

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
<b>Net (loss) income</b>	<b>\$ (0.05 )</b>	<b>\$ 0.21</b>
<b>Diluted (loss) earnings per share:</b>		
(Loss) income from continuing operations	\$ (0.05 )	\$ 0.14
<b>Net (loss) income</b>	<b>\$ (0.05 )</b>	<b>\$ 0.21</b>

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>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>
<b>(Loss) income (Numerator):</b>		
(Loss) income from continuing operations	\$ (8,942 )	\$ 26,927
<b>Shares (Denominator):</b>		
Weighted-average common shares outstanding	187,108	187,809
<b>Effect of dilutive securities:</b>		
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>
<b>(Loss) income (Numerator):</b>		
Net (loss) income	\$ (8,942 )	\$ 39,772
<b>Shares (Denominator):</b>		
Weighted-average common shares outstanding	187,108	187,809
<b>Effect of dilutive securities:</b>		
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<sup>®</sup> 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<sup>®</sup> (tobramycin solution for inhalation) for pseudomonal lung infections in cystic fibrosis patients, PROLEUKIN<sup>®</sup> (aldesleukin) for cancer (metastatic melanoma and renal cell carcinoma) and BETASERON<sup>®</sup> (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<sup>®</sup> interferon beta-1b. The biopharmaceuticals segment earns royalties on third party sales of several products, including BETAFERON<sup>®</sup> 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<sup>®</sup> 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<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 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<sup>®</sup> 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 Three Months	% Change Three Months
	2005	2004		
	(\$ 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<sup>®</sup> 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<sup>®</sup> meningococcus C conjugate vaccine to Canada. This increase is partially offset by (i) a \$1.2 million decline in MENJUGATE<sup>®</sup> vaccine tender sales in Australia and (ii) \$0.8 million from a decline in MENJUGATE<sup>®</sup> 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)			
Product sales, net:				
BETASERON® interferon beta-1b	\$ 26,634	\$ 30,136	\$ (3,502 )	(11.6 )%
TOBI® tobramycin	52,935	52,524	411	0.8