

CHIRON CORP  
Form 10-Q  
April 30, 2004

[QuickLinks](#) -- Click here to rapidly navigate through this document

---

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

---

**FORM 10-Q**

(Mark One)

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

**For the quarterly period ended March 31, 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.

Yes  No

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

Edgar Filing: CHIRON CORP - Form 10-Q

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 April 28, 2004</b>
Common Stock, \$0.01 par value	188,953,967

**CHIRON CORPORATION  
TABLE OF CONTENTS**

	<b>Page No.</b>
<b>PART I. FINANCIAL INFORMATION</b>	
<b>ITEM 1. Financial Statements (Unaudited)</b>	
Condensed Consolidated Balance Sheets at March 31, 2004 and December 31, 2003	3
Condensed Consolidated Statements of Operations for the three months ended March 31, 2004 and 2003	5
Condensed Consolidated Statements of Comprehensive Income for the three months ended March 31, 2004 and 2003	6
Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2004 and 2003	7
Notes to Condensed Consolidated Financial Statements	8
<b>ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</b>	23
<b>ITEM 3. Quantitative and Qualitative Disclosures About Market Risk</b>	48
<b>ITEM 4. Controls and Procedures</b>	48
<b>PART II. OTHER INFORMATION</b>	
<b>ITEM 1. Legal Proceedings</b>	50
<b>ITEM 4. Submission of Matters to a Vote of Security Holders</b>	50
<b>ITEM 6. Exhibits and Reports on Form 8-K</b>	51
<b>SIGNATURES</b>	53

## Item 1. Financial Statements

## CHIRON CORPORATION

## CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

(In thousands, except share data)

	March 31, 2004	December 31, 2003
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 259,079	\$ 364,270
Short-term investments in marketable debt securities	291,392	174,212
	<u>550,471</u>	<u>538,482</u>
Total cash and short-term investments	550,471	538,482
Accounts receivable, net of allowances	369,508	382,933
Current portion of notes receivable	1,489	1,479
Inventories, net of reserves	236,299	199,625
Assets held for sale	3,076	2,992
Current net deferred income tax assets	51,355	50,204
Derivative financial instruments	1,822	9,463
Income taxes, net	11,119	
Other current assets	80,349	72,471
	<u>1,305,488</u>	<u>1,257,649</u>
Total current assets	1,305,488	1,257,649
Noncurrent investments in marketable debt securities	535,022	560,292
Property, plant, equipment and leasehold improvements, at cost:		
Land and buildings	358,223	366,275
Laboratory, production and office equipment	634,198	615,814
Leasehold improvements	126,650	112,200
Construction-in-progress	156,005	144,162
	<u>1,275,076</u>	<u>1,238,451</u>
Less accumulated depreciation and amortization	(567,286)	(548,701)
	<u>707,790</u>	<u>689,750</u>
Property, plant, equipment and leasehold improvements, net	707,790	689,750
Purchased technologies, net	231,489	236,707
Goodwill	801,837	787,587
Other intangible assets, net	477,677	486,889
Investments in equity securities and affiliated companies	126,586	121,576
Equity method investments	867	953
Noncurrent notes receivable	7,500	7,500
Noncurrent derivative financial instruments		7,391
Other noncurrent assets	42,621	38,875
	<u>\$ 4,236,877</u>	<u>\$ 4,195,169</u>

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



## CHIRON CORPORATION

## CONDENSED CONSOLIDATED BALANCE SHEETS (Continued)

(Unaudited)

(In thousands, except share data)

	March 31, 2004	December 31, 2003
	<u>          </u>	<u>          </u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 111,297	\$ 102,201
Accrued compensation and related expenses	70,033	83,311
Current portion of capital lease	441	570
Current portion of unearned revenue	52,950	47,873
Income taxes payable		15,270
Other current liabilities	163,109	187,688
	<u>          </u>	<u>          </u>
Total current liabilities	397,830	436,913
Long-term debt	929,780	926,709
Capital lease	157,615	157,677
Noncurrent derivative financial instruments	2,460	
Noncurrent net deferred income tax liabilities	110,863	107,496
Noncurrent unearned revenue	40,393	45,564
Other noncurrent liabilities	83,308	69,448
Minority interest	7,877	7,002
	<u>          </u>	<u>          </u>
Total liabilities	1,730,126	1,750,809
	<u>          </u>	<u>          </u>
Commitments and contingencies		
Stockholders' equity:		
Common stock	1,917	1,917
Additional paid-in capital	2,514,292	2,503,195
Deferred stock compensation	(14,529)	(12,871)
Accumulated deficit	(32,273)	(46,634)
Accumulated other comprehensive income	192,683	216,302
Treasury stock, at cost (3,008,000 shares at March 31, 2004 and 4,567,000 shares at December 31, 2003)	(155,339)	(217,549)
	<u>          </u>	<u>          </u>
Total stockholders' equity	2,506,751	2,444,360
	<u>          </u>	<u>          </u>
	<u>\$ 4,236,877</u>	<u>\$ 4,195,169</u>

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 March 31,	
	2004	2003
<b>Revenues:</b>		
Product sales, net	\$ 281,066	\$ 218,620
Revenues from joint business arrangement	30,361	26,452
Collaborative agreement revenues	6,515	4,114
Royalty and license fee revenues	54,792	53,424
Other revenues	6,938	18,425
	<u>379,672</u>	<u>321,035</u>
<b>Operating expenses:</b>		
Cost of sales	126,701	85,589
Research and development	98,410	82,130
Selling, general and administrative	104,740	73,042
Amortization expense	21,332	7,613
Other operating expenses	2,116	1,691
	<u>353,299</u>	<u>250,065</u>
Income from operations	26,373	70,970
Interest expense	(5,925)	(3,462)
Interest and other income, net	16,074	14,318
Minority interest	(620)	(400)
	<u>35,902</u>	<u>81,426</u>
Income from continuing operations before income taxes	35,902	81,426
Provision for income taxes	8,975	20,357
	<u>26,927</u>	<u>61,069</u>
Income from continuing operations	26,927	61,069
Gain from discontinued operations	12,845	1,426
	<u>39,772</u>	<u>62,495</u>
Net income	\$ 39,772	\$ 62,495
<b>Basic earnings per share:</b>		
Income from continuing operations	\$ 0.14	\$ 0.33
	<u>0.21</u>	<u>0.33</u>
Net income	\$ 0.21	\$ 0.33
<b>Diluted earnings per share:</b>		
Income from continuing operations	\$ 0.14	\$ 0.32
	<u>0.21</u>	<u>0.32</u>

Edgar Filing: CHIRON CORP - Form 10-Q

Three Months Ended  
March 31,

Net income	\$	0.21	\$	0.33
------------	----	------	----	------

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 March 31,	
	2004	2003
Net income	\$ 39,772	\$ 62,495
Other comprehensive income (loss):		
Change in foreign currency translation adjustment during the period	(21,628)	9,295
Unrealized gains (losses) from investments:		
Net unrealized holding gains (losses) arising during the period, net of tax (provision) benefit of \$(2,498) and \$257 for the three months ended March 31, 2004 and 2003, respectively	1,277	(443)
Reclassification adjustment for net gains included in net income, net of tax provision of \$6,388 and \$1,792 for the three months ended March 31, 2004 and 2003, respectively	(3,268)	(2,804)
Net unrealized losses from investments	(1,991)	(3,247)
Other comprehensive income (loss)	(23,619)	6,048
Comprehensive income	\$ 16,153	\$ 68,543

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

## CHIRON CORPORATION

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(In thousands)

	Three Months Ended March 31,	
	2004	2003
Net cash provided by operating activities	\$ 11,080	\$ 65,316
Cash flows from investing activities:		
Purchases of investments in marketable debt securities	(202,899)	(190,569)
Proceeds from sales and maturities of investments in marketable debt securities	109,542	192,777
Capital expenditures	(44,600)	(33,891)
Purchases of equity securities and interests in affiliated companies	(2,390)	(1,440)
Proceeds from sale of equity securities and interests in affiliated companies	3,537	2,007
Cash paid for acquisitions, net of cash acquired	(1,006)	(205)
Other, net	(766)	(5,065)
Net cash used in investing activities	(138,582)	(36,386)
Cash flows from financing activities:		
Net repayment of short-term borrowings		(71)
Repayment of debt and capital leases	(84)	(22)
Payments to acquire treasury stock	(8,459)	(37,084)
Proceeds from reissuance of treasury stock	35,603	3,542
Proceeds from issuance of debt	973	
Proceeds from put options		1,398
Net cash provided by (used in) financing activities	28,033	(32,237)
Effect of exchange rate changes on cash and cash equivalents	(5,722)	864
Net decrease in cash and cash equivalents	(105,191)	(2,443)
Cash and cash equivalents at beginning of the period	364,270	247,950
Cash and cash equivalents at end of the period	\$ 259,079	\$ 245,507

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

CHIRON CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2004

(Unaudited)

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

*Basis of Presentation*

The information presented in the Condensed Consolidated Financial Statements at March 31, 2004, and for the three months ended March 31, 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 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.

*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 of several venture capital funds. Chiron is obligated to pay \$60.0 million over ten years in equity contributions to these venture capital funds, of which approximately \$34.5 million was paid through March 31, 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 VIE's 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 revenues from the joint business contractual arrangement for the three months ended March 31, 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 March 31, 2004.

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

Chiron, prior to filing its financial statements on Form 10-Q, publicly releases an unaudited condensed balance sheet and statement of operations. Between the date of Chiron's earnings release and the filing of Form 10-Q, reclassifications may be required. These reclassifications, when made, have no effect on income from continuing operations, net income or earnings per share. There has been no such reclassification in the first quarter of 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>March 31, 2004</b>	<b>December 31, 2003</b>
Finished goods	\$ 37,488	\$ 38,640
Work-in-process	135,950	105,359
Raw materials	62,861	55,626
	<b>\$ 236,299</b>	<b>\$ 199,625</b>

### *Income Taxes*

The effective tax rate for the three months ended March 31, 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 March 31, 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

Edgar Filing: CHIRON CORP - Form 10-Q

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:

	<b>Three Months Ended March 31,</b>	
	<b>2004</b>	<b>2003</b>
<b>(in thousands, except per share data)</b>		
<b>Net income:</b>		
As reported	\$ 39,772	\$ 62,495
Add: Stock-based employee compensation expense included in reported net income, net of related tax effects	1,340	901
Less: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	21,507	18,112
<b>Pro forma</b>	<b>\$ 19,605</b>	<b>\$ 45,284</b>
<b>Basic net income per share:</b>		
As reported	\$ 0.21	\$ 0.33
<b>Pro forma</b>	<b>\$ 0.10</b>	<b>\$ 0.24</b>
<b>Diluted net income per share:</b>		
As reported	\$ 0.21	\$ 0.33
<b>Pro forma</b>	<b>\$ 0.10</b>	<b>\$ 0.24</b>

*Comprehensive Income*

For the three months ended March 31, 2004 and 2003, the foreign currency translation component of comprehensive income was not adjusted for income taxes, as they relate to permanent investments in non-U.S. subsidiaries.

*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." For the three months ended March 31, 2004 and 2003, Chiron charged losses of \$25.4 million and \$7.5 million, respectively, to "Accumulated deficit" in the Condensed Consolidated Balance Sheets.

For the three months ended March 31, 2004, Chiron did not repurchase any Chiron common stock. Chiron made payments of \$8.5 million in January 2004 for treasury stock repurchases recognized in December 2003. In any period, cash used in financing activities related to common stock repurchases may differ from the comparable change in stockholders' equity, reflecting timing differences between the recognition of the share repurchase transactions and their cash settlement.

**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.

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 March 31,	
	2004	2003
<b>Income (Numerator):</b>		
Income from continuing operations	\$ 26,927	\$ 61,069
<b>Shares (Denominator):</b>		
Weighted-average common shares outstanding	187,809	186,649
<b>Effect of dilutive securities:</b>		
Stock options and equivalents	4,190	3,038
Weighted-average common shares outstanding, plus impact from assumed conversions	191,999	189,687
Basic earnings per share	\$ 0.14	\$ 0.33
Diluted earnings per share	\$ 0.14	\$ 0.32

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

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 March 31,	
	2004	2003
<b>Income (numerator):</b>		
Net income	\$ 39,772	\$ 62,495
<b>Shares (Denominator):</b>		
Weighted-average common shares outstanding	187,809	186,649
<b>Effect of dilutive securities:</b>		
Stock options and equivalents	4,190	3,038
Weighted-average common shares outstanding, plus impact from assumed conversions	191,999	189,687
Basic earnings per share	\$ 0.21	\$ 0.33
Diluted earnings per share	\$ 0.21	\$ 0.33

For the three months ended March 31, 2004 and 2003, stock options to purchase 7.0 million and 17.3 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.

Excluded from the computations of diluted earnings per share for the three months ended March 31, 2004 and 2003, were 8.5 million and 5.2 million shares, respectively of common stock issuable upon conversion of the Liquid Yield Option Notes and 7.3 million shares of common stock issuable upon conversion of the Convertible Debentures for the three months ended March 31, 2004, as their inclusion would be antidilutive.

### **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 of 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 three months ended March 31, 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 will make a payment to Bayer. 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 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 three months ended March 31, 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. 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 preliminary purchase price, and the allocation thereof based on estimated fair values are summarized in the following table (in thousands). Chiron is in the process of finalizing certain estimates; thus both the purchase price and the allocation of the purchase price are subject to change. The preliminary purchase price and allocation reflect management's decision to cease operations at the Madison, Wisconsin facility and the Swedish facility. Chiron has accrued approximately \$28.1 million in estimated exit costs associated with these operations. These exit costs

Edgar Filing: CHIRON CORP - Form 10-Q

are included in the estimated acquisition costs. In addition, Chiron is finalizing certain estimates associated with various other direct acquisition costs.

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 March 31, 2004	17,722
Acquisition costs not yet paid as of March 31, 2004	39,924
	<hr/>
Total preliminary purchase price	\$ 947,825
	<hr/>
Allocation of preliminary purchase price:	
Cash and cash equivalents	\$ 92,178
Short-term marketable securities	8,840
Accounts receivable, net	42,732
Inventories	68,375
Property, plant and equipment	64,599
Goodwill	502,961
Acquired intangible assets	335,500
Other assets	6,361
Income taxes payable	(17,741)
Current liabilities	(61,465)
Net deferred tax liability	(60,170)
Long-term liabilities	(79,645)
Purchased in-process research and development	45,300
	<hr/>
Total preliminary purchase price	\$ 947,825
	<hr/>

Chiron allocated the preliminary 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 \$60.2 million is comprised of current and non-current deferred tax assets of \$40.5 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.

Chiron paid \$1.0 million, which was previously accrued, related to acquisition costs for PowderJect Pharmaceuticals for the three months ended March 31, 2004. Chiron paid \$0.2 million related acquisition costs for Matrix Pharmaceutical for the three months ended March 31, 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 three months ended March 31, 2004 and 2003.

**Note 5 Intangible Assets**

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

	March 31, 2004			December 31, 2003		
	Gross Carrying Value	Accumulated Amortization	Net Carrying Value	Gross Carrying Value	Accumulated Amortization	Net Carrying Value
Purchased technologies	\$ 332,377	\$ 100,888	\$ 231,489	\$ 332,543	\$ 95,836	\$ 236,707
Patents	\$ 121,735	\$ 63,887	\$ 57,848	\$ 119,675	\$ 61,747	\$ 57,928
Trademarks	60,164	20,974	39,190	61,082	20,507	40,575
Licenses and technology rights	48,740	30,259	18,481	49,087	27,818	21,269
Developed product technologies	356,979	35,606	321,373	347,233	23,093	324,140
Customer relationships	28,092	10,067	18,025	28,824	9,952	18,872
Know how(1)	12,758	6,100	6,658	13,090	6,023	7,067
Databases	7,100	1,657	5,443	7,100	1,538	5,562
Other	26,282	15,623	10,659	26,328	14,852	11,476
Total other intangible assets	\$ 661,850	\$ 184,173	\$ 477,677	\$ 652,419	\$ 165,530	\$ 486,889
Total intangible assets subject to amortization	\$ 994,227	\$ 285,061	\$ 709,166	\$ 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 three months ended March 31, 2004 (reported)	\$ 23,264
For the remaining nine months in the year ended December 31, 2004 (estimated)	67,021
For the year ended December 31, 2004 (estimated)	\$ 90,285
For the year ended December 31, 2005 (estimated)	\$ 89,457
For the year ended December 31, 2006 (estimated)	\$ 93,904
For the year ended December 31, 2007 (estimated)	\$ 91,749
For the year ended December 31, 2008 (estimated)	\$ 67,133
For the year ended December 31, 2009 (estimated)	\$ 43,201

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

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

	<b>Biopharmaceuticals</b>	<b>Vaccines</b>	<b>Total</b>
Balance as of December 31, 2003	\$ 187,492	\$ 600,095	\$ 787,587
Effect of exchange rate changes		14,250	14,250
Balance as of March 31, 2004	\$ 187,492	\$ 614,345	\$ 801,837

### 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 in the U.S., Germany, Italy, the United Kingdom and 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.

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.

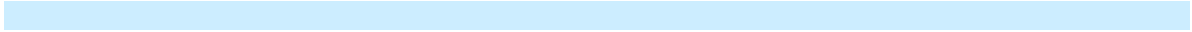
Edgar Filing: CHIRON CORP - Form 10-Q

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

	Three Months Ended March 31,	
	2004	2003
<i>Revenues</i>		
Blood-testing:		
Product sales, net:		
Procleix® System	\$ 61,886	\$ 42,123
Ortho-Clinical Diagnostics	6,234	6,408
	<hr/>	<hr/>
Total product sales, net	68,120	48,531
Revenues from joint business arrangement	30,361	26,452
Collaborative agreement revenues	2,064	1,949
Royalty and license fee revenues	16,434	15,636
Other revenues	195	
	<hr/>	<hr/>
Total blood-testing revenues	117,174	92,568
Vaccines:		
Product sales, net:		
Influenza vaccines	7,705	4,253
Menjugate®	4,549	7,538
Travel vaccines	23,010	25,700
Pediatric and other vaccines	51,182	30,913
	<hr/>	<hr/>
Total product sales, net	86,446	68,404
Collaborative agreement revenues	3,966	2
Royalty and license fee revenues	2,650	3,185
Other revenues	3,643	2,791
	<hr/>	<hr/>
Total vaccines revenues	96,705	74,382
Biopharmaceuticals:		
Product sales, net:		
Betaseron®	30,136	29,300
TOBI®	52,524	40,734
Proleukin®	31,868	25,983
Other	11,972	5,668
	<hr/>	<hr/>
Total product sales, net	126,500	101,685
Collaborative agreement revenues	485	2,163
Royalty and license fee revenues	17,297	17,817
Other revenues	3,100	15,634
	<hr/>	<hr/>
Total biopharmaceuticals revenues	147,382	137,299
Other:		
Royalty and license fee revenues	18,411	16,786

Edgar Filing: CHIRON CORP - Form 10-Q

	<b>Three Months Ended March 31,</b>	
	<u>                    </u>	<u>                    </u>
Total revenues	\$ 379,672	\$ 321,035
	<u>                    </u>	<u>                    </u>



Edgar Filing: CHIRON CORP - Form 10-Q

<i>Income (loss) from continuing operations</i>			
Blood-testing	\$	63,640	\$ 50,562
Vaccines		(50,039)	(5,302)
Biopharmaceuticals		19,249	24,943
Other		(6,477)	767
		<b>26,373</b>	<b>70,970</b>
Segment income from operations			
Interest expense		(5,925)	(3,462)
Interest and other income, net		16,074	14,318
Minority interest		(620)	(400)
		<b>35,902</b>	<b>81,426</b>
Income from continuing operations before income taxes	\$		\$

**Note 7 Debt Obligations**

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 are carried net of an original issue discount of \$328.2 million, which is 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.

Beginning on June 12, 2004 and continuing through June 12, 2006, the holder may receive contingent additional principal if Chiron's stock price falls below the threshold specified in the indenture. The contingent additional principal is based on two factors: Chiron's stock price and Chiron's senior debt rate. Based on Chiron's senior debt rate of 3.15% at March 31, 2004, if Chiron's average closing stock price for 20 consecutive trading days ending on the third trading day prior to June 12, 2004 was below \$41.61 Chiron would become obligated to pay contingent additional principal. The contingent additional principal will replace the original issue discount and bear an effective yield of 2.0 to 9.0% per year for the two-year period. After June 12, 2006, the original issue discount will continue to accrue at 2.0% per year.

Beginning after June 12, 2006, the holder may receive contingent cash interest during any six-month period if the average market price of the LYONs is greater than or equal to the threshold specified in the indenture. The contingent cash interest in respect of any quarterly period will equal 0.0625% of the average market price of a LYON for a five trading day measurement period preceding the applicable six-month period.



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

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

Date	Price
June 12, 2004	\$ 584.31
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

The purchase prices would increase for any accrued contingent additional principal and accrued original issue discount thereon. If the holders require Chiron to purchase all, or a portion, of the LYONs, Chiron may choose to pay the purchase price in cash, Chiron common shares, or any combination of the two. Given Chiron's ability to pay the purchase price in Chiron's common shares, the LYONs continue to be classified as long-term liabilities as of March 31, 2004.

Holders may convert the LYONs at any time on or before the maturity date. For each LYON converted, the holder will receive 7.1613 shares of Chiron common stock. Any accrued original discount, contingent additional principal and unpaid contingent cash interest are ineligible for conversion.

Upon a change in control of Chiron occurring on or before June 12, 2006, each holder may require Chiron to purchase all or a portion of such holder's LYONs for cash at a price equal to 100% of the issue price for such LYONs plus any accrued original issue discount and contingent additional principal (and accrued original issue discount thereon) to the date of purchase. The change in control definition allows Novartis to acquire beneficial ownership of up to 79.9% of Chiron's common stock without triggering a change in control for purposes of the LYONs.

Chiron may redeem all or a portion of the LYONs for cash at any time after June 12, 2006, at specified redemption prices.

### Note 8 Commitments and Contingencies

In November 2003, Chiron's 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, Chiron entered into a 25-year lease for these buildings. As of March 31, 2004, Chiron has incurred \$3.9 million for these capital improvements.

In April 2001, Chiron entered into a collaboration with Rhein Biotech N.V. (now part of Berna Biotech) and GreenCross Vaccine Corporation to research and develop certain pediatric combination vaccine products for sale outside of Europe and North America. The collaboration agreement requires capital commitments from Chiron, Berna Biotech and GreenCross Vaccine. Chiron's commitment is

approximately 26.4 million Euro (\$32.2 million) for the expansion of Chiron's Italian manufacturing facilities, of which Chiron had incurred costs of 19.1 million Euro (\$23.3 million) as of March 31, 2004. This agreement began in the fourth quarter 2001 and is expected to continue through 2008.

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, of which we have paid \$5.0 million as of March 31, 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.

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 March 31, 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.

## 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.*

We are a global pharmaceutical company that participates in three healthcare markets: blood testing, vaccines and biopharmaceuticals. Our revenues consist of product sales, revenues from a joint business contractual arrangement, collaborative agreement revenues, royalty and license fee revenues and other revenues, primarily consisting of contract manufacturing and grant revenues.

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 vaccines and two 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. 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.

For the three months ended March 31, 2004, our income from continuing operations was \$26.9 million, or \$0.14 per diluted share compared to \$61.1 million or \$0.32 per diluted share for the three months ended March 31, 2003. The decline was primarily due to (i) the seasonal impact of the PowderJect acquisition, which has flu sales primarily in the second half of the year; however, costs associated with Powderject are incurred throughout the year, (ii) the decline in the Betaseron royalty rate and (iii) amortization expense from intangible assets associated with the acquisition of PowderJect. For the three months ended March 31, 2004, total revenues were \$379.7 million compared to \$321.0 million for the three months ended March 31, 2003. For the three months ended March 31, 2004, product sales were \$281.1 million compared to \$218.6 million for the three months ended March 31, 2003. 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. For the three months ended March 31, 2004, the movement in exchange rates added approximately 5% to our total revenues. 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 per diluted share due to movement in exchange rates.

For the three months ended March 31, 2004, increases in product sales were seen across all three of our business units, and in particular Procleix® products, TOBI® tobramycin and pediatric and other vaccines. Revenues from joint business arrangements, royalty and license fees, collaborative agreement revenues and other revenues were \$98.6 million for the three months ended March 31, 2004 compared to \$102.4 million for the three months ended March 31, 2003. There were increases primarily related to increased profitability of the joint business arrangement, increased revenues following our acquisition of PowderJect and the timing of contract manufacturing activities. These increases were offset by the favorable effect of the Biogen and Serono settlements in connection with the McCormick patents owned by Schering's U.S. subsidiary, Berlex reported in the three months ended March 31, 2003.

For the three months ended March 31, 2004, gross margins decreased to 55% from 61% in the three months ended March 31, 2003, largely due to (i) the addition of PowderJect facilities, a portion of which traditionally is not in flu production for a significant part of the first quarter, (ii) the product mix reflected the shift of the traditionally high margin tick-borne encephalitis vaccines sales to the fourth quarter 2003 and (iii) the reduction in the royalty rate related to Betaseron®.

For the three months ended March 31, 2004, research and development expenses totaled \$98.4 million, compared to \$82.1 million for the three months ended March 31, 2003. Research and development expenses for PowderJect Pharmaceuticals were \$6.8 million for the three months ended March 31, 2004. Excluding PowderJect, the main beneficiaries of this increase, include our meningococcal vaccines franchise, our flu cell culture program, tifacogin, cyclosporine solution for inhalation, 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 PA-2794 and lower costs related to the development of new manufacturing processes for Betaseron®.

For the three months ended March 31, 2004, selling, general and administrative expenses totaled \$104.7 million compared to \$73.0 million for the three months ended March 31, 2003 with PowderJect

Pharmaceuticals contributing approximately \$10.6 million for the three months ended March 31, 2004. The remaining increase in selling, general and administrative expenses resulted from additional costs associated with headcount, increased facility costs, higher depreciation expense related to information systems, the Euro to U.S. Dollar exchange rate change and ongoing sales and marketing programs.

The effective tax rate for the three months ended March 31, 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 three months ended March 31, 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 \$68.1 million and \$48.5 million for the three months ended March 31, 2004 and 2003, respectively.

**Procleix® System** 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 \$61.9 million and \$42.1 million for the three months ended March 31, 2004 and 2003, respectively. The increase in product sales for the three months ended March 31, 2004 as compared with the three months ended March 31, 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 our 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 \$6.2 million and \$6.4 million for the three months ended March 31, 2004 and 2003, respectively. The decrease for the three months ended March 31, 2004 as compared with the three months ended March 31, 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.

**Revenues from joint business arrangement** Revenues from our joint business contractual arrangement with Ortho-Clinical Diagnostics, Inc. was \$30.4 million and \$26.5 million for the three months ended March 31, 2004 and 2003, respectively. The increase in revenues from our joint business arrangement for the three months ended March 31, 2004 as compared with the three months ended March 31, 2003 primarily resulted from (i) higher profits from Ortho-Clinical Diagnostics' U.S. operations driven by manufacturing efficiencies and (ii) a positive adjustment of the fourth quarter 2003 estimate of revenue to actual results. 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 \$2.1 million and \$1.9 million for the three months ended March 31, 2004 and 2003, respectively. The majority of collaborative agreement revenues recognized by our blood-testing segment related to immunodiagnostic products. The fluctuations between the three months ended March 31, 2004 and the three months ended March 31, 2003 primarily related to the timing of research services.

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 \$16.4 million and \$15.6 million for the three months ended March 31, 2004 and 2003, respectively.

*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 \$15.1 million and \$14.4 million for the three months ended March 31, 2004 and 2003, respectively. The increase for the three months ended March 31, 2004 as compared with the three months ended March 31, 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 has decided to institute arbitration proceedings in regard to the application of the U.S. patent. 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.

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 43% and 40% for the three months ended March 31, 2004 and 2003, respectively. The increase in blood-testing gross profit margin for the three months ended March 31, 2004 as compared with the three months ended March 31, 2003 was driven by 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 appropriate 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 \$5.1 million and \$5.2 million for the three months ended March 31, 2004 and 2003, respectively. The research and development spending for both periods 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 \$9.3 million and \$7.9 million for the three months ended March 31, 2004 and 2003, respectively. The increased selling, general and administrative expenses for the three months ended March 31, 2004 as compared with the three months ended March 31, 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 \$86.4 million and \$68.4 million for the three months ended March 31, 2004 and 2003, respectively.

Sales of our flu vaccines were \$7.7 million and \$4.3 million for the three months ended March 31, 2004 and 2003, respectively. Flu vaccines sales increased for the three months ended March 31, 2004 as compared with the three months ended March 31, 2003 primarily as a result of additional sales of flu vaccine products following our third quarter 2003 acquisition of PowderJect Pharmaceuticals. PowderJect Pharmaceuticals flu vaccine sales were \$2.4 million for the three months ended March 31, 2004. Excluding PowderJect Pharmaceuticals, sales of our remaining flu vaccines increased primarily as a result of additional sales to Argentina and the benefit of the movement in the Euro to U.S. Dollar exchange rate.

Menjugate®, our conjugate vaccine against meningococcal infection caused by the bacterium *N. meningitidis* serogroup C, sales were \$4.5 million and \$7.5 million for the three months ended March 31, 2004 and 2003, respectively. The decrease in Menjugate® sales for the three months ended March 31, 2004 as compared with the three months ended March 31, 2003 was primarily driven by the timing of outbreaks and vaccination programs in Ireland, France and Italy.

Sales of our travel vaccines, comprised of tick-borne encephalitis, rabies vaccines and two products we obtained as part of our third quarter 2003 acquisition of PowderJect Pharmaceuticals, Arilvax and Dukoral, were \$23.0 million and \$25.7 million for the three months ended March 31, 2004 and 2003, respectively. The decrease in travel vaccines sales for the three months ended March 31, 2004 as compared with the three months ended March 31, 2003 was primarily related to a portion of tick-borne encephalitis vaccine sales shifted from the first quarter 2004 to the fourth quarter 2003 due to customer demand, that are typically sold in the first half of the year, offset by (i) increased demand in Asia and



the U.S. for our rabies vaccine, (ii) the benefit of the movement in the Euro to U.S. dollar exchange rate and (iii) additional sales of travel vaccine products following our acquisition of PowderJect Pharmaceuticals.

Sales of our pediatric and other vaccines were \$51.2 million and \$30.9 million for the three months ended March 31, 2004 and 2003, respectively. The increase in pediatric and other vaccines sales for the three months ended March 31, 2004 as compared with the three months ended March 31, 2003 was primarily due to the timing of tender sales for our polio vaccines and diphtheria, tetanus and pertussis vaccines and increased sales following our acquisition of PowderJect Pharmaceuticals.

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.

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 \$4.0 million for the three months ended March 31, 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 \$2.7 million and \$3.2 million for the three months ended March 31, 2004 and 2003, respectively.

*GlaxoSmithKline* An agreement with GlaxoSmithKline plc provides for royalties on sales of certain vaccine products. Under this agreement, we recognized \$1.9 million and \$1.8 million of such royalties for the three months ended March 31, 2004 and 2003, respectively.

*Other* We recognized \$0.4 million and \$1.4 million for the three months ended March 31, 2004 and 2003, respectively, of royalty revenues primarily on third party sales of hepatitis B virus vaccine products. The decline is primarily related to royalties associated with a hepatitis B virus contract that ended in 2003.

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 \$3.6 million and \$2.8 million for the three months ended March 31, 2004 and 2003, respectively.

*Grant and contract revenues* Our vaccines segment other revenues included grant and contract revenues of \$2.9 million and \$2.2 million for the three months ended March 31, 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 \$2.4 million and \$1.8 million for the three months ended March 31, 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 33% and 49% for the three months ended March 31, 2004 and 2003, respectively. The decrease in gross profit margins for the three months ended March 31, 2004 as compared with the three months ended March 31, 2003 relate to the addition of PowderJect facilities, a portion of which traditionally is not in flu production for a significant part of the first quarter. In addition, the product mix reflected the shift of the traditionally high margin tick-borne encephalitis vaccines sales from the first quarter of 2004 to the fourth quarter 2003.

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

**Research and development** Our vaccines segment recognized research and development expenses of \$34.4 million and \$20.6 million for the three months ended March 31, 2004 and 2003, respectively. The increase in research and development spending for the three months ended March 31, 2004 as compared with the three months ended March 31, 2003 resulted mainly from the advancement of several programs in our meningococcal franchise and flu cell culture. Also, there was \$6.8 million of incremental research and development expense following our purchase of PowderJect in the third quarter of 2003.

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 \$39.0 million and \$22.2 million for the three months ended March 31, 2004 and 2003, respectively. The increase in selling, general and administrative expenses for the three months ended March 31, 2004 as compared with the three months ended March 31, 2003 primarily related to additional expenses following our third quarter of 2003 acquisition of PowderJect Pharmaceuticals. Excluding \$10.6 million of additional selling, general and administrative expenses associated with PowderJect Pharmaceuticals, the remaining increase in selling, general and administrative resulted from ongoing sales and marketing programs and increase in headcount.

**Amortization expense** Our vaccines segment recognized amortization expense of \$15.1 million and \$1.4 million for the three months ended March 31, 2004 and 2003, respectively. The increase in amortization expense for the three months ended March 31, 2004 as compared with the three months ended March 31, 2003 related to the intangibles acquired following our acquisition of PowderJect Pharmaceuticals in the third quarter 2003.

**Biopharmaceuticals**

**Product sales** Biopharmaceutical product sales were \$126.5 million and \$101.7 million for the three months ended March 31, 2004 and 2003, respectively. Biopharmaceutical product sales in the first quarter of 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 recorded 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. See "Research and development" below.

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®. In the first quarter 2003, the U.S. Food and Drug Administration approved new labeling for Betaseron®. The labeling expands the indication for Betaseron® to treat all relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations. Relapsing forms of multiple sclerosis include relapsing-remitting, the most common form, and secondary progressive multiple sclerosis with relapses.

Betaseron® product sales were \$30.1 million and \$29.3 million for the three months ended March 31, 2004 and 2003, respectively. The increase in Betaseron® product sales for the three months ended March 31, 2004 as compared with the three months ended March 31, 2003 primarily related to (i) increased patient demand attributed to key marketing programs and an overall increase in the market for beta interferon products for multiple sclerosis, (ii) price increases and (iii) the movement in foreign exchange rates. These increases were partially offset by fluctuations in ordering patterns and a decline in the royalty rate by five percentage points pursuant to our contractual agreement with Schering.

*TOBI® tobramycin* We sell TOBI® directly in the U.S. and certain international markets. We recognized TOBI® sales of \$52.5 million and \$40.7 million for the three months ended March 31, 2004 and 2003, respectively. Increased TOBI® sales for the three months ended March 31, 2004 as compared with the three months ended March 31, 2003 primarily related to (i) patient demand across Europe and increased use and improved compliance in the U.S., (ii) price increases, (iii) the benefit of the movement in the Euro to U.S. Dollar exchange rate and (iv) wholesaler ordering patterns.

We continue to pursue the use of TOBI® to treat other serious lung infections and to seek approval in other countries. Wholesaler ordering patterns as well as reimbursement and government

pressures, competition, foreign currency exchange rates and the level of rebates may influence future TOBI® sales.

*Proleukin® (aldesleukin)* Proleukin® is approved in Canada and the U.S. for the treatment of metastatic (Stage IV) melanoma and in the U.S. and Canada and in over 50 countries for the treatment of metastatic (Stage IV) renal cell carcinoma. Sales of Proleukin® were \$31.9 million and \$26.0 million for the three months ended March 31, 2004 and 2003, respectively. The increase in Proleukin® product sales for the three months ended March 31, 2004 as compared with the three months ended March 31, 2003 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.

Wholesale ordering patterns, reimbursement pressures and foreign currency exchange rates may influence future Proleukin® sales.

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

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 \$0.5 million and \$2.2 million for the three months ended March 31, 2004 and 2003, respectively. The decline is primarily related to the first quarter 2001 collaboration agreement with Taisho Pharmaceuticals Co. Ltd. to target macrolide mediated gene discovery which was completed in the first quarter of 2003.

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 \$17.3 million and \$17.8 million for the three months ended March 31, 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 March 31, 2004 and 2003, we recognized Betaferon® royalties of \$13.8 million and \$14.0 million, respectively, under this arrangement. Betaferon® royalties decreased for

the three months ended March 31, 2004 as compared with the three months ended March 31, 2003 primarily as the result of a decline in the royalty rate by five percentage points, pursuant to our contractual agreement with Schering. This decrease is partially offset by (i) the benefit of the movement in the Euro to U.S. Dollar exchange rate, (ii) increase in demand 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 \$1.4 million and \$2.0 million for the three months ended March 31, 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, significant reductions in royalty revenue recognized under this arrangement are expected.

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 \$3.1 million and \$15.6 million for the three months ended March 31, 2004 and 2003, respectively.

*Contract manufacturing revenues* Our biopharmaceuticals segment recognized contract-manufacturing revenues of \$2.8 million and \$0.1 million for the three months ended March 31, 2004 and 2003, respectively. The increase 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 for the three months ended March 31, 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 for the three months ended March 31, 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 76% and 79% for the three months ended March 31, 2004 and 2003, respectively. The decrease in biopharmaceutical gross profit margins for the three months ended March 31, 2004 as compared with the three months ended March 31, 2003 was primarily the result of less favorable mix of biopharmaceutical sales, the increased cost of producing the Betaseron® pre-filled syringe presentation, decline in Betaseron® product sales, based on a percentage of sales by Schering, by five percentage points pursuant to our contractual agreement with Schering, offset by price increases and increased efficiencies in the manufacturing process.

Biopharmaceutical gross profit percentages may fluctuate significantly in future periods due to production yields, increased cost to produce the Betaseron® pre-filled syringe presentation, 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 \$58.6 million and \$56.4 million for the three months ended March 31, 2004 and 2003, respectively.

The increase in research and development spending for the three months ended March 31, 2004 as compared with the three months ended March 31, 2003 primarily related to activities related to the development of (i) tifacogin, as discussed below, (ii) development of cyclosporine solution for inhalation, a therapy under evaluation for the treatment of rejection and reduction of mortality in lung transplant patients and (iii) a dry powder formulation of our inhaled TOBI® product for the treatment of *pseudomonas aeruginosa* in cystic fibrosis patients. These increases were partially offset by (i) decrease in spending on development of manufacturing processes for Betaseron®, (ii) transfer of responsibility of the SILCAAT trial to the investigators in the first quarter 2003, discussed below and (iii) decline in spending due to discontinuance of development of PA-2794. We discontinued development of tezacitabine in the first quarter of 2004 based on an analysis of the data from a Phase II trial in patients with gastroesophageal cancer. The discontinuation of this trial did not have a material impact on quarterly spending.

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 transferring responsibility for the trial. 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 March 31, 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 sales of tifacogin. We are proceeding with a Phase III trial for tifacogin in 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 \$32.0 million and \$26.2 million for the three months ended March 31, 2004 and 2003, respectively. The increase in selling, general and administrative expenses for the three months ended March 31, 2004 as compared with the three months ended March 31, 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, offset in part by a reduction in expenses to enhance business processes.

**Amortization expense** Our biopharmaceuticals segment recognized amortization expense of \$6.2 million for each of the three months ended March 31, 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 \$18.4 million and \$16.8 million for the three months ended March 31, 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 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 March 31, 2004 as compared with the three months ended March 31, 2003, primarily as a result of an increase in the quarterly minimum amounts we recognize under this agreement and an increase in the positive adjustment of estimate to actuals in the subsequent quarter. These increases were offset by decreased product sales recognized by F. Hoffman-LaRoche.

The HIV agreement also provides for royalties on future sales related to F. Hoffmann-LaRoche's use of our HIV related patent in its *in vitro* diagnostic products, which also 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 months ended March 31, 2004 were consistent with the three months ended March 31, 2003.

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 \$10.0 million milestone payment and interest as of March 31, 2004. 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 March 31, 2004 as compared with the three months ended March 31, 2003 primarily related 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) increased donations.

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 \$24.6 million and \$16.8 million for the three months ended March 31, 2004 and 2003, respectively. The increase in selling, general and administrative expenses for the three months ended March 31, 2004 as compared with the three months ended March 31, 2003 primarily resulted from increased facility related costs, higher depreciation expense related to information systems and higher employee related expenses.

**Interest expense** We recognized interest expense of \$5.9 million and \$3.5 million for the three months ended March 31, 2004 and 2003, respectively. The increase for the three months ended March 31, 2004 as compared with the three months ended March 31, 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 \$5.1 million and \$7.0 million for the three months ended March 31, 2004 and 2003, respectively. The decrease in interest income for the three months ended March 31, 2004 as compared with the three months ended March 31, 2003 was primarily due to lower average cash and investment balances following the acquisition of PowderJect Pharmaceuticals.

We recognized gains of \$9.7 million and \$4.6 million for the three months ended March 31, 2004 and 2003, respectively, related to the sale of certain equity securities.

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 three months ended March 31, 2004 and 2003, respectively.

**Income taxes** The effective tax rate for the three months ended March 31, 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's profits are earned in the United Kingdom, subject to a 30% marginal tax rate.

**Discontinued Operations** In the first quarter of 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 three months ended March 31, 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, we will make a payment to Bayer. 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 three months ended March 31, 2004.

### **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 \$1,085.5 million at March 31, 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.

In June 2001 we issued zero coupon convertible Liquid Yield Option Notes (LYONs). The holders of the LYONs may require us to purchase all, or a portion of, their LYONs on June 12, 2004 at a purchase price of \$584.31 per LYON. The accreted value on June 12, 2004 will be \$426.5 million. We may choose to pay the purchase price in cash, shares of Chiron common stock or any combination thereof. Given our ability to pay the purchase price in shares of Chiron common stock, we continue to classify the LYONs as long-term liabilities as of March 31, 2004. Additional alternatives open to us to satisfy requests to purchase the LYONs include issuing new debt or equity securities. The next dates on which the holders may require us to purchase the LYONs following June 12, 2004 are June 12, 2006, and every fifth year thereafter until maturity in 2031.

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 over at least the next twelve months including any cash utilized under our stock repurchase program, the potential purchase of all, or a portion of the LYONs 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 \$259.1 million and \$245.5 million at March 31, 2004 and 2003, respectively.

*Operating activities* For the three months ended March 31, 2004 net cash provided by operating activities was \$11.1 million as compared with \$65.3 million for the three months ended March 31, 2003.

The decrease in cash provided by operating activities primarily was due to (i) lower income from continuing operations before depreciation and amortization and other non-cash charges mainly due to higher costs in our vaccines segment related to the addition of PowderJect facilities, which traditionally are not in flu production for a significant part of the first quarter, (ii) \$14.4 million of cash received as a result of the Biogen and Serono settlements in connection with the McCormick patents for the three months ended March 31, 2003, (iii) royalty payments received under the Roche royalty arrangements for the three months ended March 31, 2003 and, (iv) increased research and development costs. These decreases were partially offset by a payment made to Bayer Corporation during the three months ended March 31, 2003 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.

At March 31, 2004, Chiron had foreign net operating loss carryforwards of approximately \$20.8 million, of which approximately \$5.3 million begin expiring over the period 2008 to 2018 and the remaining \$15.5 million is available to offset future taxable income without limitation. At March 31, 2004, Chiron had unutilized foreign net operating loss carryforwards attributable to the acquisition of PowderJect Pharmaceuticals of approximately \$0.7 million, which are available to offset future taxable income without limitation. At March 31, 2004, Chiron had federal net operating loss carryforwards attributable to the acquisition of Matrix Pharmaceutical, Inc. of approximately \$49.2 million, which are available to offset future domestic taxable income ratably through 2021. At March 31, 2004, Chiron had federal net operating loss carryforwards attributable to the acquisition of PowderJect Pharmaceuticals of approximately \$13.0 million, which are available to offset future domestic taxable income ratably through 2022. At March 31, 2004, Chiron had \$23.4 million of state net operating loss carryforwards, which expire between 2004 and 2021 and state net operating loss carryforwards of attributable to the acquisition of Matrix Pharmaceutical, Inc. of approximately \$27.3 million, which are available to offset future state taxable income ratably through 2013. At March 31, 2004, Chiron had state business tax credit carryovers of \$16.3 million, which are available to offset future state tax liabilities without limitation, and foreign business tax credit carryovers of \$22.2 million.

We anticipate that research and development expenditures in 2004 will primarily be driven by (i) those activities under our December 2001 and June 2002 collaboration agreements with Nektar Therapeutics (formerly Inhale Therapeutic Systems, Inc.) related to, among other things, the development of a dry powder formulation of our inhaled TOBI® product for the treatment of *pseudomonas aeruginosa* in cystic fibrosis patients, (ii) those activities related to the development of interleukin-2 in combination with various monoclonal antibodies, (iii) expansion of our meningococcal franchise, (iv) development of flu cell culture, (v) research activities focused on identifying several novel vaccines and therapeutics for clinical development in the areas of oncology and infectious disease and (vi) those activities related to development with tifacogin in severe community-acquired pneumonia. In addition, we are required to make capital improvements to our existing manufacturing facilities to support the supply of Betaferon® to Schering. In connection with this project, we are continuing to incur expenses relating to the development of new processes and the performance of test runs related to installed equipment. Net cash from operating activities are expected to fund these research and development activities.

*Investing activities* For the three months ended March 31, 2004, net cash used in investing activities consisted of purchases of investments in marketable debt securities of \$202.9 million, capital expenditures of \$44.6 million, purchases of equity securities and interests in affiliated companies of \$2.4 million, cash paid for direct PowderJect acquisition costs of \$1.0 million and other uses of cash of \$0.8 million. Cash used in investing activities was offset by proceeds from sales and maturities of investments in marketable debt securities of \$109.5 million and proceeds from the sale of equity securities and interests in affiliated companies of \$3.5 million.

In April 2001, we entered into collaboration with Rhein Biotech N.V. (now part of Berna Biotech) and GreenCross Vaccine Corporation to research and develop certain pediatric combination vaccine

products for sale outside of Europe and North America. The collaboration agreement requires capital commitments from Chiron, Berna Biotech and GreenCross Vaccine. Our commitment is approximately 26.4 million Euro (\$32.2 million) for the expansion of Chiron's Italian manufacturing facilities, of which Chiron had incurred costs of 19.1 million Euro (\$23.3 million) as of March 31, 2004. This agreement began in the fourth quarter 2001 and is expected to continue through 2008.

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 March 31, 2004, we have incurred \$3.9 million for these capital improvements.

The purchases of equity securities and interests in affiliated companies consisted of equity contributions under several venture capital funds including \$1.2 million in capital contributions under two 2003 limited partnership agreements, a \$0.8 million capital contributions under a 2001 limited partnership agreement and a \$0.4 million capital contribution under a 2002 limited partnership agreement. We are obligated to pay \$60.0 million over ten years in equity contributions to these venture capital funds, of which \$34.5 million was paid through March 31, 2004.

For the three months ended March 31, 2003, net cash used in investing activities consisted of purchases of investments in marketable debt securities of \$190.6 million, capital expenditures of \$33.9 million, purchases of equity securities and interests in affiliated companies of \$1.4 million, cash paid for acquisitions, net of cash acquired of \$0.2 million and other uses of cash of \$5.1 million. Cash used in investing activities was offset by proceeds from the sale and maturity of investments in marketable debt securities of \$192.8 million and proceeds from sale of equity securities and interests in affiliated companies of \$2.0 million.

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

Our Board of Directors has authorized the repurchase of our common stock on the open market. On December 5, 2003, the Board of Directors granted authority to buy 5.0 million shares and authorized the repurchases through December 31, 2004.

For the three months ended March 31, 2003, net cash used in financing activities consisted of \$37.1 million for the acquisition of treasury stock, \$0.1 million for the net repayment of short-term borrowings, and \$0.02 million for the repayment of debt. Cash used in financing activities was offset by \$3.5 million in proceeds from the reissuance of treasury stock (related to stock option exercises), and \$1.4 million in 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 March 31, 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.

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

We also have various credit facilities available outside the U.S. There were no outstanding borrowings under these facilities at March 31, 2004 and December 31, 2003. One facility is maintained for our 51%-owned Indian subsidiary, and allows for total borrowings of 200 million Indian Rupee (\$4.4 million at March 31, 2004). Our Italian subsidiary also has various facilities, related to its receivables, which allow for total borrowings of 10.9 million Euro (\$13.3 million at March 31, 2004).

**Capital Lease** In July 2003, we entered into a new six-year lease to rent a research and development facility in Emeryville, California following the expiration of the existing operating lease. Effective July 1, 2003, we accounted for this new lease as a capital lease and, as a result, recorded the leased facility and the corresponding liability on our balance sheet. The amount recorded on the balance sheet for the leased facility is \$157.5 million. The amount of the leased facility less the expected value of the facility at the end of the lease term is being amortized on a straight-line basis over the lease term. We expect the value of the facility at the end of the lease term to be approximately \$151.6 million. At the inception of the lease, the future minimum lease payments, exclusive of a residual value guarantee, are approximately \$15.7 million over the lease term. The interest payments represent variable-rate interest payments indexed to a three-month London interbank offered rate plus 40 basis points. The lease provides a \$156.0 million residual value guarantee from us to the lessors in the event of property value declines. Consequently, our maximum payment obligation is \$156.0 million upon termination of the lease on or before July 1, 2009. On or before July 1, 2009, we can choose to either purchase the facility from the lessors or sell the facility to a third party. This option accelerates if we default on our lease payments or in the event of other defined events. As of July 1, 2003, Novartis AG had guaranteed (under provisions of the Investment Agreement) payments on this lease commitment, including payment of the residual value guarantee, to a maximum of \$173.3 million.

### 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.

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 immunodiagnosics, under the Ortho-Clinical Diagnostics, Inc. contract, we manufacture bulk reagents and antigens and confirmatory test kits sold in the clinical diagnostics and blood screening fields. While we and our partners work to mitigate the risks associated with being a key provider, there can be no assurance that our partner, Gen-Probe, will be able to provide sufficient quantities of the Procleix® 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 immunodiagnosics, 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



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

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. For example, we are currently in the process of completing the integration of PowderJect Pharmaceuticals including the disposition of non-strategic assets. The failure to adequately address the financial, operational or legal risks raised by such transactions, including our integration of PowderJect, 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.

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

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, foreign currency exchange rates and levels of indebtedness 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.

We have significant debt balances following the issuance of our most recent convertible debt offerings. Therefore, our financial results will reflect increased interest expense and we could be harmed by a negative change to our credit rating by the debt rating agencies.

The holders of the Liquid Yield Option Notes (LYONs) due 2031 may require us to purchase all, or a portion, of the LYONs on June 12, 2004. We may choose to pay the purchase price in cash or in shares of Chiron common stock. To the extent we elect to purchase the LYONs for cash, our inability to replace the LYONs with new debt securities could adversely affect our cash balances and our business. To the extent we elect to pay for the LYONs in shares of Chiron common stock, the existing common stockholders would experience dilution as a result of the newly issued shares of Chiron common stock.

*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 March 31, 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.

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

*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:

Edgar Filing: CHIRON CORP - Form 10-Q

Inventory management practices, including wholesale ordering patterns;

The level of pre-clinical and clinical trial-related activities;

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

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 3. Quantitative and Qualitative Disclosures About Market Risk

**Market risk management** Our cash flow and earnings are subject to fluctuations due to changes in foreign currency exchange rates, changes in interest rates and changes in the fair value of equity securities held for sale. We attempt to limit our exposure to some or all of these market risks through the use of various financial and derivative instruments. As of March 31, 2004, there have been no material changes in these market risks since December 31, 2003. We seek to manage our exposures to market risks as discussed in further detail in Part II, Item 7A, "Quantitative and Qualitative Disclosures About Market Risk" in our annual Report on Form 10-K for the year ended December 31, 2003.

### Item 4. Controls and Procedures

(a)

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

(b)

**Changes in internal controls** There have been no significant changes in Chiron's internal controls over financial reporting or in other factors that could significantly affect internal controls over financial reporting during the most recent fiscal quarter.

(c)

**Limitations on the effectiveness of controls** It should be noted that any system of controls, however well designed and operated, can provide only reasonable, and not absolute, assurance that the objectives of the system are met. In addition, the design of any control system is based in part upon certain assumptions about the likelihood of future events. Because of these and other inherent limitations of control systems, there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

**PART II**

**Item 1. Legal Proceedings**

We are party to certain lawsuits and legal proceedings, which are described in Part I, Item 3. "Legal Proceedings" of our Annual Report on Form 10-K for the year ended December 31, 2003. The following is a description of material developments during the period covered by this Quarterly Report and should be read in conjunction with the Annual Report on Form 10-K for the year ended December 31, 2003.

*Active Biotech AB*

In June 2003, PowderJect Pharmaceuticals Plc ("PowderJect") filed a Request for Arbitration before the Arbitral Tribunal of the Arbitration Institute of the Stockholm Chamber of Commerce in Sweden against Active Biotech AB ("Active Biotech"). PowderJect claimed that Active Biotech breached certain warranties and representations made in the July 2, 2001 Agreement by which PowderJect acquired SBL Vaccin AB ("SBL") from Active Biotech (the "Agreement"), and sought compensatory damages and legal fees. In a settlement agreement reached in April 2004, Active Biotech agreed to waive all rights to further royalty and milestone payments upon payment by PowderJect of \$4.5 million, and PowderJect withdrew all claims relating to the Agreement. The matter is thus concluded.

*Laboratory Corporation of America Holdings*

In April 2003, Chiron filed a complaint in the United States District Court for the Northern District of California against Laboratory Corporation of America Holdings ("LabCorp Holdings"), Laboratory Corporation of America ("LabCorp") and National Genetics Institute ("NGI") (collectively, the "Defendants"), seeking damages and an injunction against Defendants' manufacture, use and sale of the UltraQual HCV RT-PCR assay and HCV SUPERQUANT assay for infringing Chiron's U.S. Patent No. 6,074,816 (the "816 patent"). The Defendants filed a complaint in the United States District Court for the District of Delaware against Chiron seeking a declaratory judgment that Defendants infringe neither the "816 patent, nor U.S. Patent Nos. 5,712,088, 5,863,719, 6,074,816, and 5,714,596 (collectively, the "Chiron Hepatitis C virus-related patents"), and that the Chiron Hepatitis C virus-related patents are invalid. In August 2003, the Delaware Court granted Defendants' motion to enjoin Chiron from proceeding with the California action and compel Chiron to dismiss that action. Chiron has appealed this judgment to the United States Court of Appeals for the Federal Circuit, and a hearing was held in March 2004. Chiron is awaiting a decision from the court. The Delaware Court has scheduled a trial for May 2005.

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

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

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

None.



**Item 6. Exhibits and Reports on Form 8-K**

**(a) Exhibits**

Exhibit Number	Exhibit
3.01	Restated Certificate of Incorporation of Chiron, as filed with the Office of the Secretary of State of Delaware on August 17, 1987, incorporated by reference to Exhibit 3.01 of Chiron's report on Form 10-K for fiscal year 1996.
3.02	Certificate of Amendment of Restated Certificate of Incorporation of Chiron, as filed with the Office of the Secretary of State of Delaware on December 12, 1991, incorporated by reference to Exhibit 3.02 of Chiron's report on Form 10-K for fiscal year 1996.
3.03	Certificate of Amendment of Restated Certificate of Incorporation of Chiron, as filed with the Office of the Secretary of State of Delaware on May 22, 1996, incorporated by reference to Exhibit 3.04 of Chiron's report on Form 10-Q for the period ended June 30, 1996.
3.04	Bylaws of Chiron, as amended and restated, incorporated by reference to Exhibit 10.304 of Chiron's report on Form 10-K for fiscal year 2003.
4.01	Indenture between Chiron and State Street Bank and Trust Company, dated as of June 12, 2001, incorporated by reference to Exhibit 4.01 of Chiron's report on Form 10-Q for the period ended June 30, 2001.
4.02	Registration Rights Agreement dated as of June 12, 2001, between Chiron and Merrill Lynch & Co., Inc., and Merrill Lynch, Pierce, Fenner & Smith, Incorporated, incorporated by reference to Exhibit 4.02 of Chiron's report on Form 10-Q for the period ended June 30, 2001.
4.03	Form of Liquid Yield Option Note due 2031 (Zero Coupon Senior) (included as exhibits A-1 and A-2 to the Indenture filed as Exhibit 4.01 hereto), incorporated by reference to Exhibit 4.03 of Chiron's report on Form 10-Q for the period ended June 30, 2001.
4.04	Indenture between Chiron and U.S. Bank National Association, as trustee, dated as of July 30, 2003, incorporated by reference to Exhibit 4.1 of Chiron's registration statement on Form-3 filed with the Commission on September 23, 2003.
4.05	Registration Rights Agreement dated as of July 30, 2003, between Chiron and Morgan Stanley & Co., Goldman, Sachs & Co., Banc of America Securities LLC and BNP Paribas Securities Corp., incorporated by reference to Exhibit 4.3 of Chiron's registration statement on Form-3 filed with the Commission on September 23, 2003.
4.06	Form of Convertible Debentures (included in Exhibit 4.04), incorporated by reference to Exhibit 4.2 of Chiron's registration statement on Form-3 filed with the Commission on September 23, 2003.
10.102	Amended and Restated Revolving Credit Agreement, dated as of August 13, 2002 (the "Credit Agreement"), by and between Chiron and Bank of America, N.A. (the "Bank"), and exhibits thereto, incorporated by reference to Exhibit 10.102 of Chiron's report on Form 10-Q for September 30, 2002.
10.519	Chiron Corporate Governance Guidelines, as amended.
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.

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

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.

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

On January 9, 2004, Chiron filed a Current Report on Form 8-K, furnishing under Item 5, the announcement that the Securities and Exchange Commission had declared effective its registration statement on Form S-3, relating to the resale of \$500 million principal amount of its 1<sup>5</sup>/<sub>8</sub>% Convertible Debentures due 2033 and the shares of its common stock issuable upon conversion of the debentures.

On January 28, 2004, Chiron filed a Current Report on Form 8-K, furnishing under Item 12, Chiron's preliminary results for its fourth quarter ended December 31, 2003, via a press release.

**CHIRON CORPORATION**  
**March 31, 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 30, 2004

By: /s/ HOWARD H. PIEN

---

Howard H. Pien  
*President and Chief Executive Officer*

DATE: April 30, 2004

By: /s/ DAVID V. SMITH

---

David V. Smith  
*Vice President and Chief Financial Officer*

53

---

QuickLinks

CHIRON CORPORATION TABLE OF CONTENTS

Item 1. Financial Statements

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

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

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

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

CHIRON CORPORATION NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS March 31, 2004 (Unaudited)

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Item 4. Controls and Procedures

PART II

Item 1. Legal Proceedings

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

Item 6. Exhibits and Reports on Form 8-K

SIGNATURES