

CHIRON CORP  
Form 10-Q/A  
April 06, 2005

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

# FORM 10-Q/A

(Mark one)

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

**For the quarterly period ended June 30, 2004**

**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**

**CHIRON CORPORATION**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**94-2754624**

(I.R.S. Employer Identification No.)

**4560 Horton Street, Emeryville, California**

(Address of principal executive offices)

**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)

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.

Edgar Filing: CHIRON CORP - Form 10-Q/A

Yes  No

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.

<b>Title of Class</b>	<b>Outstanding at July 30, 2004</b>
Common Stock, \$0.01 par value	187,718,517

---

**EXPLANATORY NOTE**

## Edgar Filing: CHIRON CORP - Form 10-Q/A

This Form 10Q/A (the Report) is being filed to amend Chiron Corporation's (the Company) Quarterly Report on Form 10-Q filed on August 9, 2004 (the Original Report) for the quarterly period ended June 30, 2004 to reflect the restatement of the Company's previously issued financial statements as of and for the three and six month periods ended June 30, 2004, and the notes related thereto, as described below, and to make related changes. The information in this Report presented as of the date of the Original Report does not reflect subsequent results, events or developments. Such subsequent results, events or developments include, among others, the information and events subsequently described in our Quarterly Reports on Form 10-Q, our Annual Reports on Form 10-K and our Current Reports on Form 8-K. For a description of such subsequent results, events or developments, please read our Exchange Act Reports filed with the Securities and Exchange Commission since the date of the Original Report, which update and supersede information contained in the Original Report and this Report.

Chiron has determined that certain sales of a 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. See Note 1 to Chiron's Condensed Consolidated Financial Statements, included herein, for additional discussion.

Chiron has reflected the results of the restatement for the fiscal year ended December 31, 2004 in its Annual Report on Form 10-K for such year, filed with the SEC on March 16, 2005, and has restated its interim financial statements in this Report and in an additional Quarterly Report on Form 10-Q/A for the quarterly period ended September 30, 2004.

In 2004, the Emerging Issues Task Force (EITF) reached a consensus on EITF Issue No. 04-8 The Effect of Contingently Convertible Instruments on Diluted Earnings per Share, that the dilutive effect of contingently convertible debt instruments (CoCos) must be included in diluted earnings per share regardless of whether the triggering contingency has been satisfied, if dilutive. Adoption of Issue No. 04-8 would be on a retroactive basis and would require restatement of prior period diluted earnings per share. Chiron adopted EITF Issue No. 04-08 in the fourth quarter of 2004. The adoption of EITF Issue No. 04-08 did not result in additional dilution to our diluted earnings per share from our \$500.0 million convertible debentures due 2033 nor from our \$385.0 million convertible debentures due 2034 for the three and six months ended June 30, 2004, as discussed in Note 2 to Chiron's Condensed Consolidated Financial Statements.

### CHIRON CORPORATION

#### TABLE OF CONTENTS

	Page No.
<b>PART I. FINANCIAL INFORMATION</b>	
<b><u>ITEM 1. Financial Statements (Unaudited)</u></b>	
<u>Condensed Consolidated Balance Sheets at June 30, 2004 and December 31, 2003</u>	<u>3</u>
<u>Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2004 and 2003</u>	<u>5</u>
<u>Condensed Consolidated Statements of Comprehensive Income for the three and six months ended June 30, 2004 and 2003</u>	<u>6</u>
<u>Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2004 and 2003</u>	<u>7</u>
<u>Notes to Condensed Consolidated Financial Statements</u>	<u>8</u>
<b><u>ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u></b>	<b><u>20</u></b>

<b><u>ITEM 4. Controls and Procedures</u></b>	<b><u>38</u></b>
<b><u>ITEM 6. Exhibits</u></b>	<b><u>39</u></b>
<b><u>SIGNATURES</u></b>	<b><u>40</u></b>

**Item 1. Financial Statements**



**CHIRON CORPORATION**

**CONDENSED CONSOLIDATED BALANCE SHEETS**

(Unaudited)

(In thousands, except share data)

	June 30, 2004 Restated	December 31, 2003
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 595,023	\$ 364,270
Short-term investments in marketable debt securities	235,964	174,212
Total cash and short-term investments	830,987	538,482
Accounts receivable, net of allowances	329,856	382,933
Current portion of notes receivable	500	1,479
Inventories, net of reserves	275,574	199,625
Assets held for sale	3,044	2,992
Current net deferred income tax assets	59,992	50,204
Derivative financial instruments	3,871	9,463
Other current assets	78,217	72,471
Total current assets	1,582,041	1,257,649
Noncurrent investments in marketable debt securities	202,979	560,292
Property, plant, equipment and leasehold improvements, at cost:		
Land and buildings	368,791	366,275
Laboratory, production and office equipment	614,178	615,814
Leasehold improvements	114,377	112,200
Construction-in-progress	175,956	144,162
	1,273,302	1,238,451
Less accumulated depreciation and amortization	(544,635)	(548,701)
Property, plant, equipment and leasehold improvements, net	728,667	689,750
Purchased technologies, net	226,297	236,707
Goodwill	806,759	787,587
Other intangible assets, net	464,695	486,889
Investments in equity securities and affiliated companies	114,633	121,576
Equity method investments	889	953
Noncurrent notes receivable	7,500	7,500
Noncurrent derivative financial instruments		7,391
Other noncurrent assets	51,030	38,875
	\$ 4,185,490	\$ 4,195,169

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)

	June 30, 2004 Restated	December 31, 2003
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 112,778	\$ 102,201
Accrued compensation and related expenses	64,296	83,311
Current portion of capital lease	244	570
Current portion of unearned revenue	72,681	47,873
Income taxes payable	13,099	15,270
Other current liabilities	124,940	187,688
Total current liabilities	388,038	436,913
Long-term debt	938,087	926,709
Capital lease	157,075	157,677
Noncurrent derivative financial instruments	3,677	
Noncurrent net deferred income tax liabilities	90,848	107,496
Noncurrent unearned revenue	35,330	45,564
Other noncurrent liabilities	85,776	69,448
Minority interest	7,984	7,002
Total liabilities	1,706,815	1,750,809
Commitments and contingencies		
Stockholders' equity:		
Common stock	1,917	1,917
Additional paid-in capital	2,527,313	2,503,195
Deferred stock compensation	(18,929)	(12,871)
Accumulated deficit	(1,719)	(46,634)
Accumulated other comprehensive income	171,805	216,302
Treasury stock, at cost (4,063,000 shares at June 30, 2004 and 4,567,000 shares at December 31, 2003)	(201,712)	(217,549)
Total stockholders' equity	2,478,675	2,444,360
	\$ 4,185,490	\$ 4,195,169

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)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004 Restated	2003	2004 Restated	2003
<b>Revenues:</b>				
Product sales, net	\$ 281,221	\$ 245,928	\$ 562,287	\$ 464,548
Revenues from joint business arrangement	28,532	27,475	58,893	53,927
Collaborative agreement revenues	3,828	3,624	10,343	7,738
Royalty and license fee revenues	55,196	66,876	109,988	120,300
Other revenues	10,975	6,369	17,913	24,794
Total revenues	379,752	350,272	759,424	671,307
<b>Operating expenses:</b>				
Cost of sales	129,228	97,420	255,929	183,009
Research and development	100,326	89,915	198,736	172,045
Selling, general and administrative	106,857	80,226	211,597	153,268
Amortization expense	21,179	7,701	42,511	15,314
Other operating expenses	4,644	1,259	6,760	2,950
Total operating expenses	362,234	276,521	715,533	526,586
Income from operations	17,518	73,751	43,891	144,721
Interest expense	(6,452)	(2,839)	(12,377)	(6,301)
Interest and other income, net	19,809	11,613	35,883	25,931
Minority interest	(459)	(581)	(1,079)	(981)
Income from continuing operations before income taxes	30,416	81,944	66,318	163,370
Provision for income taxes	7,604	20,485	16,579	40,842
Income from continuing operations	22,812	61,459	49,739	122,528
Gain from discontinued operations	12,459	538	25,304	1,964
Net income	\$ 35,271	\$ 61,997	\$ 75,043	\$ 124,492
<b>Basic earnings per share:</b>				
Income from continuing operations	\$ 0.12	\$ 0.33	\$ 0.26	\$ 0.66
Net income	\$ 0.19	\$ 0.33	\$ 0.40	\$ 0.67
<b>Diluted earnings per share:</b>				
Income from continuing operations	\$ 0.12	\$ 0.32	\$ 0.26	\$ 0.65
Net income	\$ 0.18	\$ 0.33	\$ 0.39	\$ 0.66

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

**CHIRON CORPORATION**

**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME**

(Unaudited)

(In thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004 Restated	2003	2004 Restated	2003
Net income	\$ 35,271	\$ 61,997	\$ 75,043	\$ 124,492
Other comprehensive income (loss):				
Change in foreign currency translation adjustment during the period	(15,784)	35,823	(37,412)	45,118
Unrealized gains (losses) from investments:				
Net unrealized holding gains (losses) arising during the period, net of tax (provision) benefit of \$4,610 and (\$1,541) for the three months ended June 30, 2004 and 2003, respectively, and \$2,112 and (\$1,284) for the six months ended June 30, 2004 and 2003, respectively	6,267	3,083	7,544	2,640
Reclassification adjustment for net gains included in net income, net of tax provision of \$2,965 and \$1,834 for the three months ended June 30, 2004 and 2003, respectively, and \$9,353 and \$3,626 for the six months ended June 30, 2004 and 2003, respectively	(11,361)	(2,940)	(14,629)	(5,744)
Net unrealized gains (losses) from investments	(5,094)	143	(7,085)	(3,104)
Other comprehensive income (loss)	(20,878)	35,966	(44,497)	42,014
Comprehensive income	\$ 14,393	\$ 97,963	\$ 30,546	\$ 166,506

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

**CHIRON CORPORATION**

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**



(Unaudited)

(In thousands)

	Six Months Ended June 30,	
	2004 Restated	2003
Net cash provided by operating activities	\$ 74,730	\$ 112,706
Cash flows from investing activities:		
Purchases of investments in marketable debt securities	(218,815)	(277,514)
Proceeds from sales and maturities of investments in marketable debt securities	508,121	917,794
Capital expenditures	(93,770)	(52,371)
Purchases of equity securities and interests in affiliated companies	(4,349)	(36,889)
Proceeds from sale of equity securities and interests in affiliated companies	16,277	7,428
Cash paid for acquisitions, net of cash acquired	(19,548)	(1,180)
Other, net	783	(777)
Net cash provided by investing activities	188,699	556,491
Cash flows from financing activities:		
Net repayment of short-term borrowings		(71)
Repayment of debt and capital leases	(380,035)	(95)
Payments to acquire treasury stock	(71,726)	(68,079)
Proceeds from reissuance of treasury stock	45,001	24,526
Proceeds from issuance of debt	2,317	
Payment of bond issuance costs	(7,766)	
Proceeds from issuance of convertible debentures	385,000	
Proceeds from put options		2,144
Net cash used in financing activities	(27,209)	(41,575)
Effect of exchange rate changes on cash and cash equivalents	(5,467)	471
Net increase in cash and cash equivalents	230,753	628,093
Cash and cash equivalents at beginning of the period	364,270	247,950
Cash and cash equivalents at end of the period	\$ 595,023	\$ 876,043

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

**CHIRON CORPORATION**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**June 30, 2004**

**(Unaudited)**

**Note 1 Basis of Presentation and Summary of Significant Accounting Policies**

*Basis of Presentation*



## Edgar Filing: CHIRON CORP - Form 10-Q/A

The information presented in the Condensed Consolidated Financial Statements at June 30, 2004, and for the three and six months ended June 30, 2004 and 2003, 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, 2003, 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, 2003, which are included in the Annual Report on Form 10-K filed by Chiron with the Securities and Exchange Commission.

### *Restatement of Financial Statements*



## Edgar Filing: CHIRON CORP - Form 10-Q/A

Chiron determined that certain sales of a 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 of the restatement, for the three and six months ended June 30, 2004, product sales were reduced by \$13.9 million, cost of sales were reduced by \$1.5 million and income taxes were reduced by \$3.1 million. This resulted in a \$9.3 million reduction in income from continuing operations and net income and a \$0.05 reduction of diluted income from continuing operations per share (\$0.12 per share instead of the \$0.17 per share as previously reported). On the June 30, 2004 consolidated balance sheet, the current portion of unearned revenue was increased by \$12.3 million and income taxes payable was reduced by \$3.1 million.

### *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.

On July 8, 2003, Chiron acquired PowderJect Pharmaceuticals plc, a company based in Oxford, England that develops and commercializes vaccines. Chiron included PowderJect Pharmaceuticals' operating results in its consolidated operating results beginning July 8, 2003. PowderJect Pharmaceuticals is part of Chiron's vaccines segment.

Chiron is a limited partner in several venture capital funds. Chiron is obligated to pay up to \$60.0 million over ten years in equity contributions to these venture capital funds, of which approximately \$36.5 million was paid through June 30, 2004. Chiron accounts for these investments under the equity method of accounting.

### *Adoption of New Accounting Pronouncements*

Financial Accounting Standards Board (or FASB) Interpretation No. 46 (or FIN 46), Consolidation of Variable Interest Entities, an interpretation of Accounting Research Bulletin No. 51 as revised, requires a variable interest entity (or VIE) to be consolidated by a company if that company absorbs a majority of the VIEs expected losses, receives a majority of the entity's expected residual returns, or both, as a result of ownership, contractual or other financial interest in the VIE. Prior to the adoption of FIN 46, VIEs were generally consolidated by companies owning a majority voting interest in the VIE. The consolidation requirements of FIN 46 applied immediately to VIEs created after January 31, 2003, however, the FASB deferred the effective date for VIEs created before February 1, 2003 to the quarter ended March 31, 2004 for calendar year companies. Adoption of the provisions of FIN 46 prior to the deferred effective date was permitted.

We adopted the remaining provisions of FIN 46 in the first quarter of 2004. The adoption of these provisions did not have a material effect on our Condensed Consolidated Financial Statements.





*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's blood-testing segment includes Chiron's one-half share in the pretax operating earnings generated by the joint business contractual arrangement with Ortho-Clinical Diagnostics, Inc., a Johnson & Johnson company. Chiron accounts separately for research and development and manufacturing cost reimbursements and certain product sale revenues received from Ortho-Clinical Diagnostics, but relating to the joint business contractual arrangement. Chiron's joint business arrangement with Ortho-Clinical Diagnostics is 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. Prior to the first quarter 2003, Chiron had accounted for revenues relating to Ortho-Clinical Diagnostics' non-U.S. affiliate sales on a one-quarter lag, with an adjustment of the estimate to actual in the subsequent quarter. More current information of Ortho-Clinical Diagnostics' non-U.S. affiliate sales became available in the first quarter 2003, and as a result, Chiron is able to recognize revenues relating to Ortho-Clinical Diagnostics' non-U.S. affiliate sales on a one-month lag. The effect of this change, net of tax, was an increase to net income by \$3.2 million for revenue from the joint business contractual arrangement for the six months ended June 30, 2003.

Chiron currently owns a facility in London, England for international operations. This facility became available for sale in the fourth quarter of 2003 and Chiron expects to complete the sale of this facility within one year of the date it became available for sale. Chiron has committed to a plan to sell this facility and is actively marketing this facility. This facility is classified as *Assets held for sale* in the Condensed Consolidated Balance Sheet at June 30, 2004.

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 second quarter 2004.

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

*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.

Inventories, net of reserves, consisted of the following:

	<b>June 30, 2004</b>		<b>December 31, 2003</b>
Finished goods	\$ 49,734	\$	38,640
Work-in-process	169,715		105,359
Raw materials	56,125		55,626
	\$ 275,574	\$	199,625

*Income Taxes*

The effective tax rate for the three and six months ended June 30, 2004 and 2003 was 25% of pretax income from continuing operations. The effective tax rate may be affected in future periods by changes in Chiron's estimates with respect to the deferred tax assets, acquisitions and other items affecting the overall tax rate.

*Put Options*

Chiron has, in the past, used written put options to reduce the effective costs of repurchasing its common stock. After expiration of existing put options in the second quarter of 2003, Chiron discontinued the use of put options. Chiron had no put options outstanding at June 30, 2004.

*Stock-Based Compensation*

Chiron measures compensation expense for its stock-based employee compensation plans 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. Compensation expense is included primarily in "Selling, general and administrative" in the Condensed Consolidated Statements of Operations.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
	(in thousands, except per share data)			
<b>Net income:</b>				
As reported	\$ 35,271	\$ 61,997	\$ 75,043	\$ 124,492
Add: Stock-based employee compensation expense included in reported net income, net of related tax effects	1,349	1,750	2,689	2,651
Less: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	22,769	19,933	44,277	38,045
Pro forma	\$ 13,851	\$ 43,814	\$ 33,455	\$ 89,098
<b>Basic net income per share:</b>				
As reported	\$ 0.19	\$ 0.33	\$ 0.40	\$ 0.67
Pro forma	\$ 0.07	\$ 0.24	\$ 0.18	\$ 0.48
<b>Diluted net income per share:</b>				

Edgar Filing: CHIRON CORP - Form 10-Q/A

As reported	\$	0.18	\$	0.33	\$	0.39	\$	0.66
Pro forma	\$	0.07	\$	0.23	\$	0.18	\$	0.47

*Comprehensive Income*

For the three and six months ended June 30, 2004 and 2003, the foreign currency translation component of comprehensive income relates to permanent investments in non-U.S. subsidiaries, and accordingly, was not adjusted for income taxes.

*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 \$4.7 million and \$30.1 million for the three and six months ended June 30, 2004, respectively, and \$16.3 million and \$23.8 million for the three and six months ended June 30, 2003, respectively, to Accumulated deficit in the Condensed Consolidated Balance Sheets.

**Note 2 Earnings 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, warrants and equivalents, which are included under the treasury-stock method; (ii) performance units 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. Due to rounding, quarterly amounts may not sum fully to yearly amounts.

Contingently convertible debt instruments ( CoCos ) are included in diluted earnings per share, if dilutive. For the three and six months ended June 30, 2004, 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 each of these CoCos were not dilutive.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
<b>Income (Numerator):</b>				
Income from continuing operations	\$ 22,812	\$ 61,459	\$ 49,739	\$ 122,528
<b>Shares (Denominator):</b>				
Weighted-average common shares outstanding	188,275	186,408	187,952	186,584
<b>Effect of dilutive securities:</b>				
Stock options and equivalents	2,710	3,550	3,450	3,294
Put options		5		3
Weighted-average common shares outstanding, plus impact from assumed conversions	190,985	189,963	191,402	189,881
Basic earnings per share	\$ 0.12	\$ 0.33	\$ 0.26	\$ 0.66
Diluted earnings per share	\$ 0.12	\$ 0.32	\$ 0.26	\$ 0.65

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
<b>Income (Numerator):</b>				
Net income	\$ 35,271	\$ 61,997	\$ 75,043	\$ 124,492
<b>Shares (Denominator):</b>				
Weighted-average common shares outstanding	188,275	186,408	187,952	186,584
<b>Effect of dilutive securities:</b>				
Stock options and equivalents	2,710	3,550	3,450	3,294
Put options		5		3

Edgar Filing: CHIRON CORP - Form 10-Q/A

Weighted-average common shares outstanding, plus impact from assumed conversions		190,985		189,963		191,402		189,881
Basic earnings per share	\$	0.19	\$	0.33	\$	0.40	\$	0.67
Diluted earnings per share	\$	0.18	\$	0.33	\$	0.39	\$	0.66

For the three months ended June 30, 2004 and 2003, stock options to purchase 11.8 million and 16.8 million shares, respectively, and for the six months ended June 30, 2004 and 2003, stock options to purchase 7.6 million and 17.1 million shares, respectively, with exercise prices greater than the average market prices of common stock, 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 and six months ended June 30, 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 and six months ended June 30, 2004, the assumed conversion of the 2034 Debentures was not dilutive.

For the three and six months ended June 30, 2004, 4.1 million and 6.2 million shares of common stock that would be issued upon conversion of the Liquid Yield Option Notes (LYONs) were excluded from the computations of diluted earnings per share, as their inclusion would be antidilutive. For each of the three and six months ended June 30, 2003, 5.2 million shares of common stock that would be issued upon conversion of the LYONs were excluded from the computation of diluted earnings per share, as their inclusion would be antidilutive. During the second quarter of 2004, Chiron was required to purchase a significant portion of the LYONs as discussed in Note 7 Debt Obligations .

### **Note 3 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 and Chiron Vision in 1998 and 1997, respectively.

In the first quarter 2003, Chiron and Bayer Corporation reached a settlement agreement relating to certain claims raised by Bayer under the Stock Purchase Agreement dated September 17, 1998, between Chiron and Bayer for Chiron Diagnostics. Under this settlement agreement, Chiron was required to make a payment to Bayer during the first quarter 2003. Pursuant to this settlement, Chiron recorded a charge, net of adjustment to its previously provided reserve for indemnity obligations, of \$7.6 million, offset by an income tax benefit of \$9.0 million, resulting in a net gain of \$1.4 million which was reported as a Gain from discontinued operations for the six months ended June 30, 2003.

In the second quarter 2003, we reversed approximately \$0.5 million related to unutilized reserves of Chiron Diagnostics and Chiron Vision, which were recorded as a Gain from discontinued operations for the three and six months ended June 30, 2003.

Chiron and Bayer also were involved in a separate 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 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 in excess of the required payments for the indemnity obligations in the first quarter of

## Edgar Filing: CHIRON CORP - Form 10-Q/A

2004. This settlement resulted in a benefit of \$0.3 million and an income tax benefit of \$12.5 million, resulting in a net gain of \$12.8 million, which was reported as a Gain from discontinued operations for the six months ended June 30, 2004.

In the second quarter 2004, Chiron and the IRS entered into a settlement agreement closing the open tax years 1996 to 1998. Pursuant to this settlement agreement Chiron recognized a tax benefit of approximately \$12.5 million, which was reported as a Gain from discontinued operations for the three and six months ended June 30, 2004.

### **Note 4 Acquisitions**

**PowderJect Pharmaceuticals plc** On July 8, 2003, Chiron acquired PowderJect Pharmaceuticals, a company based in Oxford, England that develops and commercializes vaccines. Chiron acquired all of the outstanding shares of common stock of PowderJect Pharmaceuticals for 550 pence per ordinary share, which, including estimated acquisition costs, resulted in a total preliminary purchase price of approximately \$947.8 million.



During the second quarter of 2004, Chiron completed the planned divestiture of certain research operations in Madison, Wisconsin and Oxford, England and certain vaccines operations in Sweden. The divestiture of these operations included the disposition of net assets of \$14.7 million which included \$15.5 million of cash, deferred tax assets of \$9.4 million, and exit liabilities of \$21.6 million. The net impact of the divestiture resulted in an increase to goodwill of \$2.5 million. Also during second quarter of 2004, Chiron adjusted the previously recorded obligation related to an assumed defined benefit plan, which resulted in an increase to goodwill of \$8.1 million. The purchase price includes accruals for estimated exit costs and certain other direct acquisition costs. As a result of the adjustment to exit liabilities and estimated direct acquisition costs, the purchase price was revised to \$925.8 million. The aggregate purchase price and the allocation of the purchase price may change upon finalization of these estimates.

PowderJect Pharmaceuticals is part of Chiron's vaccines segment. PowderJect Pharmaceuticals' products, including vaccines for influenza, expand Chiron's portfolio of vaccine products. Chiron accounted for the acquisition as a business combination and included PowderJect Pharmaceuticals' operating results in its consolidated operating results beginning July 8, 2003.

The components of the purchase price, and the allocation thereof based on estimated fair values are summarized in the following table (in thousands).

Consideration and acquisition costs:	
Cash paid for common stock	\$ 831,026
Cash paid for options on common stock	59,153
Acquisition costs paid as of June 30, 2004	20,739
Acquisition costs not yet paid as of June 30, 2004	14,883
Total purchase price	\$ 925,801
Allocation of purchase price:	
Cash and cash equivalents	\$ 76,685
Short-term marketable securities	8,840
Accounts receivable, net	39,600
Inventories	64,924
Property, plant and equipment	60,589
Goodwill	513,520
Acquired intangible assets	335,500
Other assets	4,876
Income taxes payable	(17,741)
Current liabilities	(54,383)
Net deferred tax liability	(69,566)
Long-term liabilities	(82,343)
Purchased in-process research and development	45,300
Total purchase price	\$ 925,801

Chiron allocated the purchase price based on the fair value of the assets acquired and liabilities assumed. Chiron allocated a portion of the purchase price to purchased in-process research and development, which it charged to earnings in 2003. Purchased in-process research and development represented the valuation of acquired, to-be-completed research projects. Purchased in-process research and development was determined using the income approach, which is based on the premise that the value of a security or asset is the present value of the future earning capacity that is available for distribution to the subject investors in the security or asset. In valuing the purchased in-process research and development, Chiron used probability-of-success-adjusted cash flows and a 14% discount rate. Cash flows from projects including those relating to (i) certain travel vaccines and (ii) vaccines for allergies were assumed to commence between 2004 and 2012. Given the high risk associated with the development of new drugs, Chiron probability-adjusted the revenue and expense forecasts to reflect the risk of advancement through the regulatory approval process based on the stage of development in the regulatory process. Such a valuation requires significant estimates and assumptions. Chiron believes that the fair value assigned to purchased in-process research and development is based on reasonable assumptions. However, these assumptions may be incomplete or inaccurate, and unanticipated events and circumstances may occur. To assist in determining the value of the purchased in-process research and development, a third-party valuation was obtained as of the acquisition date.



Acquired intangible assets included the fair value of distribution rights, a contract manufacturing agreement and developed product technologies. The distribution rights and the contract manufacturing agreement are being amortized on a straight-line basis over 1 to 4 years. The weighted average amortization period for these intangible assets is 2 years. Developed product technologies are being amortized using either the estimated sales method over 10 years or on a straight-line basis over 1 to 15 years. The weighted average amortization period for these intangible assets is 11 years. The weighted average amortization period for total acquired intangible assets is 10 years.

Income taxes payable of \$17.7 million relates to current tax liabilities associated with PowderJect Pharmaceuticals at the date of acquisition. The net deferred tax liability of \$69.6 million is comprised of current and non-current deferred tax assets of \$31.1 million primarily related to net operating losses incurred from April 1, 2003 through the acquisition date, reserves and depreciation timing differences and a non-current deferred tax liability of \$100.7 million related to acquired intangibles.

For acquisition costs related to PowderJect Pharmaceuticals, Chiron paid \$4.0 million for the six months ended June 30, 2004. These payments are reflected in the Condensed Consolidated Statement of Cash Flows as a component of Cash paid for acquisitions, net of cash acquired for the six months ended June 30, 2004.

Chiron paid \$1.0 million and \$0.2 million related to severance payments included in acquisition costs for PathoGenesis Corporation and Matrix Pharmaceutical, respectively, for the six months ended June 30, 2003. These payments are reflected in the Condensed Consolidated Statement of Cash Flows as a component of Cash paid for acquisitions, net of cash acquired for the six months ended June 30, 2003.

## Note 5 Intangible Assets

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

	June 30, 2004			December 31, 2003		
	Gross Carrying Value	Accumulated Amortization	Net Carrying Value	Gross Carrying Value	Accumulated Amortization	Net Carrying Value
Purchased technologies	\$ 332,338	\$ 106,041	\$ 226,297	\$ 332,543	\$ 95,836	\$ 236,707
Patents	\$ 123,804	\$ 66,171	\$ 57,633	\$ 119,675	\$ 61,747	\$ 57,928
Trademarks	60,033	21,725	38,308	61,082	20,507	40,575
Licenses and technology rights	48,473	32,693	15,780	49,087	27,818	21,269
Developed product technologies	353,195	46,972	306,223	347,233	23,093	324,140
Customer relationships	27,912	10,369	17,543	28,824	9,952	18,872
Know how (1)	12,676	6,289	6,387	13,090	6,023	7,067
Databases	7,100	1,775	5,325	7,100	1,538	5,562
Other	34,884	17,388	17,496	26,328	14,852	11,476
Total other intangible assets	\$ 668,077	\$ 203,382	\$ 464,695	\$ 652,419	\$ 165,530	\$ 486,889
Total intangible assets subject to amortization	\$ 1,000,415	\$ 309,423	\$ 690,992	\$ 984,962	\$ 261,366	\$ 723,596

---

(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 .

Aggregate amortization expense is as follows (in thousands):

For the six months ended June 30, 2004 (reported)	\$	47,549
For the remaining six months in the year ended December 31, 2004 (estimated)		44,640
For the year ended December 31, 2004 (estimated)	\$	92,189
For the year ended December 31, 2005 (estimated)	\$	89,732
For the year ended December 31, 2006 (estimated)	\$	94,130
For the year ended December 31, 2007 (estimated)	\$	91,987
For the year ended December 31, 2008 (estimated)	\$	67,474
For the year ended December 31, 2009 (estimated)	\$	43,825

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, 2003	\$	187,492	\$	600,095	\$ 787,587
PowderJect adjustments (See Note 4)				10,559	10,559
Effect of exchange rate changes				8,613	8,613
Balance as of June 30, 2004	\$	187,492	\$	619,267	\$ 806,759

## Note 6 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 Incorporated and Chiron's one-half share in the pretax operating earnings generated by the joint business contractual arrangement with Ortho-Clinical Diagnostics, Inc., a Johnson & Johnson company. 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 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 diseases, using the development and acquisition of technologies related to therapeutic proteins and small molecules.

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.

## Edgar Filing: CHIRON CORP - Form 10-Q/A

The accounting policies of Chiron's reportable segments are the same as those described in Note 1 Basis of Presentation and Summary of Significant Accounting Policies above and in Chiron's Annual Report on Form 10-K for the year ended December 31, 2003. Chiron evaluates the performance of its segments based on each segment's income (loss) from continuing operations.

Edgar Filing: CHIRON CORP - Form 10-Q/A

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
<b>Revenues</b>				
Blood-testing:				
Product sales, net:				
Procleix® System	\$ 60,589	\$ 45,981	\$ 122,475	\$ 88,104
Ortho-Clinical Diagnostics	6,608	7,123	12,842	13,531
Total product sales, net	67,197	53,104	135,317	101,635
Revenues from joint business arrangement	28,532	27,475	58,893	53,927
Collaborative agreement revenues	2,325	2,340	4,389	4,289
Royalty and license fee revenues	16,267	23,160	32,701	38,796
Other revenues	235		430	
Total blood-testing revenues	114,556	106,079	231,730	198,647
Vaccines:				
Product sales, net:				
Influenza vaccines	8,207	3,783	15,912	8,036
Menjugate®	5,016	13,696	9,565	21,234
Travel vaccines	26,261	23,052	49,271	48,752
Pediatric and other vaccines	47,619	45,026	98,802	75,939
Total product sales, net	87,103	85,557	173,550	153,961
Collaborative agreement revenues	1,214	166	5,180	167
Royalty and license fee revenues	25	3,343	2,675	6,529
Other revenues	5,914	3,218	9,556	6,009
Total vaccines revenues	94,256	92,284	190,961	166,666
Biopharmaceuticals:				
Product sales, net				
Betaseron®	31,626	30,478	61,762	59,778
TOBI®	51,342	38,984	103,866	79,718
Proleukin®	35,057	29,381	66,925	55,364
Other	8,896	8,424	20,867	14,092
Total product sales, net	126,921	107,267	253,420	208,952
Collaborative agreement revenues	289	1,118	774	3,282
Royalty and license fee revenues	15,183	20,758	32,480	38,574
Other revenues	4,826	3,151	7,927	18,785
Total biopharmaceuticals revenues	147,219	132,294	294,601	269,593
Other:				
Royalty and license fee revenues	23,721	19,615	42,132	36,401
Total revenues	\$ 379,752	\$ 350,272	\$ 759,424	\$ 671,307
<b>Income (loss) from continuing operations</b>				
Blood-testing	\$ 59,208	\$ 62,441	\$ 122,848	\$ 113,003
Vaccines	(46,313)	794	(96,352)	(4,508)
Biopharmaceuticals	8,777	8,353	28,026	33,452
Other	(4,154)	2,163	(10,631)	2,774
Segment income from operations	17,518	73,751	43,891	144,721
Interest expense	(6,452)	(2,839)	(12,377)	(6,301)
Interest and other income, net	19,809	11,613	35,883	25,931
Minority interest	(459)	(581)	(1,079)	(981)
Income from continuing operations before income taxes	\$ 30,416	\$ 81,944	\$ 66,318	\$ 163,370





## Note 7 Debt Obligations

### *Convertible Debentures*

On June 22, 2004, Chiron issued \$385.0 million aggregate principal amount of convertible debentures, which mature on June 30, 2034. The convertible debentures accrue interest at a rate of 2.75% per year and interest is payable on June 30 and December 30 commencing on December 30, 2004. The debentures are senior, unsecured obligations of Chiron and rank equal in right of payment with all of Chiron's existing and future unsecured and unsubordinated indebtedness.

The holders of the debentures may convert their debentures when certain Chiron common stock price targets have been met at certain times, if the trading price for the debentures falls below certain levels for a specified period of time, if the debentures have been called for redemption, if the credit rating assigned to Chiron's long-term senior debt is below specified levels, upon the occurrence and continuance of specified corporate transactions or in connection with a transaction or event constituting a change in control. The initial conversion rate is 14.9254 shares of Chiron common stock per \$1,000 principal amount of debentures. This is equivalent to an initial conversion price of approximately \$67.00 per share of Chiron common stock.

If the 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 a change in control occurs on or prior to July 5, 2010, under certain circumstances, holders of the debentures will receive a make whole premium on debentures tendered for repurchase and for debentures converted in connection with a change in control. The amount of the make whole premium will be based on the price paid per share of Chiron common stock in a transaction constituting a change in control and is payable in Chiron common stock.

The holders of the debentures may require Chiron to repurchase for cash all or part of the debentures on June 30, 2010, June 30, 2014, June 30, 2019, June 30, 2024 and June 30, 2029. The repurchase price will be equal to 100% of the principal amount of the debentures to be repurchased, plus accrued and unpaid interest, if any, up to the repurchase date payable in cash.

On or after July 5, 2010, Chiron may redeem for cash all or part of the debentures at a redemption price equal to 100% of principal amount of the debentures to be redeemed, plus accrued and unpaid interest.

Bond issuance costs in connection with the issuance of the debentures amounted to approximately \$8.6 million and are being amortized to interest expense on a straight-line basis, which approximated the effective interest method, over six years, which represents the period from the issue date to the earliest put date. Bond issuance costs are recorded in *Other intangible assets, net* in the Condensed Consolidated Balance Sheets

at June 30, 2004.

*Liquid Yield Option Notes*

In June 2001, Chiron issued zero coupon Liquid Yield Option Notes (LYONs) with a face value of \$730.0 million and a yield to maturity of 2.0%. The LYONs were carried net of an original issue discount of \$328.2 million, which was being accreted to interest expense over the life of the LYONs using the effective interest method. No beneficial conversion feature existed at the time of the issuance of the LYONs. The LYONs mature on June 12, 2031, at a face value of \$1,000 per note. The LYONs are uncollateralized and unsubordinated, and rank equal in right of payment to Chiron's existing and future uncollateralized and unsubordinated indebtedness.

On June 12, 2004, certain LYONs holders, at their option, tendered, \$649.9 million in aggregate principal amount at maturity for purchase by Chiron. The purchase price for the LYONs was \$584.31 in cash per \$1,000 in principal amount at maturity. The aggregate purchase price for all the LYONs validly surrendered for purchase was \$379.7 million. At June 30, 2004, there remains outstanding \$80.1 million in aggregate principal amount at maturity and an accreted balance of \$46.8 million for the LYONs.

At the option of the holder, Chiron may be required to purchase all, or a portion, of the remaining LYONs on the following dates at the following prices for each note with face value of \$1,000:

<b>Date</b>	<b>Price</b>
June 12, 2006	\$ 608.04
June 12, 2011	\$ 671.65
June 12, 2016	\$ 741.92
June 12, 2021	\$ 819.54
June 12, 2026	\$ 905.29

*Other Loans Payable*

Chiron has entered into various agreements with a governmental body in Italy for which Chiron may borrow up to 11.0 million Euro (\$13.4 million at June 30, 2004) for research purposes. Under these facilities, Chiron has an outstanding balance of 3.0 million Euro (\$3.6 million) as of June 30, 2004 with interest rates that range from 2% to 6% and maturities that range from 2010 to 2013.

**Note 8 Commitments and Contingencies**

In March 2004, Chiron entered into a worldwide, exclusive, multi-product, collaborative arrangement with XOMA Ltd. for the development and commercialization of antibody products for the treatment of cancer. Under the terms of the arrangement, the parties agreed to jointly research, develop, and commercialize multiple antibody product candidates. Under the arrangement, the parties agreed to share development and commercialization expenses, including preclinical and clinical development, manufacturing and worldwide marketing costs, as well as revenues, generally on a 70-30 basis, with Chiron's share being 70% and XOMA's share being 30%. Chiron agreed to make an initial payment of \$10.0 million, which has been paid as of June 30, 2004, and to make a loan facility of up to \$50.0 million available to XOMA, starting on January 1, 2005 to fund XOMA's share of development expenses. The collaboration will initially focus on preclinical, process development and scale up work, with a potential Investigative New Drug (IND) filing anticipated early in the collaboration.

On June 1, 2004, Chiron renewed its lease for a manufacturing facility in Emeryville, California from June 1, 2004 through September 30, 2015 with two 3-year options to renew at the end of the lease term and with a right to cancel the lease as of May 31, 2014 without a cancellation fee. Chiron is obligated to pay an aggregate of approximately \$17.5 million in lease payments through May 31, 2014.

Chiron is subject to indemnification provisions under its agreements with other companies in its ordinary course of business, typically with business partners, contractors, clinical sites, insurers and customers. Under these provisions, Chiron generally indemnifies and holds harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of Chiron's activities. These indemnification provisions generally survive termination of the underlying agreement. In some cases, the maximum potential amount of future payments Chiron could be required to make under these indemnification provisions is unlimited. The estimated fair value of the indemnity obligations of these agreements is minimal. Accordingly, Chiron has no liabilities recorded for these agreements as of June 30, 2004. Chiron has not incurred material costs to defend lawsuits or settle claims related to these indemnification agreements.

Chiron is party to various claims, investigations and legal proceedings arising in the ordinary course of business. These claims, investigations and legal proceedings relate to intellectual property rights, contractual rights and obligations, employment matters, claims of product liability and other issues. While there is no assurance that an adverse determination of any of such matters could not 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 of these matters will have a material adverse effect upon Chiron's consolidated financial position and results of operations or cash flows.

Chiron is 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.

In the second quarter 2004, Chiron and the IRS entered into a settlement agreement closing the open tax years 1996 to 1998. Pursuant to this settlement agreement, Chiron recognized a tax benefit of approximately \$12.5 million, which was reported as a Gain from discontinued operations, as discussed in Note 3 Discontinued Operations and a continuing operations tax benefit of \$1.1 million for the three and six months ended June 30, 2004.

#### **Note 9 Subsequent Events**

On July 2, 2004, Chiron acquired Sagres Discovery (Sagres), a privately held company headquartered in Davis, California. Sagres focuses on the discovery and validation of targets with potential application to the development of cancer therapeutics. Sagres will be part of the Biopharmaceuticals segment. Chiron acquired Sagres for a preliminary purchase price of \$11.8 million.

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

### Overview

*This 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, in- and out-licensing activities and expected cost savings that involve risks and uncertainties and are subject to change. You should read the discussion below in conjunction with Part I, Item 1., Financial Statements, of this 10-Q and Part II, Items 7., 7A. and 8., Management's Discussion and Analysis of Financial Condition and Results of Operations, Quantitative and Qualitative Disclosures About Market Risk and Financial Statements and Supplementary Data, respectively, of our Annual Report on Form 10-K for the year ended December 31, 2003. The forward-looking statements contained in this 10-Q reflect our current beliefs and expectations on the date of this 10-Q. Actual results, performance or outcomes may differ from current expectations. Our actual performance may differ from current expectations due to many factors, including the outcome of clinical trials, regulatory review and approvals, manufacturing capabilities, intellectual property protections and defenses, stock-price and interest-rate volatility, 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. 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 stockholder and 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 10-Q. Consistent with SEC Regulation FD, we do not undertake an obligation to update the forward-looking information contained in this 10-Q.*

As discussed in Note 1 to our Condensed Consolidated Financial Statements, we determined that certain sales of a 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 determined to restate the financial statements included in our Quarterly Reports on 10-Q for such quarters. The restatement is reflected in management's discussion and analysis of financial condition and results of operations below.

We are a global pharmaceutical company that participates in three healthcare markets: blood-testing, vaccines and biopharmaceuticals. Chiron is focused on developing products for cancer, which include immune-based therapies, antibodies and novel small molecule anti-cancer agents, and infectious disease, which have a range of products spanning all three of our business units. 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.

The blood-testing segment consists of an alliance with Gen-Probe Incorporated and our one-half share in the pretax operating earnings generated by the joint business contractual arrangement with Ortho-Clinical Diagnostics, Inc., a Johnson & Johnson company. 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 vaccines segment consists of flu vaccines, including Fluvirin®, a product we obtained as part of our third quarter 2003 acquisition of PowderJect Pharmaceuticals (discussed below), a meningococcal vaccine, travel vaccines, which include rabies and tick-borne encephalitis

## Edgar Filing: CHIRON CORP - Form 10-Q/A

vaccines and two other products we obtained as part of our acquisition of PowderJect Pharmaceuticals, Arilvax and Dukoral, and pediatric and other 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.

The biopharmaceuticals segment consists of therapeutic products and services, with an emphasis on the treatment of cancer and infectious 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 pseudomonas 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.

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.

On July 8, 2003, we acquired PowderJect Pharmaceuticals plc, a company based in Oxford, England that develops and commercializes vaccines. We accounted for the acquisition of this business under the purchase method of accounting and included PowderJect Pharmaceuticals' operating results in our consolidated operating results beginning July 8, 2003. PowderJect Pharmaceuticals is part of our vaccines segment.

Income from continuing operations was \$22.8 million, or \$0.12 per diluted share, and \$61.5 million or \$0.32 per diluted share, for the three months ended June 30, 2004 and 2003, respectively and \$49.7 million, or \$0.26 per diluted share, and \$122.5 million, or \$0.65 per diluted share, for the six months ended June 30, 2004 and 2003, respectively. These declines were primarily due to (i) the effect of our acquisition of PowderJect, which includes amortization expense from intangible assets associated with the acquisition and (ii) the contractual decline in the Betaseron® royalty rate. As a result of our acquisition of PowderJect, which has flu sales primarily in the second half of the year, our earnings per share from continuing operations declined \$0.12 per diluted share for the three months ended June 30, 2004 and \$0.23 per diluted share for the six months ended June 30, 2004. Our earnings per share from continuing operations declined \$0.04 per diluted share for the three months ended June 30, 2004 and \$0.08 per diluted share for the six months ended June 30, 2004 as a result of the decline in the Betaseron® royalty rate.

Total revenues were \$379.8 million and \$350.3 million for the three months ended June 30, 2004 and 2003, respectively, and \$759.4 million and \$671.3 million for the six months ended June 30, 2004 and 2003, respectively. Product sales were \$281.2 million and \$245.9 million for the three months ended June 30, 2004 and 2003, respectively, and \$562.3 million and \$464.5 million for the six months ended June 30, 2004 and 2003, respectively. Our total revenues were affected by 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 2% and 3% to our total revenues for the three and six months ended June 30, 2004, respectively. However, since our Euro and British Pound expenses have also increased due to the movement in exchange rates, our earnings per share from continuing operations declined \$0.01 and \$0.03 per diluted share for the three and six months ended June 30, 2004, respectively, due to higher expenses compared to revenues in Euros and British Pounds.

For the three months ended June 30, 2004, increases in product sales were seen across all three of our business units, in particular Procleix® products, TOBI® tobramycin and Proleukin®. For the six months ended June 30, 2004, increases in product sales were also seen across all three of our business units, in particular Procleix® products, TOBI®, pediatric and other vaccines, and Proleukin®. Revenues from the joint business arrangement, royalty and license fees, collaborative agreement revenues and other revenues were \$98.5 million and \$104.3 million for the three months ended June 30, 2004 and 2003, respectively, and \$197.1 and \$206.8 million for the six months ended June 30, 2004 and 2003, respectively. For the three months ended June 30, 2004 as compared to the three months ended June 30, 2003, these revenues decreased primarily due to the decline in the Betaseron® royalty rate and the timing of license fees from our intellectual property portfolio. The decrease was offset by increased profitability of the joint business arrangement and contract manufacturing activities. For the six months ended June 30, 2004 compared to the six months ended June 30, 2003, these revenues decreased primarily due to the Biogen and Serono settlements in connection with the McCormick patents owned by Schering's U.S. subsidiary, Berlex, reported in the six months ended June 30, 2003, the decline in the Betaseron® royalty rate and the timing of license fees from our intellectual property portfolio. This decrease was offset by increased profitability of the joint business arrangement, contract manufacturing activities and royalties from our hepatitis C virus and HIV-related patents.

Gross margins were 54% and 60% for the three months ended June 30, 2004 and 2003, respectively, and 54% and 61% for the six months ended June 30, 2004 and 2003, respectively. For the three and six months ended June 30, 2004, gross margins decreased due to a decline in the gross margin of the vaccines business, a reduction in the royalty rate related to Betaseron® and the increased cost of producing the Betaseron® pre-filled diluent syringe.

Research and development expenses were \$100.3 million and \$89.9 million for the three months ended June 30, 2004 and 2003, respectively, and \$198.7 million and \$172.0 million for the six months ended June 30, 2004 and 2003, respectively. Research and development expenses for PowderJect Pharmaceuticals were \$0.9 million and \$7.7 million for the three and six months ended June 30, 2004. Research and development expenses associated with PowderJect Pharmaceuticals declined for the three months ended June 30, 2004 as we completed the planned divestiture of certain research operations in Madison, Wisconsin and Oxford, England. For the three and six months ended June 30, 2004, excluding PowderJect, the main beneficiaries of this increase include tifacogin, our meningococcal vaccines franchise, our flu cell culture program, cyclosporine solution for inhalation, CHIR-258, a growth factor kinase inhibitor and our first small molecule oncology compound in development, and a dry powder formulation of inhaled TOBI®. These increases were partially offset by decreases due to transfer of responsibility for the SILCAAT trial, discontinuance of development of tezacitabine and PA-2794 and lower costs related to the development of new manufacturing processes for Betaseron®.



## Edgar Filing: CHIRON CORP - Form 10-Q/A

Selling, general and administrative expenses were \$106.9 million and \$80.2 million for the three months ended June 30, 2004 and 2003, respectively, and \$211.6 million and \$153.3 million for the six months ended June 30, 2004 and 2003, respectively. PowderJect Pharmaceuticals, including associated integration costs, contributed approximately \$8.0 million and \$18.6 million for the three and six months ended June 30, 2004. The remaining increase in selling, general and administrative expenses resulted from additional costs associated with increase in sales across our businesses, investment in geographic penetration, defense of our patents and technology, increased headcount and ongoing sales and marketing programs.

The effective tax rate for the three and six months ended June 30, 2004 and 2003 was 25% of pretax income from continuing operations.

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

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.

Our blood-testing segment includes our one-half share in the pretax operating earnings generated by the joint business contractual arrangement with Ortho-Clinical Diagnostics, Inc., a Johnson & Johnson company. Our joint business arrangement with Ortho-Clinical Diagnostics is 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. Prior to 2003, we had accounted for revenues relating to non-U.S. affiliate sales on a one-quarter lag, with an adjustment of the estimate to actual in the subsequent quarter. More current information of non-U.S. affiliate sales of our joint business contractual arrangement became available for the three months ended March 31, 2003, and as a result, we are able to recognize revenues relating to non-U.S. affiliate sales on a one-month lag. The effect of this change, net of tax, was an increase to net income by \$3.2 million for revenues from the joint business arrangement for the six months ended June 30, 2003.

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 Chiron's Annual Report on Form 10-K for the year ended December 31, 2003.

## Results of Operations

### *Blood-testing*

**Product sales** Our blood-testing segment recognized product sales of \$67.2 million and \$53.1 million for the three months ended June 30, 2004 and 2003, respectively, and \$135.3 million and \$101.6 million for the six months ended June 30, 2004 and 2003, respectively.

*Procleix®* On February 27, 2002, the U.S. Food and Drug Administration approved the Procleix® HIV-1/HCV Assay. Under a collaboration agreement with Gen-Probe Incorporated, we market and sell the Procleix® HIV-1/HCV Assay and the related instrument system. In addition to selling directly in the U.S., we also sell in various European and Asia/Pacific 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 the provision of service on the instruments, we recognize revenue ratably over the life of the service agreement.

Worldwide product sales related to tests, instruments and the provision of services were \$60.6 million and \$46.0 million for the three months ended June 30, 2004 and 2003, respectively, and \$122.5 million and \$88.1 million for the six months ended June 30, 2004 and 2003, respectively. The increase in product sales for the three and six months ended June 30, 2004 as compared with the three and six months ended June 30, 2003 primarily related to (i) the introduction of the West Nile virus assay on an investigational-use basis in the U.S. and (ii) market share gains in the U.S. and continued penetration into several markets abroad for the Procleix® HIV-1/HCV Assay. In March 2003, the U.S. Food and Drug Administration accepted an investigational new drug (IND) for the West Nile virus assay. The new assay runs on the same instrumentation platform as the currently approved Procleix® HIV-1/HCV assay.

*Ortho-Clinical Diagnostics* Under the joint business contractual arrangement with Ortho-Clinical Diagnostics, Inc., we manufacture bulk reagents and antigens and confirmatory test kits for immunodiagnostic products. We recognized product sales under this arrangement of \$6.6 million and \$7.1 million for the three months ended June 30, 2004 and 2003, respectively, and \$12.8 million and \$13.5 million for the six months ended June 30, 2004 and 2003, respectively. The decrease in product sales for the three and six months ended June 30, 2004 as compared with the three and six months ended June 30, 2003, primarily related to the timing of manufacturing services under the arrangement. We also supply bulk antigens for Ortho-Clinical Diagnostics to be included in products to be sold by Bayer under a June 2001 agreement with Ortho-Clinical Diagnostics and Bayer Corporation (see also Royalty and license fee revenues Bayer below).

We expect competitive pressures related to our blood-testing products to continue, primarily as a result of the introduction of competing products into the market, as listed in Part I, Item 1. Business-Competition of our Annual Report on Form 10-K for the year ended December 31, 2003.

**Revenue from joint business arrangement** Revenues from our joint business contractual arrangement with Ortho-Clinical Diagnostics, Inc. were \$28.5 million and \$27.5 million for the three months ended June 30, 2004 and 2003, respectively, and \$58.9 million and \$53.9 million for the six months ended June 30, 2004 and 2003, respectively. The increase in revenues from our joint business arrangement for the three months ended June 30, 2004 as compared with the three months ended June 30, 2003 primarily resulted from (i) increased profitability of Ortho-Clinical Diagnostics foreign affiliates and (ii) an increase in royalties. These increases were offset by the timing of Ortho-Clinical Diagnostics shipments to third parties and an adjustment of the first quarter 2004 estimate of revenue to actual results. The increase in revenues from our joint business arrangement for the six months ended June 30, 2004 as compared with the six months ended June 30, 2003 primarily resulted from (i) higher profits from Ortho-

Clinical Diagnostics U.S. operations and foreign affiliates and (ii) an increase in royalties. These increases are offset by a one-time benefit for the three months ended March 31, 2003 due to a change in estimate from a three-month lag to a one-month lag relating to the Ortho-Clinical Diagnostics, Inc.'s non-U.S. affiliate sales.

**Collaborative agreement revenues** We recognize collaborative agreement revenues for fees received as we perform research services and achieve specified milestones. Under the Ortho-Clinical Diagnostics, Inc. joint business arrangement, we conduct research and development services related to immunodiagnostic products. Our blood-testing segment recognized total collaborative agreement revenues of \$2.3 million and \$2.3 million for the three months ended June 30, 2004 and 2003, respectively, and \$4.4 million and \$4.3 million for the six months ended June 30, 2004 and 2003, respectively. The majority of collaborative agreement revenues recognized by our blood-testing segment related to immunodiagnostic products.

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 and HIV-related patents, for use in the blood screening and plasma fractionation markets. Our blood-testing segment also earns license fees related to our hepatitis C virus and HIV-related patents for technologies used by third parties to develop products for use in the blood screening and plasma fractionation markets. The blood-testing segment recognized royalty and license fee revenues of \$16.3 million and \$23.2 million for the three months ended June 30, 2004 and 2003, respectively, and \$32.7 million and \$38.8 million for the six months ended June 30, 2004 and 2003, respectively. The decrease in royalty and license fees for the three months ended June 30, 2004 as compared to the three months ended June 30, 2003 as well as the six months ended June 30, 2004 compared with the six months ended June 30, 2003 primarily related to two license agreements with Baxter A.G. for which we recognized a license fee in the second quarter 2003.

**F. Hoffmann-La Roche settlement** In October 2000, we entered into three license agreements with F. Hoffmann-La Roche Limited and several of its affiliated companies related to the settlement of certain litigation in the U.S. and certain other countries for the use of our hepatitis C virus and HIV intellectual property. Two agreements relate to *in vitro* diagnostic products. See Other Royalty and license fee revenues below. The third agreement for blood screening was superseded in May 2001 by two new agreements, one for each of hepatitis C virus and HIV. Revenues under these agreements were \$14.6 million and \$14.2 million for the three months ended June 30, 2004 and 2003, respectively, and \$29.6 million and \$28.6 million for the six months ended June 30, 2004 and 2003, respectively. The increase for the six months ended June 30, 2004 as compared with the six months ended June 30, 2003 related to a positive adjustment of the fourth quarter 2003 estimate to actual results. Under these new agreements, royalties continue through the lives of the hepatitis C virus and HIV-related patents covering F. Hoffmann-La Roche's nucleic acid testing products. Currently, the applicable issued hepatitis C virus-related patents begin to expire in 2015 for the U.S. and in 2010 for Europe. Currently, the applicable issued HIV-related patent in Europe expires in 2005. An

HIV-related patent was issued in the U.S. on March 13, 2003. This patent will expire seventeen years from the date of issuance. As permitted under the terms of its licensing agreement, F. Hoffmann-La Roche instituted arbitration proceedings in regard to the application of the U.S. patent. We have deferred recognition of \$5.5 million and \$1.3 million as of June 30, 2004 and 2003, of royalty revenue, respectively. During any pending arbitration proceedings, F. Hoffmann-La Roche remains obligated to make all quarterly royalty payments, subject to a right to be reimbursed by us if it is determined in the arbitration that such royalty payments were not due.

*Bayer* In June 2001, Chiron and Ortho-Clinical Diagnostics, Inc. entered into an agreement with Bayer Corporation for the clinical diagnostic market. Under this agreement, Bayer manufactures and sells certain of Ortho-Clinical Diagnostics' hepatitis C virus and HIV immunodiagnostic products for use on Bayer's instrument platforms. Bayer paid us a license fee of \$45.3 million, which we deferred (due to our continuing manufacturing obligations) and began recognizing as revenue in the third quarter 2001. We will recognize the remaining amount ratably through 2010.

*Baxter A.G.* In June 2003, we entered into two license agreements with Baxter A.G. related to our hepatitis C virus and HIV technology for use in the plasma fractionation market for which we recognized a license fee in the second quarter 2003.

Royalty and license fee revenues may fluctuate based on the nature of the related agreements and the timing of receipt of license fees. 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. We have no assurance that we will be able to do so or that future royalty and license fee revenues will not decline.

**Gross profit** Blood-testing gross profit as a percentage of net product sales was 42% and 46% for the three months ended June 30, 2004 and 2003, respectively, and 42% and 44% for the six months ended June 30, 2004 and 2003, respectively. The blood-testing gross profit margins for the three months ended June 30, 2003 as well as for the six months ended June 30, 2003 were positively impacted by an adjustment to cost of goods sold pursuant to our collaboration agreement with Gen-Probe Incorporated. The blood-testing gross profit margins for the three and six months ended June 30, 2004 benefited from an amendment in November 2003 to the worldwide blood screening collaboration agreement between Chiron and Gen-Probe Incorporated in order to adopt permanent, fixed revenue shares for each party. Effective January 1, 2004, Gen-Probe's share was set at 45.75% of net revenues for assays, which include a test for the hepatitis C virus. For commercial assays, which do not test for hepatitis C virus, such as the West Nile test, the

agreement remains unchanged with each party retaining 50% of the net revenues after deduction of specified expenses.

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

**Research and development** Our blood-testing segment recognized research and development expenses of \$6.3 million and \$5.6 million for the three months ended June 30, 2004 and 2003, respectively, and \$11.4 million and \$10.8 million for the six months ended June 30, 2004 and 2003, respectively. The research and development spending in 2004 and 2003 related to the continued development of nucleic acid testing products and activities under the Ortho-Clinical Diagnostics joint business arrangement.

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** Our blood-testing segment recognized selling, general and administrative expenses of \$10.3 million and \$9.6 million for the three months ended June 30, 2004 and 2003, respectively, and \$19.6 million and \$17.6 million for the six months ended June 30, 2004 and 2003, respectively. The increased selling, general and administrative expenses for the three months ended June 30, 2004 as compared with the three months ended June 30, 2003, as well as for the six months ended June 30, 2004 compared with the six months ended June 30, 2003, related to increased headcount to support the expansion of our customer base for the Procleix® HIV-1/HCV Assay in the U.S., Europe and other international markets.

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*

**Product sales** We sell flu, meningococcal, travel, pediatric, and other vaccines in the U.S., Germany, Italy, and the United Kingdom, as well as in other international markets. Vaccine product sales were \$87.1 million and \$85.6 million for the three months ended June 30, 2004 and 2003, respectively, and \$173.6 million and \$154.0 million for the six months ended June 30, 2004 and 2003, respectively.

Sales of our flu vaccines were \$8.2 million and \$3.8 million for the three months ended June 30, 2004 and 2003, respectively, and \$15.9 million and \$8.0 million for the six months ended June 30, 2004 and 2003, respectively. Flu vaccines sales increased for the three months ended June 30, 2004 as compared with the three month ended June 30, 2003 primarily as a result of sales to South Korea. PowderJect Pharmaceuticals flu vaccine sales were \$2.4 million for the six months ended June 30, 2004. Excluding PowderJect Pharmaceuticals, sales of our remaining flu

vaccines increased for the six months ended June 30, 2004 compared with the six months ended June 30, 2003 primarily as a result of additional sales to South Korea and Argentina and the benefit of the movement in the Euro to U.S. Dollar exchange rate.

Sales of Menjugate®, our conjugate vaccine against meningococcal infection caused by the bacterium *N. meningitidis* serogroup C, were \$5.0 million and \$13.7 million for the three months ended June 30, 2004 and 2003, respectively, and \$9.6 million and \$21.2 million for the six months ended June 30, 2004 and 2003, respectively. The decrease in Menjugate® sales for the three months ended June 30, 2004 as compared with the three months ended June 30, 2003 as well as for the six months ended June 30, 2004 compared with the six months ended June 30, 2003 was primarily driven by (i) an Australian tender in the state of New South Wales in the second quarter 2003, (ii) the timing of outbreaks and vaccination programs in various countries and (iii) increased competition for tender sales.

Sales of our travel vaccines, comprised of tick-borne encephalitis and rabies vaccines and two products we obtained as part of our third quarter 2003 acquisition of PowderJect Pharmaceuticals, Arilvax, and Dukoral, were \$26.3 million and \$23.1 million for the three months ended June 30, 2004 and 2003, respectively, and \$49.3 million and \$48.8 million for the six months ended June 30, 2004 and 2003, respectively. The increase in travel vaccines for the three months ended June 30, 2004 as compared with the three months ended June 30, 2003 as well as the six months ended June 30, 2004 as compared with the six months ended June 30, 2003 is primarily due to increased demand for our rabies vaccines in the U.S., primarily due to a product recall from a competitor, Europe and Asia and additional sales of travel vaccine products following our acquisition of PowderJect Pharmaceuticals. For the three and six months ended June 30, 2004 as compared with the three and six months ended June 30, 2003, the increase was partially offset by lower sales of our tick-borne encephalitis vaccine for the three and six months ended June 30, 2004. Such lower sales of tick-borne encephalitis for the three and six months ended June 30, 2004 were due to higher sales in the fourth quarter of 2003, which is typically sold in the first half of the year.

Sales of our pediatric and other vaccines were \$47.6 million and \$45.0 million for the three months ended June 30, 2004 and 2003, respectively, and \$98.8 million and \$75.9 million for the six months ended June 30, 2004 and 2003, respectively. The increase in pediatric and other vaccines sales for the three months ended June 30, 2004 as compared with the three months ended June 30, 2003 was primarily due to increased sales following our acquisition of PowderJect Pharmaceuticals. The increase in pediatric and other vaccines for the six months ended June 30, 2004 compared with the six months ended June 30, 2003 was primarily due to (i) the timing of tender sales for our polio vaccines and diphtheria, tetanus and pertussis vaccines and (ii) increased sales following our acquisition of PowderJect Pharmaceuticals, partially offset by the timing of tender sales of measles, mumps and rubella vaccines.

Certain of our vaccine products are seasonal, particularly our flu vaccines, which have higher sales primarily in the second half of the year. In addition, we expect Menjugate® sales to continue to fluctuate as public health authorities consider adoption of broad vaccination programs and competitive pressures continue to increase.

We expect competitive pressures related to many of our vaccine products to continue into the future, primarily as a result of the introduction of competing products into the market, including, but not limited to, new combination vaccines, as listed in Part I, Item 1., Business Competition of our Annual Report on Form 10-K for the year ended December 31, 2003.

**Collaborative agreement revenues** We recognize collaborative agreement revenues for fees received as we perform research services and achieve specified milestones. Our vaccines segment recognized collaborative agreement revenues of \$1.2 million for the three months ended June 30, 2004 primarily related to increased collaboration agreement revenues following our acquisition of PowderJect Pharmaceuticals. Our vaccines segment recognized collaborative agreement revenues of \$5.2 million for the six months ended June 30, 2004 primarily related to an agreement to supply a vaccine for meningococcal meningitis caused by the bacterium *N. meningitidis* serogroup B to the Ministry of Health in New Zealand and increased collaborative agreement revenues following our acquisition of PowderJect Pharmaceuticals.

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. The vaccines segment recognized royalty and license fee revenues of \$3.3 million for the three months ended June 30, 2003, and \$2.7 million and \$6.5 million for the six months ended June 30, 2004 and 2003, respectively. Royalty and license fee revenues for the vaccines segment for the three months ended June 30, 2004 were not material.

*GlaxoSmithKline* An agreement with GlaxoSmithKline plc provides for royalties on sales of certain vaccine products. Under this agreement, we recognized \$1.4 million and \$3.4 million of such royalties for the six months ended June 30, 2004 and 2003, respectively. Under this agreement, any future royalties have ceased.

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. 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** Our vaccines segment recognized other revenues of \$5.9 million and \$3.2 million for the three months ended June 30, 2004 and 2003, respectively, and \$9.6 million and \$6.0 million for the six months ended June 30, 2004 and 2003, respectively.

*Grant and contract revenues* Our vaccines segment other revenues included grant and contract revenues of \$5.1 million and \$2.5 million for the three months ended June 30, 2004 and 2003, respectively, and \$8.0 million and \$4.7 million for the six months ended June 30, 2004 and 2003, respectively. We have entered into a series of agreements with the U.S. National Institutes of Health to advance our HIV vaccine program into human clinical trials. We recognized grant and contract revenues under these arrangements of \$3.1 million and \$2.3 million for the three months ended June 30, 2004 and 2003, respectively, and \$5.5 million and \$4.1 million for the six months ended June 30, 2004 and 2003, respectively.

The balance of other revenues consisted of various other agreements, which individually were not material.

Other revenues recognized in our vaccines segment may fluctuate due to the nature of the revenues recognized and the timing of events giving rise to these revenues.

**Gross profit** Vaccines gross profit as a percentage of net product sales was 34% and 56% for the three months ended June 30, 2004 and 2003, respectively, and 34% and 52% for the six months ended June 30, 2004 and 2003, respectively. The decrease in gross profit margins for the three months ended June 30, 2004 as compared with the three months ended June 30, 2003 was primarily due to additional product reserves in the second quarter 2004 as well as reduced sales and margins of the Menjugate® product and reduced sales of our tick-borne encephalitis vaccine. The decrease in gross profit margins for the six months ended June 30, 2004 as compared with the six months ended June 30, 2003 was primarily due to the addition of PowderJect facilities, a portion of which traditionally is not in flu production for a significant part of the first quarter, and additional product reserves in the second quarter 2004 as well as reduced sales and margins of the Menjugate® product and reduced sales of our tick-borne encephalitis vaccine.

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

**Research and development** Our vaccines segment recognized research and development expenses of \$31.9 million and \$26.8 million for the three months ended June 30, 2004 and 2003, respectively, and \$66.3 million and \$47.4 million for the six months ended June 30, 2004 and 2003, respectively. The increase in research and development spending for the three months ended June 30, 2004 as compared with the three months ended June 20, 2003, as well as for the six months ended June 30, 2004 compared with the

six months ended June 30, 2003, resulted mainly from the advancement of several programs in our meningococcal franchise and flu cell culture. Also, there was \$0.9 million and \$7.7 million of incremental research and development expenses for the three and six months ended June 30, 2004, respectively, following our third quarter of 2003 acquisition of PowderJect. Research and development expenses associated with PowderJect declined for the three months ended June 30, 2004 as we completed the planned divestiture of certain research operations in Madison, Wisconsin and Oxford, England.

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** Our vaccines segment recognized selling, general and administrative expenses of \$35.9 million and \$24.7 million for the three months ended June 30, 2004 and 2003, respectively, and \$74.9 million and \$46.8 million for the six months ended June 30, 2004 and 2003, respectively. The increase in selling, general and administrative expenses for the three months ended June 30, 2004 as compared with the three months ended June 30, 2003, as well as the six months ended June 30, 2004 compared with the six months ended June 30, 2003 primarily related to additional expenses following our third quarter of 2003 acquisition of PowderJect. Excluding \$8.0 million and \$18.6 million of additional selling, general and administrative expenses, including integration costs, associated with PowderJect Pharmaceuticals for the three and six months ended June 30, 2004, respectively, the remaining increase in selling, general and administrative resulted from ongoing sales and marketing programs and headcount additions.

**Amortization expense** Our vaccines segment recognized amortization expense of \$14.9 million and \$1.5 million for the three months ended June 30, 2004 and 2003, respectively, and \$30.0 million and \$2.9 million for the six months ended June 30, 2004 and 2003. The increase in amortization expense for the three months ended June 30, 2004 as compared with the three months ended June 30, 2003, as well as the six months ended June 30, 2004 compared with six months ended June 30, 2003 related to the intangibles acquired following our third quarter of 2003 acquisition of PowderJect.

### ***Biopharmaceuticals***

**Product sales** Biopharmaceutical product sales were \$126.9 million and \$107.3 million for the three months ended June 30, 2004 and 2003, respectively, and \$253.4 million and \$209.0 million for the six months ended June 30, 2004 and 2003, respectively. Biopharmaceutical product sales in 2004 and 2003 consisted principally of Betaseron®, TOBI® and Proleukin®.

*Betaseron® 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® (in the U.S and other non-European markets) and Betaferon® (in Europe). Boehringer Ingelheim also supplies Betaferon® to Schering for sale in Europe. For product manufactured by us, 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®, 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. Starting in the fourth quarter 2003, the amount we record as product sales, based on a percentage of sales by Schering, and Betaferon® royalties, declined by five percentage points pursuant to our contractual agreement with Schering. As a result, we estimate that the percentage of sales per unit on which our payments are based will decrease, reducing our per unit revenue by approximately 18% (for sales of Chiron product) and approximately 34% (for royalties from sales of Boehringer Ingelheim product) from that received prior to the decline. However, there are a number of mitigating considerations, including (i) the transitional supply agreement, discussed in Royalty and license fee revenues Betaferon® interferon beta-1b below, (ii) the volume mix of Chiron product and Boehringer Ingelheim product and (iii) the launch of product upgrades with ease-of-use features. We believe these considerations will partially offset this contractual change. In order to supply Betaferon® to Schering, we continue to make capital improvements to our existing manufacturing facilities to increase capacity.

In October 2003, the U.S. Food and Drug Administration approved a new pre-filled diluent syringe for Betaseron®. The pre-filled diluent syringe was launched in January 2004 and enhances the delivery mode and shortens preparation, helping to simplify injections of Betaseron®.

Betaseron® product sales were \$31.6 million and \$30.5 million for the three months ended June 30, 2004 and 2003, respectively, and \$61.8 million and \$59.8 million for the six months ended June 30, 2004 and 2003, respectively. The increase in Betaseron® product sales for the three months ended June 30, 2004 as compared with the three months ended June 30, 2003 primarily related to (i) increased sales of clinical materials, (ii) price increases and (iii) increased patient demand attributed to key marketing programs. These increases were partially offset by a decline in the royalty rate by five percentage points pursuant to our contractual agreement with Schering and by fluctuations in ordering patterns.

The increase in Betaseron® product sales for the six months ended June 30, 2004 as compared to the six months ended June 30, 2003 primarily related to (i) price increases, (ii) increased patient demand attributed to key marketing programs, (iii) increased sales of clinical materials and (iv) the benefit of foreign exchange rates. These increases were partially offset by a decline in the royalty rate by five percentage points pursuant to our contractual agreement with Schering and by fluctuations in ordering patterns.

*TOBI® tobramycin* We sell TOBI® directly in the U.S. and certain international markets. We recognized TOBI® sales of \$51.3 million and \$39.0 million for the three months ended June 30, 2004 and 2003, respectively, and \$103.9 million and

\$79.7 million for the six months ended June 30, 2004 and 2003, respectively. Increased TOBI® sales for the three months ended June 30, 2004 as compared with the three months ended June 30, 2003, as well as for the six months ended June 30, 2004 compared with the six months ended June 30, 2003, primarily related to (i) wholesaler ordering patterns, (ii) increased patient demand in the U.S., (iii) price increases and (iv) the benefit of the movement in the Euro to U.S. Dollar exchange rate.

*Proleukin® (aldesleukin)* Sales were \$35.1 million and \$29.4 million for the three months ended June 30, 2004 and 2003, respectively, and \$66.9 million and \$55.4 million for the six months ended June 30, 2004 and 2003, respectively. The increase in Proleukin® product sales for the three months ended June 30, 2004 as compared with the three months ended June 30, 2003, as well as for the six months ended June 30, 2004 as compared with the six months ended June 30, 2003 is primarily related to (i) wholesaler ordering patterns, (ii) price increases and (iii) 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. We expect competitive pressures related to many of our biopharmaceutical products to continue into the future, primarily as a result of the introduction of competing products into the market, as listed in Part I, Item 1., Business Competition of our Annual Report on Form 10-K for the year ended December 31, 2003.

**Collaborative agreement revenues** We recognize collaborative agreement revenues for fees received as we perform research services and achieve specified milestones. Our biopharmaceuticals segment recognized collaborative agreement revenues of \$0.3 million and \$1.1 million for the three months ended June 30, 2004 and 2003, respectively, and \$0.8 million and \$3.3 million for the six months ended June 30, 2004 and 2003, respectively. The decline for the three months ended June 30, 2004 as compared with the three months ended June 30, 2003 is due to the near completion of our fourth quarter 2002 collaboration activities under our collaboration agreement and license agreement with GlaxoSmithKline plc related to certain of our MC-4R compound patents. The decline for the six months ended June 30, 2004 as compared with the six months ended June 30, 2003 is due to the near completion of our fourth quarter 2002 collaboration activities under our collaboration agreement and license agreement with GlaxoSmithKline plc related to certain of our MC-4R compound patents and due to completion in the first quarter 2003 of our 2001 collaboration agreement with Taisho Pharmaceuticals Co. Ltd. to target macrolide mediated gene discovery.

Collaborative agreement revenues tend to fluctuate based on the amount and timing of research services performed, the status of projects under collaboration and our achievement of performance 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 Betaferon® 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. The biopharmaceuticals segment recognized royalty and license fee revenues of \$15.2 million and \$20.8 million for the three months ended June 30, 2004 and 2003, respectively, and \$32.5 million and \$38.6 million for the six months ended June 30, 2004 and 2003, respectively.

*Betaferon® 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® (in the U.S and other non-European markets) and Betaferon® (in Europe). Boehringer Ingelheim also supplies Betaferon® to Schering for sale in Europe. For product manufactured by Boehringer Ingelheim, we receive royalties calculated as a percentage of sales less the amount paid or incurred by Schering for supply costs, including Schering's cost to purchase product from Boehringer Ingelheim.

For the three months ended June 30, 2004 and 2003, we recognized Betaferon® royalties of \$11.6 million and \$17.2 million, respectively, and for the six months ended June 30, 2004 and 2003, we recognized Betaferon® royalties of \$25.4 million and \$31.1 million, respectively, under this arrangement. Betaferon® royalties decreased for the three months ended June 30, 2004 as compared with the three months ended June 30, 2003 as well as for the six months ended June 30, 2004 as compared with the six months ended June 30, 2003 primarily due to a decline in the royalty rate by five percentage points, pursuant to our contractual agreement with Schering, partially offset by (i) an increase in demand, (ii) the benefit of the movement in the Euro to U.S. Dollar exchange rate and (iii) the benefit of a reduction of the allocated cost under a three-year limited cost sharing arrangement under the transitional supply agreement with Schering.

We began supplying Betaferon® to Schering in the fourth quarter 2002 for certain additional European markets, which was previously supplied by Boehringer Ingelheim. This resulted in a shift of revenue recognized under this agreement to product sales, with a decrease in royalty revenues, beginning in the fourth quarter 2002. In 2003, Schering extended its supply agreement with Boehringer Ingelheim through 2008. The exact shift of revenue in the future will be contingent on our production capacity, Schering's minimum purchase commitment under the extended supply agreement with Boehringer Ingelheim and market demand. The shift to product sales is expected to increase over the next three years. Future Betaferon® royalties will be influenced by demand, price changes and foreign currency exchange rates.

*Novo Nordisk* We earn royalty revenues on insulin and glucagon product sales by Novo Nordisk AS. We recognized

\$0.9 million and \$1.9 million for the three months ended June 30, 2004 and 2003, respectively, and \$2.3 million and \$3.9 million for the six months ended June 30, 2004 and 2003, respectively, under this arrangement. Patents related to the production of insulin and glucagon began expiring in late 2003 and as a result, royalty revenues recognized under this arrangement are declining significantly.

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 our technologies. We have no assurance that we will be able to do so or that future royalty and license fee revenues will not decline.

**Other revenues** Our biopharmaceuticals segment recognized other revenues of \$4.8 million and \$3.2 million for the three months ended June 30, 2004 and 2003, respectively, and \$7.9 million and \$18.8 million for the six months ended June 30, 2004 and 2003, respectively.

*Contract manufacturing revenues* Our biopharmaceuticals segment recognized contract manufacturing revenues of \$4.7 million and \$3.0 million for the three months ended June 30, 2004 and 2003, respectively, and \$7.5 million and \$3.1 million for the six months ended June 30, 2004 and 2003, respectively. The fluctuation resulted from the level of activity and the timing of contract manufacturing activities.

*Biogen and Serono settlements* A U.S. Court of Appeals partially reversed a District Court ruling in connection with certain patents owned by Chiron and licensed exclusively to Schering AG's U.S. subsidiary, Berlex Laboratories. As a result of the ruling and prior agreements between Biogen and Berlex, Biogen was required to make a settlement payment to Schering. In accordance with an earlier contract between Chiron and Berlex, we recognized approximately \$13.0 million during the six months ended June 30, 2003, which represented our share of this settlement payment. In addition, there was a similar settlement between Berlex and Serono of which we recognized approximately \$1.4 million during the six months ended June 30, 2003.

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. We cannot guarantee that we will be successful in obtaining additional revenues or that these revenues will not decline.

**Gross profit** Biopharmaceutical gross profit as a percentage of net product sales was 74% and 71% for the three months ended June 30, 2004 and 2003, respectively, and 75% for each of the six months ended June 30, 2004 and 2003, respectively. The increase in biopharmaceutical gross profit margins for the three months ended June 30, 2004 as compared with the three months ended June 30, 2003 was primarily the result of price increases and improved efficiencies in production, partially offset by the contractual change in the royalty rate related to the sale of Betaseron® and the increased costs associated with the pre-filled diluent syringe for Betaseron®. Biopharmaceutical gross profit was consistent for the six months ended June 30, 2004 as compared with the six months ended June 30, 2003. Price increases and improved efficiencies in production were offset by the contractual change in the royalty rate related to the sale of Betaseron® and the increased costs associated with pre-filled diluent syringe for Betaseron®.

Biopharmaceutical gross profit percentages may fluctuate significantly in future periods due to production yields, increased cost to produce the Betaseron® pre-filled diluent syringe, the decline in Betaseron® product sales, based on a percentage of sales by Schering, by five percentage points pursuant to our contractual agreement with Schering and as the biopharmaceutical product and customer mix changes.

**Research and development** Our biopharmaceuticals segment recognized research and development expenses of \$61.8 million and \$57.4 million for the three months ended June 30, 2004 and 2003, respectively, and \$120.4 million and \$113.7 million for the six months ended June 30, 2004 and 2003, respectively.

The increase in research and development spending for the three months ended June 30, 2004 as compared with the three months ended June 30, 2003, as well as for the six months ended June 30, 2004 as compared with the six months ended June 30, 2003, primarily related to activities related to the development of (i) tifacogin, as discussed below, (ii) CHIR-258, a growth factor kinase inhibitor and our first small-molecule oncology compound in development, (iii) cyclosporine solution for inhalation, a therapy under evaluation for the treatment of rejection and reduction of mortality in lung transplant patients, and (iv) a dry powder formulation of inhaler, TOBI®. These increases were partially offset by (i) the discontinuance of development of tezacitabine in the first quarter of 2004 based on an analysis of the data from a Phase II trial in patients with gastroesophageal cancer, (ii) decline in spending due to discontinuance of development of PA-2794, (iii) decrease in spending on development of manufacturing processes for Betaseron®, and (iv) decrease in spending on the SILCAAT trial, as described below.

In the fourth quarter 2002, we reached an agreement in principle to transfer responsibility for the SILCAAT (referred to also as Proleukin® (aldesleukin) for HIV) trial, a Phase III study for recombinant human interleukin-2 (IL-2, aldesleukin), to the National

Institutes Allergy and Infectious Disease (NIAID) and the University of Minnesota. Responsibility for the SILCAAT study was transferred to NIAID and University of Minnesota effective February 14, 2003. Our research and development expenses related to the SILCAAT trial are expected to decrease in 2004 as a result of the transfer. Under the agreement, we are obligated to fund a maximum of \$18.0 million over the lifetime of the trial and to supply clinical materials and certain other support services of which \$9.0 million has been paid through June 30, 2004.

In October 2003, we acquired all of Pfizer, Inc.'s, formerly Pharmacia Corp.'s, interest in tifacogin, in return for which Pfizer will receive royalties on future sales of tifacogin. In the second quarter 2004, we began enrolling patients in our Phase III trial for tifacogin as a treatment for patients with severe community-acquired pneumonia.

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** Our biopharmaceuticals segment recognized selling, general and administrative expenses of \$33.2 million and \$28.7 million for the three months ended June 30, 2004 and 2003, respectively, and \$65.2 million and \$54.9 million for the six months ended June 30, 2004 and 2003, respectively. The increase in selling, general and administrative expenses for the three months ended June 30, 2004 as compared with the three months ended June 30, 2003, as well as the six months ended June 30, 2004 compared with six months ended June 30, 2003, related to increased expenses for programs and headcount in support of TOBI® and Proleukin®, and the Euro to U.S. Dollar exchange rate fluctuation, partially offset by lower consulting costs to enhance business processes.

**Amortization expense** Our biopharmaceuticals segment recognized amortization expense of \$6.2 million for each of the three months ended June 30, 2004 and 2003, respectively, and \$12.5 million and \$12.4 million for the six months ended June 30, 2004 and 2003, respectively.

*Other*

**Royalty and license fee revenues** Our other segment earns royalties on third party sales of, and license fees on, several products. Our other segment recognized royalty and license fee revenues of \$23.7 million and \$19.6 million for the three months ended June 30, 2004 and 2003, respectively, and \$42.1 million and \$36.4 million for the six months ended June 30, 2004 and 2003, respectively. The majority of royalty and license fee revenues related to the use of our hepatitis C virus and HIV-related patents for diagnostic testing purposes by various third parties.

*F. Hoffmann-La Roche settlement* In October 2000, we entered into three license agreements with F. Hoffmann-La Roche Limited related to the settlement of litigation in the U.S. and certain other countries for use of our hepatitis C virus and HIV nucleic acid testing intellectual property for use in clinical diagnostics.



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 F. Hoffmann-La Roche's use of our hepatitis C virus-related patent in its *in vitro* diagnostic products. The agreement also provides for royalties on future sales related to F. Hoffmann-La Roche's use of our hepatitis C virus-related patent in its *in vitro* diagnostic products, which commenced in the first quarter 2001. Royalty revenues increased for the three months ended June 30, 2004 as compared to the three months ended June 30, 2003 as well as for the six months ended June 30, 2004 as compared with the six months ended June 30, 2003, primarily as a result of an increase in quarterly minimum amounts we recognize under this agreement, an increase in the positive adjustment of estimated to actual royalty revenue recorded in the subsequent quarter and increased product sales recognized by F. Hoffman-La Roche.

The HIV agreement also provides for royalties on future sales related to F. Hoffmann-La 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 for the three and six months ended June 30, 2004 were consistent with the three and six months ended June 30, 2003, respectively.

Under these agreements, such royalties will continue through the lives of the hepatitis C virus and HIV-related patents covering F. Hoffmann-La Roche's nucleic acid testing products. Currently, the applicable issued hepatitis C virus-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. 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 Chiron of \$10.0 million from F. Hoffmann-La Roche, which was received in April 2003. As permitted under the terms of its licensing agreement, F. Hoffmann-La Roche has decided to institute arbitration proceedings in regard to the application of the U.S. patent. We have deferred recognition of this \$10.8 million milestone payment and interest as of June 30, 2004 and \$16.3 million and \$3.8 million of royalty revenue as of June 30, 2004 and 2003, respectively. During any pending arbitration proceedings, F. Hoffmann-La Roche remains obligated to make all quarterly royalty payments, subject to a right to be reimbursed by Chiron if it is determined in the arbitration that such royalty payments were not due.

*Bayer* A cross-license agreement provides for royalties to us on HIV and hepatitis C virus products sold by Bayer, which increased for the three months ended June 30, 2004 as compared with the three months ended June 30, 2003, due to increased donations. The six months ended June 30, 2004 as compared with the six months ended June 30, 2003 increased primarily due to

(i) additional royalties under the HIV-related patent issued in the U.S. in March 2003, discussed above, (ii) increased royalty rates and (iii) increase donations.

*Abbott Laboratories* A cross-license agreement provides for royalties to us on HIV and hepatitis C virus products sold by Abbott. We recognized royalty and license fee revenues under this agreement in the second quarter 2003.

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** Our other segment recognized selling, general and administrative expenses of \$27.4 million and \$17.2 million for the three months ended June 30, 2004 and 2003, respectively, and \$52.0 million and \$34.0 million for the six months ended June 30, 2004 and 2003, respectively. The increases in selling, general and administrative for the three and six months ended June 30, 2004 as compared with the three and six months ended June 30, 2003 were primarily due to higher litigation costs related to the defense of our patents and technology, higher facility related costs, higher employee related expenses and higher consulting expenses.

**Interest expense** We recognized interest expense of \$6.5 million and \$2.8 million for the three months ended June 30, 2004 and 2003, respectively, and \$12.4 million and \$6.3 million the six months ended June 30, 2004 and 2003, respectively. The increase in interest expense for the three and six months ended June 30, 2004 as compared with the three and six months ended June 30, 2003 primarily related to interest expense recognized on the \$500.0 million convertible debentures that were issued on July 30, 2003.

**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 \$5.8 million and \$6.3 million for the three months ended June 30, 2004 and 2003, respectively, and \$10.9 million and \$13.3 million for the six months ended June 30, 2004 and 2003, respectively. The decreases in interest income for the three and six months ended June 30, 2004 as compared with the three and six months ended June 30, 2003 were primarily due to lower average cash and investment balances following the acquisition of PowderJect Pharmaceuticals.

We recognized gains of \$14.3 million and \$4.8 million for the three months ended June 30, 2004 and 2003, respectively, and \$24.0 million and \$9.4 million for the six months ended June 30, 2004 and 2003, respectively, related to the sale of certain equity securities.

## Edgar Filing: CHIRON CORP - Form 10-Q/A

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 and \$2.0 million for 2002 during the six months ended June 30, 2004 and 2003, respectively.

**Income taxes** The effective tax rate for the three and six months ended June 30, 2004 and 2003 was 25% of pretax income 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.

Management believes the acquisition of PowderJect Pharmaceuticals may cause an increase in the future effective tax rate and is in the process of evaluating certain options that may mitigate any potential increase. Specifically, most of PowderJect Pharmaceuticals' profits are earned in the United Kingdom subject to a 30% marginal tax rate.

**Discontinued operations** During the three months ended June 30, 2004, Chiron and the IRS entered into a settlement agreement closing the open tax years 1996 to 1998. Pursuant to this settlement agreement we recognized for the three months ended June 30, 2004 a tax benefit of \$12.5 million for discontinued operations.

Chiron and 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 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 in excess of the required payments for the indemnity obligations in the first quarter of 2004. This settlement resulted in a benefit of \$0.3 million and an income tax benefit of \$12.5 million, resulting in a net gain of \$12.8 million, which was reported as a Gain from discontinued operations for the six months ended June 30, 2004.

During the three months ended June 30, 2003, we reversed approximately \$0.5 million related to unutilized reserves of Chiron Diagnostics and Chiron Vision, which were recorded as a Gain from discontinued operations for the three months ended June 30, 2003.

During the three months ended March 31, 2003, Chiron and Bayer Corporation reached a settlement agreement relating to certain claims raised by Bayer under the Stock Purchase Agreement dated September 17, 1998, between Chiron and Bayer for Chiron

Diagnostics. Under this settlement agreement, we were required to make a payment to Bayer during the first quarter 2003. Pursuant to this settlement, we recorded a charge, net of adjustment to our previously provided reserve for indemnity obligations, of \$7.6 million, offset by an income tax benefit of \$9.0 million, resulting in a net gain of \$1.4 million, which was reported as a *Gain from discontinued operations* for the six months ended June 30, 2003.

### **Liquidity and Capital Resources**

Our capital requirements have generally been funded by cash flow from operations, borrowings from commercial banks and issuance of debt securities and common stock. Our cash, cash equivalents and investments in marketable debt securities, which totaled \$1,034.0 million at June 30, 2004, are invested in a diversified portfolio of financial instruments, including money market funds and instruments, corporate notes and bonds, government or government agency securities and other debt 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.

On June 12, 2004, certain Liquid Yield Option Notes (LYONs) holders, at their option, tendered \$649.9 million in aggregate principal amount at maturity of LYONs, which were purchased by us. The purchase price for the LYONs was \$584.31 in cash per \$1,000 in principal amount at maturity. The aggregate purchase price for all the LYONs validly surrendered for purchase was \$379.7 million. At June 30, 2004, there remains \$80.1 million in aggregate principal amount at maturity and an accreted balance of \$46.8 million for the LYONs.

On June 22, 2004, we issued \$385.0 million aggregate principal amount of convertible debentures, which mature on June 30, 2034. The convertible debentures accrue interest at a rate of 2.75% per year and interest is payable on June 30 and December 30 commencing December 30, 2004. The debentures are senior, unsecured obligations and rank equal in right of payment with all of our existing and future unsecured and unsubordinated indebtedness.

We believe that our cash, cash equivalents and marketable debt securities, together with funds provided by operations and leasing arrangements, will be sufficient to meet our foreseeable operating cash requirements including any cash utilized under our stock repurchase program and our contractual obligations. In addition, we believe we could access additional funds from the debt and capital markets.

**Sources and uses of cash** We had cash and cash equivalents of \$595.0 million and \$876.0 million at June 30, 2004 and 2003, respectively.

*Operating activities* For the six months ended June 30, 2004, net cash provided by operating activities was \$74.7 million as compared with \$112.7 million for the six months ended June 30, 2003. The decrease in cash provided by operating activities primarily was due to lower income from continuing operations before depreciation and amortization and non-cash charges mainly from higher costs in our vaccines segment related to the effect of our acquisition of PowderJect. This was partially offset by higher royalty payments received under the Roche royalty arrangements for the six months ended June 30, 2004. In addition, the cash provided by operations for the six months ended June 30, 2003 was negatively impacted by tax payments and a payment to Bayer Corporation as a result of a

settlement agreement relating to certain claims raised by Bayer in connection with the Stock Purchase Agreement dated September 17, 1998 and positively impacted by \$14.4 million of cash received as a result of the Biogen and Serono settlements in connection with the McCormick patents during the six months ended June 30, 2003.

*Investing activities* For the six months ended June 30, 2004, net cash provided by investing activities consisted of proceeds from sales and maturities of investments in marketable debt securities of \$508.1 million, proceeds from the sale of equity securities and interests in affiliated companies of \$16.3 million and other proceeds of \$0.8 million. Cash provided by investing activities was offset by purchases of investments in marketable debt securities of \$218.8 million, capital expenditures of \$93.8 million, cash paid for acquisitions, net of cash acquired of \$19.5 million, which consists of \$15.5 million of cash delivered on the divestiture of certain research operations in Madison, Wisconsin and Oxford, England and certain vaccines operations in Sweden and \$4.0 million for previously accrued costs in connection with the acquisition of PowderJect, purchases of equity securities and interests in affiliated companies of \$4.3 million.

In 2003, our Board of Directors approved \$50.7 million in expenditures for a 25-year lease for buildings and \$42.2 million for capital improvements, both of which are part of a \$97.0 million project for a new flu vaccines manufacturing facility in Liverpool, England. The new manufacturing facility will replace existing flu vaccines manufacturing facilities in Liverpool, England. In December 2003, we entered into a 25-year lease for these buildings. As of June 30, 2004, we have incurred \$6.3 million for these capital improvements.

For the six months ended June 30, 2003, net cash provided by investing activities consisted of proceeds from sales and maturities of investments in marketable debt securities of \$917.8 million and proceeds from the sale of equity securities and interests in affiliated companies of \$7.4 million. Cash provided by investing activities was offset by purchases of investments in marketable debt securities of \$277.5 million, capital expenditures of \$52.4 million, purchases of equity securities and interests in affiliated companies of \$36.9 million, cash paid for acquisitions, net of cash acquired of \$1.2 million and other uses of cash of \$0.8 million.

*Financing activities* For the six months ended June 30, 2004, net cash used in financing activities consisted of \$380.0 million for the repayment of debt and capital leases, \$71.7 million for the acquisition of treasury stock and \$7.8 million for the payment of debt issuance costs. Cash used in financing activities was offset by \$385.0 million of proceeds from issuance of convertible debentures, \$45.0 million of proceeds from the reissuance of treasury stock and \$2.3 million of proceeds from the issuance of debt.

Our Board of Directors has authorized the repurchase of our common stock on the open market. In December 5, 2003, the Board of Directors granted authority to buy 5.0 million shares and authorized the repurchases through December 31, 2004. From January 1, 2004 through June 30, 2004, 1.5 million shares were repurchased.

For the six months ended June 30, 2003, net cash used in financing activities consisted of \$68.1 million for the acquisition of treasury stock, \$0.1 million for the net repayment of short-term borrowings and \$0.1 million for the repayment of debt. Cash used in financing activities was offset by \$24.5 million of proceeds from the reissuance of treasury stock (related to stock option exercises), and \$2.1 million of proceeds from put options.

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 in the U.S. 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 June 30, 2004 and December 31, 2003. 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.

As of June 30, 2004, Novartis had also guaranteed \$173.3 million of Chiron's lease commitments for a six-year lease to rent a research facility in Emeryville, California.

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

As a global pharmaceutical company, we are engaged in a rapidly evolving and often unpredictable business. The forward-looking statements contained in this 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.

*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.

*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 we fail to obtain or maintain the regulatory approvals we need to market our products, our business will 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 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.

*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. Manufacturing biologic products is complex. Unlike chemical pharmaceuticals, 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.

*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.

*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® 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®. 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® 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®. 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® 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. Currently, for Fluvirin® 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 are required to make specified minimum purchases from that supplier through 2007. 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 immunodiagnostics. 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® HIV-1/HCV Assay. 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 immunodiagnostics, 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® HIV-1/HCV Assay 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 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 or substitute products.

*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 June 30, 2004, our total debt was \$938.0 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 indentures 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 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 indentures 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% as of June 30, 2004. 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.

*Volatility of our stock price could negatively impact our profitability.*

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;

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, The Netherlands and, with the acquisition of PowderJect, 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. 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, Chiron Vision (subject to certain limitations) and Chiron Diagnostics. 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.

*Volatility of earnings could negatively impact our business.*

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 predict the impact, if any, on Chiron of future changes to accounting standards, financial reporting and corporate governance requirements and tax laws. In addition, 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.

#### Item 4. Controls and Procedures

(a) **Evaluation of disclosure controls and procedures** As of the end of the period covered by our Annual Report on Form 10-K for the year ended December 31, 2004, 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 the design and operation of Chiron's disclosure controls and procedures. Based on that evaluation, Chiron's management, including the CEO and CFO, concluded that as of June 30, 2004, Chiron's disclosure controls and procedures were ineffective to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms. The following paragraphs discuss the reasons and matters on which this conclusion was based.

The management of Chiron Corporation is responsible for establishing and maintaining adequate internal control over financial reporting. Chiron's internal control system was designed to provide reasonable assurance to the Company's management and board of directors regarding the preparation and fair presentation of published financial statements.

The management of Chiron assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2004. In making its assessment of internal control over financial reporting management used the criteria issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control - Integrated Framework*.

In performing the assessment management has identified three material weaknesses in internal control over financial reporting as of December 31, 2004.

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.

Management has concluded that each of the above control deficiencies represents a material weakness in internal control over financial reporting. A material weakness is a control deficiency, or combination of control deficiencies, that results in a more than remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected. As a result of the material weaknesses described above, management believes 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*.

(b) **Remediation steps to address material weakness** We have an ongoing process of analyzing and attempting to improve our internal controls, including those related to the matters identified above. With regard to the revenue recognition material weakness, the Company is taking steps designed to provide its sales force with the necessary training with respect to applicable accounting principles so that the sales force understands the impact of its activities on the Company's financial reporting. In addition, we intend to take steps to implement processes to provide that changes to our standard terms of sale will need specified levels of approval prior to being made, such as approval from finance and legal departments or personnel. Additionally, the Company is 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. With regard to the legal services accrual material weakness, we are taking steps to increase awareness and understanding of the accruals process by providing training to the legal department and redesigning the processes related to estimating the accrual and the timely recording of legal invoices, and we are also working to improve communication between the finance and legal departments.

(c) **Changes in internal controls** 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 fiscal quarter ended June 30, 2004. Refer to Item 4(b) for a discussion of remediation activities in connection with the material weaknesses in internal control over financial reporting referred to above.

## Item 6. Exhibits

(a) Exhibits

Exhibit Number	Exhibit
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.

**CHIRON CORPORATION**

**June 30, 2004**

**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.

CHIRON CORPORATION

DATE: April 6, 2005

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

DATE: April 6, 2005

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