) for the three months ended March 31, 2005 as compared with the three months ended March 31, 2004 was primarily due to (i) \$1.9 million due to a decrease in patient demand as a result of increased competition and (ii) \$1.2 million for wholesaler inventory ordering patterns. These decreases were partially offset by (i) \$0.8 million for price increases and (ii) \$0.4 million due to the benefit of the movement in the Euro to U.S. Dollar exchange rate.



The balance of product sales recognized in our biopharmaceuticals segment consisted of various other products, which individually were not material.

Wholesale ordering patterns, reimbursement and government pressures, competition, foreign currency exchange rates and the level of rebates may influence future biopharmaceutical sales.

**Collaborative agreement revenues** We recognize collaborative agreement revenues for fees received as we perform research services and achieve specified milestones.

Collaborative agreement revenues tend to fluctuate based on the amount and timing of research services performed, the status of projects under collaboration and the achievement of milestones. Due to the nature of our collaborative agreement revenues, results in any one period are not necessarily indicative of results to be achieved in the future. In addition, the collaboration agreements typically provide for certain milestone payments and various royalties on future product sales if the collaborative partners commercialize a product using our technology. Also, our ability to generate additional collaborative agreement revenues may depend, in part, on our ability to initiate and maintain relationships with potential and current collaborative partners.

**Royalty and license fee revenues** Our biopharmaceuticals segment earns royalties on third party sales of several products, including BETA FERON<sup>®</sup> interferon beta-1b and recombinant insulin and glucagon products. Our biopharmaceuticals segment also earns license fees for technologies, such as hepatitis C virus-related patents, used by third parties to develop therapeutic products.

*BETA FERON<sup>®</sup> interferon beta-1b* BETA FERON product royalties were \$15.5 million and \$13.8 million for the three months ended March 31, 2005 and 2004, respectively.

The increase in BETA FERON<sup>®</sup> product royalties for the three months ended March 31, 2005 as compared with the three months ended March 31, 2004 was primarily due to (i) \$0.8 million due to favorable movement in the Euro to U.S. Dollar exchange rate, (ii) \$0.4 million from price increases and (iii) \$0.2 million from an increase in demand.

The balance of royalty and license fee revenues recognized in our biopharmaceuticals segment consisted of various other agreements, which individually were not material.

Royalty and license fee revenues may fluctuate based on the nature of the related agreements, the timing of receipt of license fees and the expiration of patents. Results in any one period are not necessarily indicative of results to be achieved in the future. Also, the license agreements typically provide for certain milestone payments and various royalties on future product sales if the licensees commercialize a product using our technology. However, we have no assurance that the licensees will meet their development objectives or commercialize a product using our technology. In addition, our ability to generate additional royalty and license fee revenues may depend, in part, on our ability to market and capitalize on the value of our technologies.

#### **Other revenues**

*Contract manufacturing revenues* Our biopharmaceuticals segment recognized contract manufacturing revenues of \$6.1 million and \$2.8 million for the three months ended March 31, 2005 and 2004, respectively. The fluctuation resulted from the timing of contract manufacturing activities.

The balance of other revenues recognized in our biopharmaceuticals segment consisted of various other arrangements, which individually were not material.

Other revenues recognized in our biopharmaceuticals segment may fluctuate due to the nature of the revenues recognized and the timing of events giving rise to these revenues. There can be no assurance that we will be successful in obtaining additional revenues or that these revenues will not decline.



**Gross profit margin** The decrease in gross profit margin for the three months ended March 31, 2005 as compared with the three months ended March 31, 2004 was primarily due to a planned increase in idle time for manufacturing facilities.

Biopharmaceutical gross profit margin does not include amortization expense of intangible assets from acquired developed products related to business combinations. Such amortization expense is included in the caption amortization expense of intangible assets acquired in business combinations and asset purchases .

Biopharmaceutical gross profit margin may fluctuate significantly in future periods due to production yields, increased cost to produce the BETASERON® pre-filled diluent syringe and as the biopharmaceutical product and customer mix changes.

**Research and development expense** The increase in research and development expenses for the three months ended March 31, 2005 as compared with the three months ended March 31, 2004 was primarily due to (i) \$3.4 million increase in expense related to the development of new processes and performance of test runs related to installed equipment of our existing manufacturing facilities to support the supply of BETAFERON® interferon beta-1b to Schering, (ii) \$2.5 million for development activities related to CUBICIN® (daptomycin for injection) for treatment of complicated skin and soft tissue infections, (iii) \$2.1 million for activities related to the development of tifacogin, (iv) \$1.9 million for the progression of phase 1 clinical studies of our oncology compound CHIR-258 and (v) \$3.5 million for research and early stage development activities, primarily related to oncology compounds. These increases are partially offset by (i) a \$2.3 million decrease related to the discontinued development of tezacitabine in the first quarter of 2004 based on an analysis of the data from a Phase II trial in patients with gastro esophageal cancer and (ii) \$1.9 million decrease in expenses related to the SILCAAT trial.

Research and development expenses may fluctuate from period to period depending upon the stage of certain projects and the level of pre-clinical and clinical trial-related activities.

**Selling, general, and administrative expense** The increase in selling, general and administrative expenses for the three months ended March 31, 2005 as compared with the three months ended March 31, 2004 was primarily due to (i) \$1.9 million of pre-launch costs for CUBICIN (daptomycin for injection), (ii) \$1.4 million for increased TOBI sales and marketing activities, (iii) \$0.9 million of pre-launch costs for PULMINIQ (cyclosporine, USP) inhalation solution, (iv) \$1.0 million for increased marketing and medical activities in Europe and other international markets and (v) \$0.4 million due to movement in the Euro to U.S. Dollar exchange rate.

#### Other

We view certain other revenues and expenses, particularly certain royalty and license fee revenues primarily related to HIV and HCV-related patents, and unallocated corporate expenses, as not belonging to any one reportable segment. As a result, we have aggregated these items into an Other segment.

	Three Months Ended March 31, 2005	Three Months Ended March 31, 2004	\$ Change Three Months	% Change Three Months
	(\$ in 000 s, except percentages)			
Royalty and license fee revenues	\$ 34,815	\$ 18,411	\$ 16,404	89.1 %
Selling, general and administrative expenses	42,774	24,554	18,220	74.2 %
Interest expense	7,079	5,925	1,154	19.5 %
Interest and other income, net	21,447	16,074	5,373	33.4 %

**Royalty and license fee revenues** Our other segment earns royalties on third party sales of, and license fees on, several products. The majority of royalty and license fee revenues related to the use of our HCV and HIV-related patents for diagnostic testing purposes by various third parties.



*Roche settlement* In October 2000, we entered into three license agreements with Roche and several of its affiliated companies related to the settlement of certain litigation in the U.S. and certain other countries for use of our HCV and HIV nucleic acid testing intellectual property. Two agreements relate to *in vitro* diagnostics products. The third agreement relates to blood screening.

Under the hepatitis C virus agreement, we received \$85.0 million, of which we recognized \$40.0 million in the fourth quarter 2000. We deferred the remaining \$45.0 million, which becomes nonrefundable ratably through 2005. In the first quarter 2001, we began recognizing portions of the \$45.0 million based upon the greater of (i) the scheduled quarterly minimum non-refundable amount or (ii) the actual earned credits as royalties on future sales related to Roche's use of our HCV-related patent in its *in vitro* diagnostic products. The agreement also provides for royalties on future sales related to Roche's use of our HCV-related patent in its *in vitro* diagnostic products, which commenced in the first quarter 2001. Royalty revenues under the hepatitis C virus agreement increased for the three months ended March 31, 2005 as compared with the three months ended March 31, 2004, by \$1.8 million and 15.2%.

The HIV agreement also provides for royalties on future sales related to Roche's use of our HIV-related patent in its *in vitro* diagnostic products, which commenced in the first quarter 2001 when the European Patent Office Board of Technical Appeals upheld our HIV-related patent. Royalty revenues recognized under this agreement increased by \$11.1 million for the three months ended March 31, 2005 as compared with the three months ended March 31, 2004. This increase is mainly due to a settlement agreement with Roche, described in more detail below, under which we recognized revenues for a portion of a nonrefundable royalty payment.

An HIV-related patent directed to nucleic acid testing methods for HIV-1 was issued in the U.S. on March 13, 2003. This patent will expire seventeen years from the date of issuance. The issuance of the patent triggered a milestone payment to us of \$10.0 million from Roche, which was received in April 2003. As permitted under the terms of its licensing agreement, Roche decided to institute arbitration proceedings in regard to the application of the U.S. patent. We had deferred recognition of the \$10.0 million milestone payment, interest, royalties received and royalties accrued under the patent until the resolution of this dispute. On September 10, 2004, we reached a settlement agreement with Roche. Under the terms of the settlement agreement, the milestone payment along with any royalties received prior to March 31, 2004 became non-refundable. Accordingly, during the third quarter 2004, we recognized \$10.0 million in license fees and \$21.8 million in royalties up until June 30, 2004, which had previously been deferred, of which \$16.3 million has been recognized as revenue in our other segment and \$5.5 million has been recognized as revenue in our blood testing segment. During the third quarter 2004, we also recognized \$0.8 million in interest on the license fee. Also under the settlement agreement, in the first quarter of 2005, we received a lump-sum payment of \$78.0 million in lieu of royalties beyond January 1, 2005. Roche may elect under the terms of the agreement to obtain a partial refund and revert to paying royalties on the sales of its products in North America. The amount of such potential refund ranges between \$64.0 million and \$0.0 million. The amount of the refund available decreases in increments over the quarters of 2005 and 2006. As such, Chiron expects to recognize \$64.0 million of the payment as revenue over 2005 and 2006. The remaining \$14.0 million is nonrefundable and was recognized as revenue in the third quarter 2004, of which, \$9.3 million has been recognized as revenue in our other segment and \$4.7 million has been recognized as revenue in our blood-testing segment. Currently, the applicable issued HCV-related patents expire in 2015 for the U.S. and in 2010 for Europe. Currently, the applicable issued HIV-related patent in Europe expires in 2005. For the three months ended March 31, 2005, we recognized \$10.7 million of revenue for this settlement in our other segment and \$5.3 million of revenue for this settlement in our blood-testing segment. Revenues earned from diagnostic products are included in our other segment and revenues earned from blood screening are included in our blood-testing segment.



*Bayer* A cross-license agreement provides for royalties to us on HIV and hepatitis C virus products sold by Bayer Corporation. Royalties increased for the three months ended March 31, 2005 as compared with the three months ended March 31, 2004 due to a fee of \$1.8 million for a license agreement in the first quarter of 2005.

The balance of royalty and license fee revenues consisted of various other agreements, which individually were not material.

Royalty and license fee revenues may fluctuate based on the nature of the related agreements, the timing of receipt of license fees and the expiration of patents. Results in any one period are not necessarily indicative of results to be achieved in the future. In addition, our ability to generate additional royalty and license fee revenues may depend, in part, on our ability to market and capitalize on our technologies.

**Selling, general, and administrative** The increase in selling, general and administrative expenses for the three months ended March 31, 2005 as compared with the three months ended March 31, 2004 was primarily due to (i) \$10.0 million of legal costs associated with the FLUVIRIN vaccine-related developments discussed above under FLUVIRIN<sup>®</sup> Influenza Virus Vaccine Recent Events, (ii) \$3.7 million in employee related expenses, (iii) \$2.2 million in consulting expenses and (iv) \$1.6 million for corporate governance costs. These increases were offset by lower facility and depreciation expenses of \$3.2 million.

**Interest expense** The increase in interest expense for the three months ended March 31, 2005 as compared with the three months ended March 31, 2004 primarily related to interest expense recognized on the \$385.0 million convertible debentures that were issued on June 22, 2004 partially offset by the interest expense recognized on the Liquid Yield Option Notes (LYONs), which were put to us in June 2004. The \$385.0 million convertible debentures incur interest at a higher rate than the LYONs.

**Interest and other income, net** Interest and other income, net, primarily consisted of interest income on our cash and investment balances and other non-operating gains and losses. We recognized interest income of \$7.2 million and \$5.1 million for the three months ended March 31, 2005 and 2004, respectively. The increase is due to higher interest rates in the first quarter 2005 as compared with the first quarter 2004.

We recognized gains of \$14.5 million and \$9.7 million for the three months ended March 31, 2005 and 2004, respectively, related to the sale of certain equity securities. The increase is due to the expiration of certain equity forward contracts.

On December 31, 1998, we completed the sale of our 30% interest in General Injectibles & Vaccines, Inc., a distribution business, to Henry Schein, Inc. and received payment in full of certain advances we made to General Injectibles & Vaccines. The agreement also provided for us to receive additional payments, calculated as a pre-determined percentage of Henry Schein's gross profit, through 2003. We received \$3.5 million for 2003 during the three months ended March 31, 2004.

**Income taxes** The effective tax rate for the three months ended March 31, 2005 and 2004 was 25% of pretax income (loss) from continuing operations. The effective tax rate may be affected in future periods by changes in management's estimates with respect to our deferred tax assets and other items affecting the overall tax rate.

**Discontinued operations** In a strategic effort to focus on our core businesses of blood-testing, vaccines and biopharmaceuticals, we completed the sale of Chiron Diagnostics to Bayer in 1998.

Chiron and Bayer Corporation, or Bayer, were involved in a dispute with respect to their respective rights to certain royalty refunds receivable for which a settlement was reached in 2004. Under this settlement agreement, we made a settlement payment to Bayer in 2004. This settlement includes an agreement that all outstanding items with Bayer related to the sale of Chiron Diagnostics are resolved and no future indemnity obligations are required. We released previously established reserves deemed to be in



excess following this settlement. This settlement resulted in a net gain of \$12.8 million for the three months ended March 31, 2004. This net gain primarily relates to a tax benefit as a result of the settlement payment to Bayer.

### **New Accounting Pronouncements**

In December 2004, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment* (SFAS 123(R)), which requires the cost resulting from all share-based payment transactions to be recognized in the consolidated financial statements. That cost will be measured based on the fair value of the equity instruments issued or on the fair value of liabilities incurred. Under SFAS 123(R), the fair-value-based method for recognition or disclosure of compensation expense will be applied using the modified prospective application transition method or the modified retrospective application transition method. We currently measure compensation expense for our stock-based employee compensation under the intrinsic method. We are currently evaluating transition methods, option valuation methodologies and assumptions in light of SFAS 123(R), and therefore cannot estimate the impact of our adoption at this time, although we expect that its adoption will have a material impact on our consolidated financial statements. Current option values determined using the Black-Scholes-Merton formula, used for purposes of proforma disclosure, may not be indicative of results from the valuation methodologies we finally adopt. The effective date of SFAS 123(R) is the first reporting period beginning after June 15, 2005. However, on April 14, 2005, the Securities and Exchange Commission (SEC) announced the adoption of a new rule that amends the compliance date of SFAS 123(R). The SEC's new rule allows calendar year companies to implement SFAS 123(R) at the beginning of 2006, which makes SFAS 123(R) effective for Chiron in the first quarter of 2006.

On October 22, 2004, the American Jobs Creation Act of 2004 (the Act) was signed into law. The Act includes a temporary incentive for U.S. multinationals to repatriate accumulated income earned outside the U.S. at an effective tax rate of 5.25%. On December 21, 2004, the FASB issued Staff Position 109-2, *Accounting and Disclosure Guidance for the Foreign Earnings Repatriation Provisions within the American Jobs Creation Act of 2004* (FSP 109-2). FSP 109-2 allows companies additional time to evaluate the effect of the law on whether unrepatriated foreign earnings continue to qualify for SFAS No. 109's exception to recognizing deferred tax liabilities and would require explanatory disclosures from those who need the additional time. Through March 31, 2005, we have not provided deferred taxes on foreign earnings because such earnings were intended to be indefinitely reinvested outside the U.S. Whether we will ultimately take advantage of this provision depends on a number of factors including reviewing future Congressional and regulatory guidance before a decision can be made. Until that time, we will make no change in our current intention to indefinitely reinvest accumulated earnings of our foreign subsidiaries. If we repatriate these earnings, a one-time tax charge to our consolidated results of operations could occur. We will continue to evaluate the impact of this provision in 2005.

### **Liquidity and Capital Resources**

Our capital requirements have generally been funded by cash flow from operations, borrowings from commercial banks and issuance of convertible debt securities and common stock. Our cash, cash equivalents and investments in marketable debt securities, which totaled \$1,032.3 million at March 31, 2005, are invested in a diversified portfolio of fixed income securities, including money market instruments, corporate notes and bonds, and government agency securities issued by financial institutions and other issuers with strong credit ratings. By policy, the amount of credit exposure to any one institution is limited. Investments are generally not collateralized and primarily mature within three years.

The recent events regarding FLUVIRIN vaccine, as discussed above, will continue to impact our cash flow going forward. As we continue to implement our remediation plan, our efforts will entail additional cash payments, which will be material. The MHRA's lifting of our license suspension is conditioned upon the understanding that our commitment to remediation will continue.

In addition, we have incurred and expect to continue to incur substantial expense relating to the investigation by the U.S. Attorney's Office for the Southern District of New York, the Securities and Exchange Commission formal investigation and the shareholder class action and derivative private lawsuits and other claims arising out of or related to these developments regarding FLUVIRIN vaccine. The results of any such investigations, proceedings or disputes could have a material adverse effect on our cash flow.

Furthermore, our inability to supply FLUVIRIN vaccine for the 2004-2005 season may also lead to loss of market share because competitors have announced plans to introduce influenza vaccine products in the United States during the 2005-2006 season and are seeking expedited regulatory approval to do so. Even though the license suspension has been lifted, some of our customers may choose to purchase flu vaccine from other providers as their products become available in the United States. Loss of market share could have a material adverse effect on cash flow.

For additional information concerning the risks we face as a result of these FLUVIRIN vaccine developments, see *Factors That May Affect Future Results*. The recent developments with respect to FLUVIRIN<sup>®</sup> vaccine will harm our business and results of operations. For additional information on the U.S. Attorney's investigation, SEC investigation, private lawsuits and other claims arising out of or relating to the developments regarding FLUVIRIN, see Part II, Item 1. *Legal Proceedings* of this Report on Form 10-Q.

Under the terms of the Investment Agreement between Novartis and Chiron, Novartis agreed to guarantee certain Chiron obligations up to a maximum of \$702.5 million. Under this agreement, Novartis has guaranteed \$100.0 million under a U.S. credit facility in which there were no borrowings outstanding at March 31, 2005 and \$173.3 million from a lease commitment for a research and development facility in Emeryville, California.

We believe that our cash, cash equivalents and marketable debt securities, together with funds provided by operations and borrowing and leasing arrangements, will be sufficient to meet our foreseeable operating cash requirements including any cash needed for remediation efforts for our Liverpool plant, cash utilized for our stock repurchase program and our current contractual obligations. In addition, we believe we could access additional funds from the debt and capital markets should the need arise. As noted above, if we suffer a permanent loss of FLUVIRIN influenza vaccine sales, whether through loss of regulatory approvals, market share or otherwise, it would have a material adverse effect on our cash flow.

**Sources and uses of cash** We had cash and cash equivalents of \$198.8 million and \$259.1 million at March 31, 2005 and 2004, respectively.

*Operating activities* For the three months ended March 31, 2005, net cash provided by operating activities was \$57.2 million as compared with \$11.1 million for the three months ended March 31, 2004. The increase in cash provided by operating activities was primarily due to (i) \$78.0 million lump-sum payment received in lieu of royalties beyond January 1, 2005 as part of the Roche settlement reached on September 10, 2004. This increase was partially offset by costs associated with our remediation efforts for our Liverpool plant and legal costs related to the FLUVIRIN vaccine developments discussed above.

*Investing activities* For the three months ended March 31, 2005, net cash used in investing activities consisted of purchases of investments in marketable debt securities of \$321.6 million, capital expenditures of \$48.4 million, other uses of cash of \$1.8 million, purchases of equity securities and interests in affiliated companies of \$1.6 million and cash paid for acquisitions net of cash acquired of \$1.3 million. Included in net cash paid for acquisitions was \$1.1 million for previously accrued costs in connection with acquisition costs related to the acquisition of PowderJect and \$0.2 million of cash paid for the acquisition of Sagres. Cash used in investing activities was offset by proceeds from maturities of investments in marketable debt securities of \$249.7 million, proceeds from sales of investments in marketable debt securities of \$37.5 million, and proceeds from the sale of equity securities and interests in affiliated companies of \$8.3 million.

For the three months ended March 31, 2004, net cash used in investing activities consisted of purchases of investments in marketable debt securities of \$202.9 million, capital expenditures of \$44.6 million, purchases of equity securities and interests in affiliated companies of \$2.4 million, cash paid for direct PowderJect acquisition costs of \$1.0 million and other uses of cash of \$0.8 million. Cash used in investing activities was offset by proceeds from sales of investments in marketable debt securities of \$30.6 million, proceeds from maturities of investments in marketable debt securities of \$78.9 million and proceeds from the sale of equity securities and interests in affiliated companies of \$3.5 million.

*Financing activities* For the three months ended March 31, 2005, net cash provided by financing activities consisted of \$10.0 million of proceeds from the reissuance of treasury stock offset by \$0.06 million for the repayment of debt and capital leases.

On March 10, 2005, the Board of Directors authorized Chiron to repurchase 5.0 million shares of Chiron common stock through December 31, 2005. From January 1, 2005 through March 31, 2005, no shares were repurchased.

For the three months ended March 31, 2004 net cash provided by financing activities consisted of \$35.6 million of proceeds from the reissuance of treasury stock and \$1.0 million of proceeds from the issuance of debt. Cash provided by financing activities was offset by \$8.5 million for the acquisition of treasury stock, \$0.08 million for the repayment of debt and capital leases.

From time to time, we evaluate a number of business development opportunities. To the extent that we are successful in reaching agreements with third parties, these transactions may involve selling a significant portion of our current investment portfolio, incurring additional debt or issuing additional Chiron shares.

**Borrowing arrangements** Under a revolving, committed, uncollateralized credit agreement with a major financial institution, we can borrow up to \$100.0 million. This credit facility is guaranteed by Novartis AG under a November 1994 Investment Agreement, provides various interest rate options and matures in February 2006. There were no borrowings outstanding under this credit facility at March 31, 2005 and December 31, 2004. In July 2003, we entered into a new six-year lease to rent a research and development facility in Emeryville, California. Under provisions of the November 1994 Investment Agreement, Novartis AG guaranteed payments on this lease commitment to a maximum of \$173.3 million. In December 1999, Chiron and Novartis amended the November 1994 Investment Agreement to reduce the maximum amount of our obligations that Novartis would guarantee from \$725.0 million to \$702.5 million. Out of the maximum guarantee of \$702.5 million, the credit agreement and lease discussed above have reduced the amount of our debt Novartis would be required to guarantee by \$273.3 million. There remains \$429.2 million of the guarantee available at March 31, 2005. The Novartis loan guarantee will expire on January 1, 2008 unless certain debt ratings are triggered which would extend the guarantee on a declining basis ratably over the subsequent three-year period.

#### **Off-Balance Sheet Arrangements**

As of March 31, 2005, we did not have any off-balance sheet arrangements.

#### **Factors That May Affect Future Results**

As a global biopharmaceutical company, we are engaged in a rapidly evolving and often unpredictable business. The forward-looking statements contained in this Form 10-Q and in other periodic reports, press releases and other statements issued by us from time to time reflect our current beliefs and expectations concerning objectives, plans, strategies, future performance and other future events. The following discussion highlights some of the factors, many of which are beyond our control, which could cause actual results to differ.

*The recent developments with respect to FLUVIRIN<sup>®</sup> vaccine will harm our business and results of operations.*

During the third quarter of 2004, in conducting final internal release procedures for our FLUVIRIN influenza virus vaccine, our quality systems identified lots that did not meet product sterility specifications. As a result, we determined at the time to delay releasing any FLUVIRIN vaccine doses pending completion of internal investigations. On October 5, 2004, the U.K. regulatory body, the Medicines and Healthcare products Regulatory Agency, or MHRA, sent us a letter prohibiting us from releasing any FLUVIRIN<sup>®</sup> influenza vaccine doses manufactured at our Liverpool facility since March 2, 2004 and suspending our license to manufacture influenza virus vaccine in our Liverpool facility for three months (later extended for an additional three months). In that letter, the MHRA asserted that our manufacturing process did not comply with U.K. good manufacturing practices regulations. Following the MHRA's decision and an inspection by the Food and Drug Administration, or FDA, the FDA sent us a warning letter on December 9, 2004 citing violations of good manufacturing practices. We provided the FDA with a written response to the warning letter on January 7, 2005. In a subsequent letter to us, the FDA stated that our responses appear to be adequate, but that implementation and effectiveness of our corrective actions and overall compliance would be evaluated in a subsequent inspection. As a result of the license suspension, we did not release any FLUVIRIN product during the 2004-2005 influenza season.

On March 2, 2005, the MHRA notified us that it had lifted the license suspension, giving Chiron clearance to initiate full production of FLUVIRIN vaccine, conditioned on the understanding that Chiron's commitment to its remediation plan will continue and will be subject to further inspections by the MHRA. The FDA is still expected to conduct a full inspection to determine whether deficiencies noted in its warning letter have been resolved. If we fail to adequately address the matters discussed in the warning letter, the FDA may modify our U.S. license in an adverse manner, take action that could result in imposition of fines, require temporary or permanent cessation of future selling of FLUVIRIN vaccine or take other action that could reduce our ability to market FLUVIRIN vaccine.

We received a grand jury subpoena issued by the U.S. Attorney's Office for the Southern District of New York in October 2004 requesting production of certain documents relating to FLUVIRIN vaccine and the suspension by the MHRA of our license. In February 2005, after having previously commenced an informal inquiry, the Securities and Exchange Commission, or SEC, notified us that it would commence a formal investigation into whether we or our employees have violated any federal securities laws in connection with these developments regarding FLUVIRIN vaccine, and in April 2005, we received a subpoena from the SEC requesting production of certain documents relating to our Liverpool facility and FLUVIRIN vaccine. We also received a voluntary request for information from the United States House of Representatives Committee on Energy and Commerce requesting production of certain documents. Numerous documents have been collected and produced in response to these requests, and several witnesses have been interviewed by the U.S. Attorney's Office and the SEC staff and additional interviews are anticipated. Additional investigations regarding these matters may arise. In addition, we and certain of our officers and directors have also been named as defendants in several putative shareholder class action and derivative lawsuits alleging various claims arising out of or relating to these developments regarding FLUVIRIN vaccine, which are described below in Part II, Item 1, "Legal Proceedings". Certain parties with which we have contracted to supply FLUVIRIN vaccine are considering claims against us as a result of our inability to supply FLUVIRIN vaccine, and additional parties may do so in the future. On January 27, 2005, the U.S. Centers for Disease Control and Prevention terminated its contracts with Chiron for the supply of flu vaccine for default on the basis of Chiron's failure to supply such vaccine to the U.S. government for the 2004-2005 flu season. The CDC has reserved the right to hold Chiron liable for any excess costs it may incur if it chooses to replace the flu vaccine that Chiron failed to deliver and further has reserved all other remedies provided under the contract. Chiron maintains that its failure to deliver does not constitute default, because its reasons for non-performance fall within the "excusable delay" provisions of contracts with the CDC. We have also received communications from certain distributors of

FLUVIRIN vaccine suggesting that they are entitled to compensation under their contracts for the 2004-2005 season. It is not possible to predict whether any of these claims will be pursued and, if so, whether those claims will be upheld. Investigations, litigation and disputes have caused us to incur substantial expense and have required significant time and attention from our management and will continue to do so in the future and could result in civil action and/or criminal penalties against Chiron. The results of any such investigations, proceedings or disputes could have a material adverse effect on our consolidated financial position and results of operations and/or cash flow. For more information on these lawsuits, investigations and claims, see Part II, Item 1. Legal Proceedings below.

We did not release any FLUVIRIN vaccine during the 2004-2005 influenza season. As a result, our results of operations for 2004 were materially adversely affected by these matters. Additional issues with respect to FLUVIRIN vaccine could cause us to have to recognize an impairment charge with respect to the goodwill, certain other intangible assets and the Liverpool plant resulting from the PowderJect acquisition and the new flu vaccines manufacturing facility under construction in Liverpool, which could have a material adverse effect on our results of operations.

Our inability to supply FLUVIRIN vaccine during the 2004-2005 influenza season may also lead to loss of market share in the 2005-2006 season and future seasons. Following the announcement of our license suspension, competitors announced plans to introduce influenza vaccine products in the United States and are seeking expedited regulatory approval to do so. Even though the license suspension has been lifted, some of our customers may choose to purchase flu vaccine from other providers as their products become available in the United States. Loss of market share could have a material adverse effect on our business and results of operations.

Although the MHRA has lifted its suspension of our license to manufacture FLUVIRIN vaccine, we expect to incur additional expenses in connection with ongoing FLUVIRIN vaccine matters, which could be material, including in connection with (1) our continuing remediation efforts at our Liverpool facility; and (2) responding to the U.S. Attorney for the Southern District of New York, the SEC, the United States House of Representatives Committee on Energy and Commerce and the private lawsuits and other claims and investigations that may arise.

For additional information on the U.S. Attorney's investigation, SEC investigation, private lawsuits and other claims, see Part II, Item 1. Legal Proceedings of this report on Form 10-Q.

*If we fail to obtain or maintain the regulatory approvals we need to market our products or substantial changes in the regulatory environment occur, our business may suffer.*

We must obtain and maintain regulatory approval in order to market most of our products. Generally, these approvals are on a product-by-product and country-by-country basis. In the case of FLUVIRIN vaccine, the failure to obtain or maintain our licenses, or delays imposed by regulatory actions, could lead to the loss of our entire inventory during any given season since each year's vaccines are manufactured to meet specific strains of flu. In the case of therapeutic products, a separate approval is required for each therapeutic indication. Product candidates that appear promising based on early, and even large-scale, clinical trials may not receive regulatory approval. The results of clinical trials often are susceptible to varying interpretations that may delay, limit or prevent approval or result in the need for post-marketing studies. In addition, regulations may be amended from time to time. Revised regulations may require us to reformulate products on a country or regional basis, obtain additional regulatory approvals, or accept additional risks that our products will not maintain market acceptance or be eligible for third party insurance coverage. Increased regulatory scrutiny and restrictions regarding marketing practices for products that are subject to government reimbursement may impact the sales of such products. There is no guarantee that we will be able to satisfy these new regulatory requirements and may suffer a loss of revenue as a result.

*If our focus on the research and development of emerging technologies does not result in the creation of commercial products, our business could be harmed.*

We focus our research and development activities on areas in which we have particular strengths and on technologies that appear promising. These technologies often are on the cutting edge of modern science. As a result, the outcome of any research or development program is highly uncertain. Only a very small fraction of these programs ultimately result in commercial products or even product candidates. Product candidates that initially appear promising often fail to yield successful products. In many cases, preclinical or clinical studies will show that a product candidate is not efficacious (that is, it lacks the intended therapeutic or prophylactic effect), or that it raises safety concerns or has other side effects, which outweigh the intended benefit. Success in preclinical or early clinical trials (which generally focus on safety issues) may not translate into success in large-scale clinical trials (which are designed to show efficacy), often for reasons that are not fully understood. Further, success in clinical trials will likely lead to increased investment, adversely affecting short-term profitability, to bring such products to market. And even after a product is approved and launched, general usage or post-marketing studies may identify safety or other previously unknown problems with the product which may result in regulatory approvals being suspended, limited to narrow indications or revoked, or which may otherwise prevent successful commercialization.

*Our products are complex and difficult to manufacture on a large-scale basis, which could cause us to delay product launches, experience shortages of products or prevent us from offering products on a volume basis.*

Most of our products are biologics and manufacturing biologic products is complex. A biologic product generally cannot be sufficiently characterized (in terms of its physical and chemical properties) to rely on assaying of the finished product alone to ensure that the product will perform in the intended manner. Accordingly, it is essential to be able to both validate and control the manufacturing process, that is, to show that the process works and that the product is made strictly and consistently in compliance with that process. Slight deviations anywhere in the manufacturing process, including quality control, labeling and packaging, may result in unacceptable changes in the products that may result in lot failures or product recalls, or liability to a third party to the extent we are contract manufacturing products in our facilities for such third party. Manufacturing processes which are used to produce the smaller quantities of material needed for research and development purposes may not be successfully scaled up to allow production of commercial quantities at reasonable cost or at all. All of these difficulties are compounded when dealing with novel biologic products that require novel manufacturing processes. Additionally, manufacturing is subject to extensive government regulation. Even minor changes in the manufacturing process require regulatory approval, which, in turn, may require further clinical studies. For some of our products, we rely on others to supply raw materials and to manufacture those products according to regulatory requirements.

In addition, any prolonged interruption in our operations or those of our partners could result in our inability to satisfy the product demands of our customers. A number of factors could cause interruptions, including equipment malfunctions or failures, interruptions due to labor action, damage to a facility due to natural disasters, such as an earthquake, suspension of power supplied to these facilities arising out of regional power shortages or terrorist activities and armed conflict, including as a result of the disruption of operations of our subsidiaries and our customers, suppliers, distributors, couriers, collaborative partners, licensees and clinical trial sites.

*If we are unable to successfully compete in the highly competitive healthcare industry, our business could be harmed.*

We operate in a highly competitive environment, and the competition is expected to increase. Competitors include large pharmaceutical, chemical and blood testing companies, compounding



pharmacies, and biotechnology companies. Some of these competitors, particularly large pharmaceutical and blood testing companies, have greater resources than us. Accordingly, even if we are successful in launching a product, we may find that a competitive product dominates the market for any number of reasons, including:

- The possibility that the competitor may have launched its product first;
- The competitor may have greater access to certain raw materials;
- The competitor may have more efficient manufacturing processes;
- The competitor may adapt more quickly to technological change;
- The competitor may have greater marketing capabilities;
- The competitive product may have therapeutic or other advantages; or
- New competitors may enter into markets where we currently have significant competitive advantage.

The technologies applied by our competitors and us are rapidly evolving, and new developments frequently result in price competition and product obsolescence. In addition, we may be impacted by competition from generic forms of our products, substitute products or imports of products from lower priced markets.

*Conflicts with or decisions by third parties we collaborate with could harm our business.*

An important part of our business strategy depends upon collaborations with third parties, including research collaborations and joint efforts to develop and commercialize new products. As circumstances change, Chiron and our strategic partners may develop conflicting priorities or other conflicts of interest. We may experience significant delays and incur significant expenses in resolving these conflicts and may not be able to resolve these matters on acceptable terms. Even without conflicts of interest, we may disagree with our strategic partners as to how best to realize the value associated with a current product or a product in development. In some cases, the strategic partner may have responsibility for formulating and implementing key strategic or operational plans. In addition, merger and acquisition activity within the pharmaceutical and biotechnology industries may affect our strategic partners, causing them to reprioritize their efforts related to the research collaborations and other joint efforts with us. Decisions by corporate partners on key clinical, regulatory, marketing (including pricing), inventory management and other issues may prevent successful commercialization of the product or otherwise impact our profitability.

*If any of our third party suppliers or manufacturers cannot adequately meet our needs, our business could be harmed.*

We use raw materials and other supplies that generally are available from multiple commercial sources. Certain manufacturing processes, however, use materials that are available from sole sources, or that are in short supply, or are difficult for the supplier to produce and certify in accordance with our specifications. From time to time, concerns are raised with respect to potential contamination of biological materials that are supplied to us. These concerns can further tighten market conditions for materials that may be in short supply or available from limited sources. Moreover, regulatory approvals to market our products may be conditioned upon obtaining certain materials from specified sources. Our ability to substitute material from an alternate source may be delayed pending regulatory approval of such alternate source. Although we work to mitigate the risks associated with relying on sole suppliers, there is a possibility that material shortages could impact production.

We purchase bulk powdered tobramycin, the primary basic raw material in TOBI<sup>®</sup> tobramycin, from two of the principal worldwide suppliers of the drug. We anticipate that either one of these suppliers alone will be able to supply sufficient quantities to meet current needs; however, there can be no assurance that these suppliers will be able to meet future demand in a timely and cost-effective manner. As a result, our operations could be adversely affected by an interruption or reduction in the supply of bulk powdered tobramycin.

We have entered into contracts with third parties for the production and packaging of TOBI<sup>®</sup> tobramycin. Over time, we can use alternative production and packaging sources. However, if the contracted third parties become unable to produce or package sufficient quantities of TOBI solution due to work stoppages or other factors, our operations could be disrupted until alternative sources are secured.

We have entered into contracts with third parties for the packaging of the pre-filled diluent syringe for BETASERON<sup>®</sup> interferon beta-1b. Over time, we can use alternative packaging sources. However, if the contracted third parties become unable to produce or package sufficient quantities of the pre-filled diluent syringe for BETASERON<sup>®</sup> interferon beta-1b due to work stoppages or other factors, our operations could be disrupted until alternative sources are secured.

In connection with the production of our flu vaccine products, we must purchase large quantities of chicken eggs. For FLUVIRIN<sup>®</sup> vaccine, we purchase those eggs and incubation services from a single supplier in the United Kingdom and, pursuant to the contract with that supplier, we have agreed to make specified purchases from that supplier through 2009, subject to our right to terminate this agreement earlier upon payment of a termination fee. If our supplier were to fail to supply eggs in sufficient quantities or quality, including as a result of any health or other issues related to the chickens, our business would be materially adversely affected.

We are a key provider for the blood screening field of nucleic acid testing and immunodiagnosics. In nucleic acid testing, we rely on our collaborative partner, Gen-Probe, to manufacture the West Nile virus assay, currently in use on an investigational-use basis in the U.S. and the PROCLEIX<sup>®</sup> HIV-1/HCV and PROCLEIX<sup>®</sup> ULTRIO Assays. We currently source the related instrument system from third party suppliers. Currently, Gen-Probe is the only manufacturer of nucleic acid testing products using Transcription-Mediated Amplification technology. In immunodiagnosics, under the Ortho-Clinical Diagnostics, Inc. contract, we manufacture bulk reagents and antigens and confirmatory test kits sold in the clinical diagnostics and blood screening fields. While we and our partners work to mitigate the risks associated with being a key provider, there can be no assurance that our partner, Gen-Probe, will be able to provide sufficient quantities of the PROCLEIX<sup>®</sup> HIV-1/HCV and PROCLEIX<sup>®</sup> ULTRIO Assays or that we will be able to manufacture sufficient bulk reagents and antigens and confirmatory test kits for immunodiagnostic products. Our difficulties or delays or those of our partners could cause a public health concern for the blood supply, as well as increase costs and cause loss of revenue or market share.

*If we cannot obtain necessary licenses to third party patents for the manufacture or sale of our products, we may have to withdraw from the market or delay the introduction of the affected product.*

Third parties, including competitors, have patents and patent applications in the U.S. and other significant markets that may be useful or necessary for the manufacture, use or sale of certain products and products in development by our strategic partners and us. It is likely that third parties will obtain these patents in the future. Certain of these patents may be broad enough to prevent or delay us and our strategic partners from manufacturing or marketing products important to our current and future business. We cannot accurately predict the scope, validity and enforceability of these patents, if granted, the extent to which we may wish or need to obtain licenses to these patents, and the cost and availability of these licenses. If we do not or cannot obtain these licenses, products may be withdrawn from the market or delays could be encountered in market introduction while an attempt is made to design around these

patents, or we could find that the development, manufacture or sale of such products is foreclosed. We could also incur substantial costs in licensing or challenging the validity and scope of these patents.

*Because most of our products are based on technologies that are unfamiliar to the healthcare community, they may not be accepted by healthcare providers and patients, which could harm our business.*

We may experience difficulties in launching new products, many of which are novel products based on technologies that are unfamiliar to the healthcare community. We have no assurance that healthcare providers and patients will accept such products. In addition, government agencies, as well as private organizations involved in healthcare, from time to time publish guidelines or recommendations to healthcare providers and patients. Such guidelines or recommendations can be very influential and may adversely affect the usage of our products directly (for example, by recommending a decreased dosage of our product in conjunction with a concomitant therapy or a government entity withdrawing its recommendation to screen blood donations for certain viruses) or indirectly (for example, by recommending a competitive product over our product).

*If we are unable to avoid significant exposure to product liability claims, our business could be harmed.*

We are exposed to product liability and other claims in the event that the use of our products is alleged to have resulted in adverse effects. While we will continue to take precautions, we may not avoid significant product liability exposure. Although we maintain product liability insurance, there is no guarantee that this coverage will be sufficient. It is not feasible to obtain adequate insurance coverage for certain products and we are self-insured in relation to these products. If we are sued for any injury caused by our products, we could suffer a significant financial loss.

As we are a key provider for the blood screening field of nucleic acid testing and immunodiagnostics, we may have product liability in addition to contract exposure in the event that our difficulties or delays or those of our partners could cause a public health concern for the blood supply.

*If we market products in a manner that violates state, federal or foreign laws that govern pharmaceuticals and health care products, including FDA, FTC, and health care fraud and abuse laws, we may be subject to civil or criminal penalties, including the potential for exclusion from federal, state and foreign programs.*

The federal laws and regulations administered by the FDA and FTC place restrictions on the promotion of medical products. FDA law and regulations prohibit the marketing and promotion of unapproved drug and device products and unapproved uses of approved drug and device products. FTC and FDA also place restrictions on the promotion of approved drugs and devices to ensure that marketing material is not false or misleading. In addition to these restrictions on the marketing of pharmaceutical products without regulatory approval, other types of state and federal health care fraud and abuse laws have been applied in recent years to restrict certain marketing practices in the healthcare industry, and to otherwise determine the eligibility of pharmaceutical manufacturers to have their products reimbursed by Medicare, Medicaid, and other federal and state programs. These laws include anti-kickback statutes, false claims statutes, and others. Likewise, various foreign laws may restrict the manner in which healthcare products are marketed in other countries.

The federal anti-kickback statute prohibits, among other things, knowingly offering, paying, soliciting, or receiving remuneration to induce or in return for purchasing, ordering, recommending, or arranging for the purchase, order, or lease of any health care item reimbursable under Medicare, Medicaid, or other federally funded health care programs. This statute has been interpreted broadly to apply to arrangements between drug manufacturers on one hand and prescribers, purchasers, pharmacies, GPOs, and pharmacy benefit and formulary managers on the other, along with such indirect purchasers as health plans. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain

activities from prosecution, the exemptions and safe harbors are drawn narrowly. Activities that fall outside of a safe harbor are not necessarily illegal, but practices that involve direct or indirect remuneration intended to induce prescribing, purchasing, or recommending of products may be subject to governmental scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability.

Federal false claims laws generally prohibit a person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. Recently, several pharmaceutical and other health care companies have been subject to investigative and enforcement activity under these laws, including qui tam suits filed by whistleblowers, for a variety of alleged inappropriate promotional and marketing activities, such as providing free product to customers with the expectation that the customers would bill federal programs for the product; engaging in off-label promotion that caused claims to be submitted to federal and state programs for non-covered off-label uses; and submitting inflated best price and otherwise incorrect pricing data for Medicaid rebate purposes. In some cases, the manufacturers have been alleged to have aided and abetted in the submission of false claims.

In addition, state Attorneys General and private class action plaintiffs have filed civil suits under the federal RICO statute and a variety of state consumer protection laws claiming that pharmaceutical companies reported inflated average wholesale prices to pricing services used by the federal programs to set reimbursement rates, and that as a result, Medicare beneficiaries, Medicaid programs and private payers overpaid for drugs. Still other manufacturers have been subject to enforcement activity for alleged violations of such federal statutes as the Prescription Drug Marketing Act, involving pharmaceutical sampling practices. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Sanctions under federal, state and foreign laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

*Our mishandling of hazardous materials could result in substantial costs and harm to our business.*

In connection with our research and manufacturing activities, we utilize some hazardous materials. We believe we take great care to ensure we have appropriate procedures and permits in place for storing and handling such hazardous materials. We could be subject to loss of our permits, government fines or penalties and/or other adverse governmental action if such hazardous materials are stored, handled or released into the environment in violation of law or any permit. A substantial fine or penalty, the payment of significant environmental remediation costs or the loss of a permit or other authorization to operate or engage in our ordinary course of business could result in material, unanticipated expenses and the possible inability to satisfy customer demand.

*Our patents may not prevent competition or generate revenues.*

We seek to obtain patents on many of our inventions. Without the protection of patents, competitors may be able to use our inventions to manufacture and market competing products without being required to undertake the lengthy and expensive development efforts made by us and without having to pay royalties or otherwise compensate us for the use of the invention. We have no assurance that patents and patent applications owned or licensed to us will provide substantial protection. Important legal questions remain to be resolved as to the extent and scope of available patent protection for biotechnology products and processes in the U.S. and other important markets. We do not know how many of our pending patent

applications will be granted, or the effective coverage of those that are granted. In the U.S. and other important markets, the issuance of a patent is neither conclusive as to its validity nor the enforceable scope of its claims. We have engaged in significant litigation to determine the scope and validity of certain of our patents and expect to continue to do so. An adverse outcome of litigation could result in the reduction or loss of royalty revenues. Engaging in patent litigation against one party may place significant royalty revenues received or to be received from other parties at risk. Even if we are successful in obtaining and defending patents, there can be no assurance that these patents will provide substantial protection. The length of time necessary to resolve patent litigation successfully may allow infringers to gain significant market advantage. Third parties may be able to design around the patents and develop competitive products that do not use the inventions covered by our patents. Many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties (for example, the third party's product is needed to meet a threat to public health or safety in that country, or the patent owner has failed to work the invention in that country, or the third party has patented improvements). In addition, most countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may be limited to monetary relief and may be unable to enjoin infringement, which could materially diminish the value of the patent. In addition, royalty revenues may decline as patents expire.

*Sales of our products may be adversely affected by the availability and amount of reimbursement to the user of our products from third parties, such as the government and insurance companies.*

In the U.S. and other significant markets, sales of our products may be affected by the availability of reimbursement from the government or other third parties, such as insurance companies. It is difficult to predict the reimbursement status of newly approved, novel biotechnology products, and current reimbursement policies for existing products may change. In certain foreign markets, governments have issued regulations relating to the pricing and profitability of pharmaceutical companies. There have been proposals in the U.S. (at both the federal and state level) to implement such controls. If the United States Congress enacts legislative proposals addressing parallel importation currently being deliberated, revenues from certain products may be affected by this change in U.S. policy. The growth of managed care in the U.S. also has placed pressure on the pricing of healthcare products. These pressures can be expected to continue.

*If our efforts to integrate acquired or licensed businesses or technologies into our business are not successful, our business could be harmed.*

As part of our business strategy, we expect to continue to grow our business through in-licensing, collaborations or acquisitions of products or companies. The failure to adequately address the financial, operational or legal risks raised by such transactions could harm our business. Financial aspects related to these transactions may alter our financial position, reported operating results or stock price, and include:

- Use of cash resources;
- Potentially dilutive issuances of equity securities;
- The incurrence of debt and contingent liabilities, impairment losses or restructuring charges;
- Large write-offs and difficulties in assessment of the relative percentages of in-process research and development expense that can be immediately written off as compared to the amount which must be amortized over the appropriate life of the asset; and
- Amortization expenses related to other intangible assets.

Operational risks that could harm our existing operations or prevent realization of anticipated benefits from such transactions include:

- Challenges associated with managing an increasingly diversified business;
- Difficulties in assimilating the operations, products, technology, information systems or personnel of the acquired company;
- Diversion of management's attention from other business concerns;
- Inability to maintain uniform standards, controls, procedures and policies;
- The assumption of known and unknown liabilities of the acquired company, including intellectual property claims; and
- Subsequent loss of key personnel.

Legal risks may include requirements to obtain the consent of our stockholders or a third party, or the approval of various regulatory authorities.

If such efforts to integrate acquired or licensed businesses or technologies into our business are not successful, our business could be harmed.

*If we cannot initiate and maintain revenue-generating relationships with third parties, we may not be able to grow our revenues in the near to medium-term.*

Many products in our current pipeline are in relatively early stages of research or development. Our ability to grow earnings in the near- to medium-term may depend, in part, on our ability to initiate and maintain other revenue generating relationships with third parties, such as licenses to certain of our technologies, and on our ability to identify and successfully acquire rights to later-stage products from third parties. We may fail to establish such other sources of revenue.

*Fluctuations in interest rates and foreign currency exchange rates could harm our business.*

We have significant cash balances and investments. Our financial results, therefore, are sensitive to interest rate fluctuations. In addition, we sell products in many countries throughout the world, and our financial results could be significantly affected by fluctuations in foreign currency exchange rates or by weak economic conditions in foreign markets.

*Our level of debt could limit cash flow available for our operations and could adversely affect our ability to service our debt or obtain additional financing, if necessary.*

As of March 31, 2005, our total debt including current portion, was \$939.0 million. Our level of debt could restrict our operations and make it more difficult for us to satisfy our obligations under the 2033 and the 2034 convertible debentures (the "debentures"). Among other things, our level of debt may:

- Limit our ability to obtain additional financing for working capital, capital expenditures, strategic acquisitions and general corporate purposes;
- Require us to dedicate all or a substantial portion of our cash flow to service our debt, which will reduce funds available for other business purposes, such as capital expenditures or acquisitions;
- Limit our flexibility in planning for or reacting to changes in the markets in which we compete;
- Place us at a competitive disadvantage relative to our competitors with less leverage;
- Render us more vulnerable to general adverse economic and industry conditions; and



- Make it more difficult for us to satisfy our financial obligations, including those relating to the debentures and our other debt obligations.

We and our subsidiaries may still be able to incur substantially more debt. The terms of our credit facility, the indenture governing the debentures and the agreements governing our other debt permit additional borrowings. Our incurrence of additional debt could further exacerbate the risks described above.

Our ability to satisfy our obligations under the debentures and our other debt agreements will depend on our future operating performance, which will be subject, in part, to factors beyond our control, including general economic and business conditions. If we are unable to generate sufficient cash flow to service our debt, we may be required to refinance all or a portion of our debt, including the debentures, obtain additional financing, sell some of our assets or operations, reduce or delay capital expenditures, or revise or delay our strategic plans. If we are required to take any of these actions, it could have a material adverse effect on our business, financial condition and results of operations. In addition, we cannot assure you that we would be able to take any of these actions, that these actions would enable us to continue to satisfy our capital requirements or that these actions would be permitted under the terms of our various debt instruments, including the indenture governing the debentures.

*Our relationship with Novartis AG could limit our ability to enter into transactions, pursue opportunities in conflict with Novartis and cause the price of our common stock to decline.*

We have an alliance with Novartis AG, a life sciences company headquartered in Basel, Switzerland. Under a series of agreements between Chiron and Novartis, and as a result of subsequent stock issuances by Chiron, Novartis' ownership interest in Chiron was approximately 42.4% as of March 31, 2005. The governance agreement between Chiron and Novartis contains provisions that require the approval of Novartis before we enter into certain corporate transactions. These transactions generally include significant debt or equity issuances, debt or equity repurchases, most mergers and acquisitions, the payment of cash dividends, amendments to Chiron's certificate of incorporation or by-laws, and other transactions that would adversely impact the rights of Novartis, or discriminate against Novartis, as a Chiron stockholder. In addition, a majority of the independent directors must approve any material transactions between Chiron and Novartis. These provisions may limit our ability to enter into transactions with third parties otherwise viewed as beneficial to Chiron. All of our shares owned by Novartis are eligible for sale in the public market subject to compliance with the applicable securities laws. We have agreed that, upon Novartis' request, we will file one or more registration statements under the Securities Act in order to permit Novartis to offer and sell shares of our common stock. Sales of a substantial number of shares of our common stock by Novartis in the public market could adversely affect the market price of our common stock.

*Our stock price could be volatile.*

The price of our stock, like that of other pharmaceutical companies, is subject to significant volatility. Any number of events, both internal and external to us, may affect our stock price. These include, without limitation:

- Fluctuations in earnings from period to period;
- Results of clinical trials conducted by us or by our competitors;
- Announcements by us or our competitors regarding product development efforts, including the status of regulatory approval applications;
- Impact from the recent FLUVIRIN vaccine developments;



- The outcome of legal proceedings, including claims filed by us against third parties to enforce our patents and claims filed by third parties against us relating to patents held by the third parties;
- The launch of competing products;
- The resolution of (or failure to resolve) disputes with strategic partners;
- Corporate restructuring by us;
- The sale of a substantial number of shares held by our existing stockholders;
- Licensing activities by us; and
- The acquisition or sale by us of products, products in development or businesses.

In connection with our research and development collaborations, from time to time we may invest in equity securities of our strategic partners. The price of these securities also is subject to significant volatility and may be affected by, among other things, the types of events that affect our stock. Changes in the market price of these securities may impact our profitability.

*We are subject to taxation in a number of jurisdictions and changes to the corporate tax rate and laws of any of these jurisdictions could increase the amount of corporate taxes we have to pay.*

We pay taxes principally in the U.S., Germany, Italy, and the United Kingdom. All of these jurisdictions have in the past and may in the future make changes to their corporate tax rates and other tax laws, which could increase our future tax provision. Specifically, on October 22, 2004, the American Jobs Creation Act of 2004 (the Act) was signed into law. The Act includes an elimination of the tax benefit of the Extraterritorial Income Exclusion over 2005 and 2006.

We have negotiated a number of rulings regarding income and other taxes that are subject to periodic review and renewal. If such rulings are not renewed or are substantially modified, income taxes payable in particular jurisdictions could increase. While we believe that all material tax liabilities are reflected properly in our balance sheet, we are presently under audit in several jurisdictions and may be subject to further audits in the future, and we have no assurance that we will prevail in all cases in the event the taxing authorities disagree with our interpretations of the tax law. In addition, we have assumed liabilities for all income taxes incurred prior to the sales of our former subsidiaries, including PowderJect Vaccines, Inc., SBL Vaccin AB, and PowderJect Research Limited. Future levels of research and development spending, capital investment and export sales will impact our entitlement to related tax credits and benefits which have the effect of lowering our effective tax rate.

*Our earnings results may be inconsistent and cause volatility in our stock price.*

Our operating results may vary considerably from quarter to quarter. Any number of factors may affect our quarterly operating results. These factors include, but are not limited to the following:

- Inventory management practices, including wholesale ordering patterns;
- The level of pre-clinical and clinical trial-related activities;
- Seasonality of certain vaccine products;
- The tender driven nature of certain vaccine products;
- The nature of our collaborative, royalty and license arrangements and other revenue sources;
- Foreign currency exchange rate fluctuations; and



- The level of product reserves due to various issues, including seasonality patterns, excess and obsolete inventory, and production yields.

Our results in any one quarter are not necessarily indicative of results to be expected for a full year.

*Revisions to accounting standards, financial reporting and corporate governance requirements and tax laws could result in changes to our standard practices and could require a significant expenditure of time, attention and resources, especially by senior management.*

We must follow accounting standards, financial reporting and corporate governance requirements and tax laws set by the governing bodies and lawmakers in the U.S. and other countries where we do business. From time to time, these governing bodies and lawmakers implement new and revised rules and laws. These new and revised accounting standards, financial reporting and corporate governance requirements and tax laws may require changes to our financial statements, the composition of our board of directors, the composition, the responsibility and manner of operation of various board-level committees, the information filed by us with the governing bodies and enforcement of tax laws against us. Implementing changes required by such new standards, requirements or laws likely will require a significant expenditure of time, attention and resources, especially by our senior management. It is impossible to completely predict the impact, if any, on Chiron of future changes to accounting standards, financial reporting and corporate governance requirements and tax laws.

It is possible that the application of certain current accounting standards may change due to environmental factors, which may necessitate a change in our standard practice related to these accounting standards. In particular, effective January 1, 2006 we will be required to adopt SFAS No. 123(R) requiring us to apply a fair-value based method to account for costs related to share-based payments including stock options and employee stock purchase plans. We expect the adoption of SFAS 123(R) to materially impact our results of operations.

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

**Market risk management** Our cash flow and earnings are subject to fluctuations due to changes in foreign currency exchange rates, changes in interest rates and changes in the fair value of equity securities held for sale. We attempt to limit our exposure to some or all of these market risks through the use of various financial and derivative instruments. During the first quarter of 2005, we added a new hedging instrument to our foreign currency hedging strategy. We purchased \$41.1 million of British Pound denominated fixed-income securities to create a natural hedge against a portion of our British Pound currency exposures. We manage our exposures to market risks as discussed in further detail in Part II, Item 7A, **Quantitative and Qualitative Disclosures About Market Risk** in our annual Report on Form 10-K for the year ended December 31, 2004.

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

**(a) Evaluation of disclosure controls and procedures** As of the end of the period covered by this report, Chiron carried out an evaluation under the supervision and with the participation of Chiron's management, including Chiron's CEO and CFO, of the effectiveness of Chiron's disclosure controls and procedures pursuant to Exchange Act Rule 13a-15(e) or 15d-15(e). Based on that evaluation, which included consideration of the design and implementation of additional controls and procedures described below, Chiron's management, including the CEO and CFO, concluded that Chiron's disclosure controls and procedures were effective in timely alerting them to material information relating to Chiron required to be included in Chiron's periodic SEC filings.

**(b) Changes in internal controls** Except as set forth below, there have been no significant changes in Chiron's internal controls over financial reporting that have materially affected, or are reasonably likely to materially affect internal controls over financial reporting during the most recent fiscal quarter.

The management of Chiron assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2004. In performing the assessment management identified three material weaknesses in internal control over financial reporting as of December 31, 2004. As a result of the material weaknesses described below, management determined that, as of December 31, 2004, the Company's system of internal control over financial reporting was not effective based on the criteria in *Internal Control - Integrated Framework*.

The first material weakness pertains to both the design and operating effectiveness of controls relating to revenue recognition at our vaccines subsidiary in Germany. Specifically, controls pertaining to the communication and evaluation of any special terms and other actions of the sales organization that may affect revenue recognition were not effective. As a result, on March 8, 2005, the Audit Committee of the Board of Directors, following discussion with and upon the recommendation of management and following discussion with Chiron's independent auditors, concluded that the previously issued financial statements for the second and third quarters of 2004 should be restated to correct certain errors contained therein and should not be relied upon. The identified errors affected product revenue, cost of goods sold, accounts receivable, and unearned revenue for the Company's vaccines segment. In addition to the restatement of the financial statements for the second and third quarters of 2004, adjustments were recorded in the consolidated financial statements for year ended December 31, 2004 to correct the identified errors.

The second material weakness pertains to both the design and operating effectiveness of controls relating to the annual income tax provision. Specifically, there were errors in the annual tax provision for the year ended December 31, 2004 as a result of ineffective controls relating to the design and use of analytical tools to analyze and calculate the tax provision, the reconciliation of certain tax accounts, and the review of those reconciliations. These errors affected income tax expense and income tax asset and liability accounts. Adjustments were recorded in the consolidated financial statements for year ended December 31, 2004 to correct the identified errors.

The third material weakness pertains to both the design and operating effectiveness of controls relating to the timely determination of the appropriate accrual for legal services. Specifically, procedures to estimate the accrual for unbilled services and controls over the timely recording of invoices payable were not effective. Errors resulting from these deficiencies affected operating expenses, intangible assets and accrued liabilities. Adjustments were recorded in the consolidated financial statements for year ended December 31, 2004 to correct the identified errors.

During the first quarter of fiscal year 2005, and in connection with the preparation of our condensed consolidated financial statements for the quarter ended March 31, 2005, we designed and implemented additional controls and procedures relating to revenue recognition at our vaccines subsidiary in Germany to address the first material weakness identified above. Such additional controls and procedures included, among others:

- Providing our sales force with training regarding the applicable accounting principles and procedures for the communication of special terms and conditions and the impact of their activities on our revenue recognition; and
- Review of a significant sample of supporting sales documentation, including customer agreements, to identify sales transactions in the first quarter with special terms and conditions to determine that the sales were recognized in accordance with applicable accounting principles

In addition, during the first quarter of 2005, and in connection with the preparation of our condensed consolidated financial statements for the quarter ended March 31, 2005, we designed and implemented

additional controls and procedures relating to the timely recording of legal services invoices payable and estimating the accrual for unbilled legal services to address the third material weakness identified above. Such additional controls and procedures included, among others:

- Designing of new procedures for invoice processing and procedures for the accrual of unbilled services and communication of the new procedures to individuals integral to the process; and
- Completion of training and awareness workshops relating to the new processes

In addition, we are in the process of establishing a remediation plan to address the ineffective controls related to the annual tax provision process. The remediation plan is expected to include consideration and identification of additional controls and reconciliations and the consideration and implementation of different analytical tools in order to enhance the analysis and calculation of the tax provision.

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## PART II

### Item 1. Legal Proceedings

We are party to certain lawsuits and legal proceedings, which are described in Part I, Item 3. *Legal Proceedings* of our Annual Report on Form 10-K for the year ended December 31, 2004. The following is a description of material developments during the period covered by this Quarterly Report and certain other events and should be read in conjunction with the Annual Report on Form 10-K for the year ended December 31, 2004.

#### *Average Wholesale Price Litigation*

In November 2004, the County of Nassau filed a complaint in the United States District Court for the Eastern District of New York against numerous biotechnology and pharmaceutical companies, including Chiron, in connection with setting average wholesale prices for various products, including TOBI® solution, which are reimbursed by Medicaid. In March 2005, the County of Nassau filed an amended complaint with the In Re Pharmaceutical Industry Average Wholesale Price Litigation pre-trial proceedings in the United States District Court for the District of Massachusetts. Plaintiff alleges that defendants violated federal racketeering laws, federal and state laws on Medicaid fraud, and state laws on unfair trade practice, breach of contract, fraud and unjust enrichment by devising and implementing a fraudulent pricing scheme against Medicaid beneficiaries, and seeks declaratory relief, as well as compensatory and punitive damages.

It is not known when nor on what basis this matter will be resolved.

#### *FLUVIRIN® influenza virus vaccine*

For a discussion of developments related to FLUVIRIN® influenza virus vaccine, see *Item 2 Management's Discussion and Analysis of Financial Condition and Results of Operations, Factors That May Affect Future Results.*

#### **FLUVIRIN® vaccine Securities Class Actions**

Between October 2004 and December 2004, five securities class action lawsuits were filed against Chiron and certain Chiron officers on behalf of purchasers of Chiron securities for class periods ranging from July 23, 2003 through October 13, 2004. Four of the suits were filed in the United States District Court for the Northern District of California. One action, although originally filed in the United States District Court for the Eastern District of Pennsylvania, was later transferred to the United States District Court for the Northern District of California. In March 2005, the Court named lead counsel, and in April 2005, plaintiffs filed a consolidated complaint. Plaintiffs allege, among other things, that the defendants violated certain provisions of the federal securities laws by making false statements preceding the suspension of Chiron's license to manufacture FLUVIRIN vaccine, and seek unspecified monetary damages and other relief from all defendants. The trial is scheduled to begin on May 1, 2006.

It is not known when nor on what basis these matters will be resolved.

In December 2004, a complaint was filed in the United States District Court for the District of Connecticut alleging that plaintiffs suffered injuries as a result of the flu vaccine they had received. In April 2005, the Court ordered the dismissal of the matter with respect to Chiron, and the matter is thus concluded.

#### *Innogenetics N.V.*

In November 2000, Innogenetics N.V. brought a complaint against Chiron and Ortho-Clinical Diagnostics Systems, Inc. before the Commission. Innogenetics N.V. alleges that Chiron and Ortho violate

Articles 81 and 82 of the Treaty relating to competitive practices. Pursuant to the complaint, the Commission has sought information from Chiron and Ortho-Clinical Diagnostics Systems, Inc. related to hepatitis C virus and HIV licensing practices in the European Union. In March 2005, Innogenetics withdrew its complaint, and the matter is thus concluded.

*Laboratory Corporation of America Holdings*

In August 2003, Chiron filed a complaint in the United States District Court for the Northern District of California against Laboratory Corporation of America Holdings, Laboratory Corporation of America and National Genetics Institute (collectively, the Defendants), seeking damages and an injunction against Defendants' manufacture, use and sale of certain HIV assays for infringing Chiron's U.S. Patent No. 6,531,276 (the 276 patent). In February 2004, Chiron voluntarily dismissed this case without prejudice and refiled the complaint before the United States District Court for the Central District of California. In April 2005, the Court stayed the case pending the outcome of two interferences declared by the U.S. Patent and Trademark Office regarding the 276 patent.

It is not known when nor on what basis this matter will be resolved.

*Investigation of Employee of Italian Subsidiary*

A sales employee of an indirect, wholly-owned Italian subsidiary of Chiron is the subject of an investigation by Italian authorities in Genoa, Italy in connection with a larger investigation by such authorities into the purchasing activities of a Genoa hospital. We believe that the employee is one of a number of individuals from a variety of companies being investigated by such authorities with respect to sales to the hospital. We further believe that the investigation of the employee of our Italian subsidiary concerns alleged undue influence by the employee in the bidding process for the supply of blood testing products to the hospital. In August 2004, the hospital awarded Chiron a contract for the supply blood testing products. The employee is also the subject of a similar investigation by Italian authorities in Milan, Italy. In connection with the Genoa investigation, authorities placed the employee under house arrest. At this time, we are not aware of any investigation of Chiron with respect to these matters. However, no assurance can be given that Chiron will not become the subject of criminal or civil charges, fines or penalties, or incur other damages or costs, in connection with these matters.

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

(c) Our Board of Directors authorized the repurchase of our common stock on the open market to offset the dilution associated with the issuance of new shares under the stock option and stock purchase plans and the granting of share rights. On March 10, 2005, the Board of Directors authorized Chiron to repurchase 5.0 million shares of Chiron common stock through December 31, 2005. There were no stock repurchases in the first quarter of 2005.

**Item 3. Defaults Upon Senior Securities**

None.

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

None.

**Item 5. Other Information**

None.

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**Item 6. Exhibits**

(a) Exhibits

**Exhibit**

**Number**

**Exhibit**

- 3.01 Restated Certificate of Incorporation of Chiron, as filed with the Office of the Secretary of State of Delaware on August 17, 1987, incorporated by reference to Exhibit 3.01 of Chiron's report on Form 10-K for fiscal year 1996.
- 3.02 Certificate of Amendment of Restated Certificate of Incorporation of Chiron, as filed with the Office of the Secretary of State of Delaware on December 12, 1991, incorporated by reference to Exhibit 3.02 of Chiron's report on Form 10-K for fiscal year 1996.
- 3.03 Certificate of Amendment of Restated Certificate of Incorporation of Chiron, as filed with the Office of the Secretary of State of Delaware on May 22, 1996, incorporated by reference to Exhibit 3.04 of Chiron's report on Form 10-Q for the period ended June 30, 1996.
- 3.04 Bylaws of Chiron, as amended and restated, incorporated by reference to Exhibit 99.1 of Chiron's current report on Form 8-K dated March 10, 2005.
- 4.01 Indenture between Chiron and State Street Bank and Trust Company, dated as of June 12, 2001, incorporated by reference to Exhibit 4.01 of Chiron's report on Form 10-Q for the period ended June 30, 2001.
- 4.02 Registration Rights Agreement between Chiron and Merrill Lynch & Co., Inc., and Merrill Lynch, Pierce, Fenner & Smith, Incorporated, incorporated by reference to Exhibit 4.02 of Chiron's report on Form 10-Q for the period ended June 30, 2001.
- 4.03 Form of Liquid Yield Option Note due 2031 (Zero Coupon Senior) (included as exhibits A-1 and A-2 to the Indenture filed as Exhibit 4.01 to Chiron's report on Form 10-Q for the period ended June 30, 2001), incorporated by reference to Exhibit 4.03 of Chiron's report on Form 10-Q for the period ended June 30, 2001.
- 4.04 Indenture between Chiron and U.S. Bank National Association, as trustee, dated as of July 30, 2003, incorporated by reference to Exhibit 4.1 of Chiron's registration statement on Form S-3 filed with the Commission on September 23, 2003.
- 4.05 Registration Rights Agreement dated as of July 30, 2003, between Chiron and Morgan Stanley & Co., Goldman, Sachs & Co., Banc of America Securities LLC and BNP Paribas Securities Corp., incorporated by reference to Exhibit 4.3 of Chiron's registration statement on Form S-3 filed with the Commission on September 23, 2003.
- 4.06 Form of Convertible Debentures (included in Exhibit 4.04), incorporated by reference to Exhibit 4.2 of Chiron's registration statement on Form S-3 filed with the Commission on September 23, 2003.
- 4.07 Indenture between Chiron and U.S. Bank National Association, as trustee, dated as of June 22, 2004, incorporated by reference to Exhibit 4.07 of Chiron's report on Form 10-Q for the period ended June 30, 2004.
- 4.08 Registration Rights Agreement dated as of June 22, 2004, between Chiron, Credit Suisse First Boston, LLC and Morgan Stanley & Co., Goldman, Sachs & Co., Incorporated, incorporated by reference to Exhibit 4.08 of Chiron's report on Form 10-Q for the period ended June 30, 2004.



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- 4.09 Specimen of Convertible Debentures (included as Exhibit A to the Indenture referenced as Exhibit 4.07 of Chiron's report on Form 10-Q for June 30, 2004) issued on June 22, 2004, incorporated by reference to Exhibit 4.09 of Chiron's report on Form 10-Q for the period ended June 30, 2004.
- 10.331 Modified Blood Screening Instrument eSAS 2 Addendum Amending the Agreement entered into as of June 11, 1998, between Chiron and Gen-Probe, effective as of January 1, 2002. (We have omitted certain information from the Addendum and filed it separately with the Securities and Exchange Commission pursuant to our request for confidential treatment under Rule 24b-2. We have identified the omitted confidential information by the following statement: Confidential Treatment Requested .)
- 10.332 Amendment No. 6, effective as of January 1, 2004, amending the Agreement dated June 11, 1998, between Chiron and Gen-Probe Incorporated. (We have omitted certain information from the Amendment and filed it separately with the Securities and Exchange Commission pursuant to our request for confidential treatment under Rule 24b-2. We have identified the omitted confidential information by the following statement: Confidential Treatment Requested .)
- 10.614 Compromise Agreement dated February 18, 2005, between John A. Lambert and Chiron.\*
- 10.615 Letter agreement dated February 28, 2005 (agreed to on March 4, 2005), between Jack Goldstein and Chiron.\*
- 31.1 Certification of the Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
- 31.2 Certification of the Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
- 32.1 Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2 Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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\* Management contract, compensatory plan or arrangement.

**CHIRON CORPORATION**  
**March 31, 2005**

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, Chiron has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

DATE: May 6, 2005

CHIRON CORPORATION

BY: */s/ HOWARD H. PIEN*  
Howard H. Pien  
*Chief Executive Officer*

DATE: May 6, 2005

BY: */s/ DAVID V. SMITH*  
David V. Smith  
*Vice President and Chief Financial Officer*