

CHIRON CORP  
Form 10-Q  
August 12, 2003

[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 June 30, 2003

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_  
Commission File Number: 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.

Title of Class	Outstanding at July 31, 2003
Common Stock, \$0.01 par value	186,524,841

**CHIRON CORPORATION  
TABLE OF CONTENTS**

	Page No.
<b>PART I. FINANCIAL INFORMATION</b>	
<b>ITEM 1. Financial Statements (Unaudited)</b>	
Condensed Consolidated Balance Sheets at June 30, 2003 and December 31, 2002	3
Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2003 and 2002	5
Condensed Consolidated Statements of Comprehensive Income for the three and six months ended June 30, 2003 and 2002	6
Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2003 and 2002	7
Notes to Condensed Consolidated Financial Statements	8
<b>ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</b>	27
<b>ITEM 3. Quantitative and Qualitative Disclosures About Market Risk</b>	58
<b>ITEM 4. Controls and Procedures</b>	58
<b>PART II. OTHER INFORMATION</b>	
<b>ITEM 1. Legal Proceedings</b>	60
<b>ITEM 4. Submission of Matters to a Vote of Security Holders</b>	64
<b>ITEM 6. Exhibits and Reports on Form 8-K</b>	65
<b>SIGNATURES</b>	68

Item 1. Financial Statements

Edgar Filing: CHIRON CORP - Form 10-Q  
**CONDENSED CONSOLIDATED BALANCE SHEETS**

(Unaudited)

(In thousands, except share data)

	<b>June 30, 2003</b>	<b>December 31, 2002</b>
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 876,043	\$ 247,950
Short-term investments in marketable debt securities	271,290	626,130
	<hr/>	<hr/>
Total cash and short-term investments	1,147,333	874,080
Accounts receivable, net	289,380	278,625
Current portion of notes receivable	750	718
Inventories, net of reserves	196,005	146,005
Current net deferred income tax assets	40,734	38,450
Derivative financial instruments	12,201	12,006
Other current assets	55,478	35,838
	<hr/>	<hr/>
Total current assets	1,741,881	1,385,722
Noncurrent investments in marketable debt securities	119,171	414,447
<b>Property, plant, equipment and leasehold improvements, at cost:</b>		
Land and buildings	176,070	168,144
Laboratory, production and office equipment	461,059	418,255
Leasehold improvements	102,234	93,463
Construction-in-progress	83,382	74,717
	<hr/>	<hr/>
	822,745	754,579
Less accumulated depreciation and amortization	(418,841)	(381,021)
	<hr/>	<hr/>
Property, plant, equipment and leasehold improvements, net	403,904	373,558
Purchased technologies, net	246,949	257,613
Goodwill	243,476	239,746
Other intangible assets, net	146,502	147,089
Investments in equity securities and affiliated companies	113,504	87,167
Noncurrent notes receivable	8,959	8,939
Noncurrent derivative financial instruments	11,504	9,007
Other noncurrent assets	41,201	37,056
	<hr/>	<hr/>
	\$ 3,077,051	\$ 2,960,344
	<hr/>	<hr/>

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

Edgar Filing: CHIRON CORP - Form 10-Q

(In thousands, except share data)

	June 30, 2003	December 31, 2002
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 67,211	\$ 59,022
Accrued compensation and related expenses	50,016	59,498
Derivative financial instruments	182	
Short-term borrowings		71
Current portion of unearned revenue	45,712	26,610
Income taxes payable	1,073	21,883
Other current liabilities	119,067	131,552
	<u>283,261</u>	<u>298,636</u>
Total current liabilities	283,261	298,636
Long-term debt	421,073	416,954
Noncurrent derivative financial instruments		253
Noncurrent net deferred income tax liabilities	46,867	45,743
Noncurrent unearned revenue	54,711	62,580
Other noncurrent liabilities	41,857	35,813
Minority interest	6,115	5,355
	<u>853,884</u>	<u>865,334</u>
Total liabilities	853,884	865,334
Commitments and contingencies		
Put options		19,054
Stockholders' equity:		
Common stock	1,917	1,917
Additional paid-in capital	2,476,039	2,445,208
Deferred stock compensation	(11,560)	(11,349)
Accumulated deficit	(128,093)	(221,236)
Accumulated other comprehensive income	96,875	54,861
Treasury stock, at cost (5,437,000 shares at June 30, 2003 and 4,830,000 shares at December 31, 2002)	(212,011)	(193,445)
	<u>2,223,167</u>	<u>2,075,956</u>
Total stockholders' equity	2,223,167	2,075,956
	<u>\$ 3,077,051</u>	<u>\$ 2,960,344</u>

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

Edgar Filing: CHIRON CORP - Form 10-Q

(In thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2003	2002	2003	2002
<b>Revenues:</b>				
Product sales, net	\$ 245,928	\$ 211,293	\$ 464,548	\$ 384,877
Earnings of unconsolidated joint business	27,475	27,394	53,927	46,192
Collaborative agreement revenues	3,624	6,602	7,738	12,809
Royalty and license fee revenues	66,876	45,494	120,300	90,372
Other revenues	6,369	8,495	24,794	17,225
<b>Total revenues</b>	<b>350,272</b>	<b>299,278</b>	<b>671,307</b>	<b>551,475</b>
<b>Operating expenses:</b>				
Cost of sales	97,420	76,225	183,009	142,391
Research and development	89,915	83,530	172,045	162,303
Selling, general and administrative	79,707	71,093	152,749	133,863
Amortization expense	7,701	7,446	15,314	14,824
Write-off of purchased in-process research and development				54,781
Restructuring and reorganization charges	519		675	
Other operating expenses	1,259	899	2,794	5,482
<b>Total operating expenses</b>	<b>276,521</b>	<b>239,193</b>	<b>526,586</b>	<b>513,644</b>
Income from operations	73,751	60,085	144,721	37,831
Interest expense	(2,839)	(3,133)	(6,301)	(6,288)
Interest and other income, net	11,613	12,613	25,931	32,760
Minority interest	(581)	(464)	(981)	(883)
Income from continuing operations before income taxes	81,944	69,101	163,370	63,420
Provision for income taxes	20,485	18,657	40,842	31,913
Income from continuing operations	61,459	50,444	122,528	31,507
Gain on disposal of discontinued operations	538		1,964	
<b>Net income</b>	<b>\$ 61,997</b>	<b>\$ 50,444</b>	<b>\$ 124,492</b>	<b>\$ 31,507</b>
<b>Basic earnings per share:</b>				
Income from continuing operations	\$ 0.33	\$ 0.27	\$ 0.66	\$ 0.17
Net income	\$ 0.33	\$ 0.27	\$ 0.67	\$ 0.17
<b>Diluted earnings per share:</b>				
Income from continuing operations	\$ 0.32	\$ 0.26	\$ 0.65	\$ 0.16
Net income	\$ 0.33	\$ 0.26	\$ 0.66	\$ 0.16

Three Months Ended  
June 30,

Six Months Ended  
June 30,

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

5

**CHIRON CORPORATION**

**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME**

(Unaudited)

(In thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2003	2002	2003	2002
Net income	\$ 61,997	\$ 50,444	\$ 124,492	\$ 31,507
Other comprehensive income (loss):				
Change in foreign currency translation adjustment during the period, net of tax provision of \$7,294 for the three months ended June 30, 2002 and \$6,449 for the six months ended June 30, 2002	35,823	61,668	45,118	55,233
Net unrealized derivative loss arising during the period, net of tax benefit of \$72 for the three months ended June 30, 2002		(118)		
Unrealized gains (losses) from investments:				
Net unrealized holding gains (losses) arising during the period, net of tax (provision) benefit of (\$1,541) and \$651 for the three months ended June 30, 2003 and 2002, respectively, and (\$1,284) and \$3,532 for the six months ended June 30, 2003 and 2002, respectively	3,083	658	2,640	(5,623)
Reclassification adjustment for net gains included in net income, net of tax provision of \$1,834 and \$1,891 for the three months ended June 30, 2003 and 2002, respectively, and \$3,626 and \$3,587 for the six months ended June 30, 2003 and 2002, respectively	(2,940)	(3,065)	(5,744)	(5,802)
Net unrealized gains (losses) from investments	143	(2,407)	(3,104)	(11,425)
Other comprehensive income	35,966	59,143	42,014	43,808
Comprehensive income	\$ 97,963	\$ 109,587	\$ 166,506	\$ 75,315

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

6

## CHIRON CORPORATION

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(In thousands)

	Six Months Ended June 30,	
	2003	2002
Net cash provided by operating activities	\$ 113,177	\$ 82,566
Cash flows from investing activities:		
Purchases of investments in marketable debt securities	(277,514)	(320,675)
Proceeds from sales and maturities of investments in marketable debt securities	917,794	311,113
Capital expenditures	(52,371)	(54,323)
Proceeds from sales of assets		182
Purchases of equity securities and interests in affiliated companies	(36,889)	(3,093)
Proceeds from sale of equity securities and interests in affiliated companies	7,428	13,415
Cash paid for acquisitions, net of cash acquired	(1,180)	(55,284)
Other, net	(777)	(877)
Net cash provided by (used in) investing activities	556,491	(109,542)
Cash flows from financing activities:		
Net repayment of short-term borrowings	(71)	(308)
Repayment of debt	(95)	
Payments to acquire treasury stock	(68,079)	(45,116)
Proceeds from reissuance of treasury stock	24,526	18,027
Proceeds from put options	2,144	2,028
Net cash used in financing activities	(41,575)	(25,369)
Net increase (decrease) in cash and cash equivalents	628,093	(52,345)
Cash and cash equivalents at beginning of the period	247,950	320,673
Cash and cash equivalents at end of the period	\$ 876,043	\$ 268,328

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

## CHIRON CORPORATION

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

# Edgar Filing: CHIRON CORP - Form 10-Q

June 30, 2003

(Unaudited)

## Note 1 The Company and Summary of Significant Accounting Policies

### *Basis of Presentation*

The information presented in the condensed consolidated financial statements at June 30, 2003, and for the three and six months ended June 30, 2003 and 2002, is unaudited but includes 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, 2002, 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, 2002, 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 joint ventures, 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 based on Chiron's ownership levels and the ability of Chiron to exert significant influence over the entity's operating, investing and financing decisions. All significant intercompany accounts and transactions have been eliminated in consolidation.

On July 1, 2002, Chiron completed its acquisition of Pulmopharm GmbH, a distributor of TOBI® products in Germany and Austria by purchasing the remaining 80.1% ownership that Chiron did not previously own. Previously, Chiron owned 19.9% of Pulmopharm and accounted for the investment under the equity method. Chiron accounted for the acquisition using the purchase method of accounting and included Pulmopharm's operating results in its consolidated operating results beginning on July 1, 2002. Pulmopharm is part of Chiron's biopharmaceuticals segment (see Note 5).

On February 20, 2002, Chiron acquired Matrix Pharmaceutical, Inc., a company that was developing tezacitabine, a drug to treat cancer. Chiron included Matrix Pharmaceutical's operating results, including the seven business days from February 20 to 28, 2002, in its consolidated operating results beginning on March 1, 2002 (see Note 5).

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 \$28.7 million was paid through June 30, 2003. Chiron accounts for these investments under the equity method of accounting.

8

---

### *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; intangible assets; 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.



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

Chiron's blood testing segment consists of Chiron's one-half interest in the pretax operating earnings of its joint business contractual arrangement with Ortho-Clinical Diagnostics, Inc., a Johnson & Johnson company. 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. Prior to the first quarter 2003, Chiron had accounted for revenues from 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 the joint business contractual arrangement became available in the first quarter 2003, and as a result, Chiron is able to recognize revenues from 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 earnings of unconsolidated joint business for the six months ended June 30, 2003.

Chiron recognizes a portion of revenue for product sales of Betaseron® upon shipment to its marketing partner, and the remainder based on a contractual percentage of sales by its marketing partner. Chiron also earns royalties on the marketing partner's European sales of Betaferon® in those cases where Chiron does not supply the product. Prior to the first quarter 2002, Chiron had accounted for revenues from non-U.S. product sales on a one-quarter lag and royalties as a percentage of forecast received from its marketing partner, with an adjustment of the estimate to actual in the subsequent quarter. More current information of non-U.S. Betaseron® sales became available in 2002, and as a result, Chiron is able to recognize revenues from Betaseron® product sales and Betaferon® royalties on a current basis. The effect of this change, net of tax, was a decrease in net loss for the first quarter 2002 and an increase in net income for the six months ended June 30, 2002 by \$3.1 million for product sales and \$2.8 million for royalties.

### *Revenue Recognition*

Chiron's blood testing segment recognizes revenues related to nucleic acid testing product sales, which primarily consist of revenue derived from the sale and use of assays, revenue derived from the

9

---

sale, lease or rental of equipment and revenue from providing field service for the instruments. In the case of assay sales and equipment rentals included as part of the assay contract (commonly referred to as "reagent rental" agreements), revenue is recorded based upon the reported results obtained from the customer for 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, revenue is recorded upon the sale and transfer of the title to the instrument or ratably over the life of the lease term. For the provision of service on the instruments, revenue is recognized ratably over the life of the service agreement term.

### *Inventories*

Inventories are stated at the lower of cost or market using the moving weighted-average cost method. 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. Inventories, net of reserves consisted of the following (in thousands):

	<b>June 30, 2003</b>	<b>December 31, 2002</b>
Finished goods	\$ 49,881	\$ 32,697
Work-in-process	99,306	77,232
Raw materials	46,818	36,076
	<b>\$ 196,005</b>	<b>\$ 146,005</b>

### *Income Taxes*

The reported effective tax rate for 2003 is 25% of pretax income from 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. Income tax expense for the six months ended June 30, 2002, was based on an estimated annual effective tax rate on pretax income from continuing operations of approximately 27%, excluding the write-off of purchased in-process research and development related to the acquisition of Matrix Pharmaceutical, Inc. (see Note 5).

Edgar Filing: CHIRON CORP - Form 10-Q

Put Options

Chiron has used written put options to reduce the effective costs of repurchasing its common stock. The put option contracts provide that Chiron, at its choice, can settle with cash or through physical delivery of shares and, accordingly, the fair value of such put option contracts (premiums received) is initially classified in equity. However, because either settlement choice could require Chiron to deliver cash if the put option is exercised, an amount equal to the cash redemption value of the put option contracts is classified as temporary equity until expiration of the option.

10

Stock-Based Compensation

Chiron measures compensation expense for its stock-based employee compensation plans using the intrinsic method prescribed by Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" and related Interpretations, including Financial Accounting Standards Board, referred to as FASB, Interpretation No. 44 "Accounting for Certain Transactions Involving Stock Compensation." Compensation expense is based on the difference, if any, between the fair value of Chiron's common stock and the exercise price of the option or share right on the measurement date, which is typically the date of grant. This amount is recorded as "Deferred stock compensation" in the Condensed Consolidated Balance Sheets and amortized as a charge to operations over the vesting period of the applicable options or share rights. Compensation expense is included primarily in "Selling, general and administrative" in the Condensed Consolidated Statements of Operations.

In accordance with Statement of Financial Accounting Standards, referred to as SFAS, No. 123, "Accounting for Stock-Based Compensation," as amended by SFAS No. 148, "Accounting for Stock-Based Compensation Transition and Disclosure," Chiron has provided, below, the pro forma disclosures of the effect on net income and net income per share as if SFAS No. 123 had been applied in measuring compensation expense for all periods presented. Due to rounding, quarterly amounts may not sum fully to yearly amounts.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2003	2002	2003	2002
	(in thousands, except per share data)			
<b>Net income:</b>				
As reported	\$ 61,997	\$ 50,444	\$ 124,492	\$ 31,507
Add: Stock-based employee compensation expense included in reported net income, net of related tax effects	1,750	675	2,651	1,510
Less: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	19,933	15,462	38,045	29,729
<b>Pro forma</b>	<b>\$ 43,814</b>	<b>\$ 35,657</b>	<b>\$ 89,098</b>	<b>\$ 3,288</b>
<b>Basic net income per share:</b>				
As reported	\$ 0.33	\$ 0.27	\$ 0.67	\$ 0.17
Pro forma	\$ 0.24	\$ 0.19	\$ 0.48	\$ 0.02
<b>Diluted net income per share:</b>				
As reported	\$ 0.33	\$ 0.26	\$ 0.66	\$ 0.16
Pro forma	\$ 0.23	\$ 0.18	\$ 0.47	\$ 0.02

11

*Comprehensive Income*

In 2003, the foreign currency translation component of comprehensive income was not adjusted for income taxes, as it relates to permanent investments in non-U.S. subsidiaries. In 2002, the foreign currency translation component of comprehensive income included the tax effects of certain profit repatriations from Chiron's German and Italian vaccines subsidiaries. Additionally in 2002, all other foreign profits, net of the German and Italian profit repatriations, were considered permanently reinvested.

*Treasury Stock*

Treasury stock is stated at cost. Gains on reissuance of treasury stock are credited to "Additional paid-in capital." Losses on reissuance of treasury stock are charged to "Additional paid-in capital" to the extent of available net gains on reissuance of treasury stock. Otherwise, losses are charged to "Accumulated deficit." Chiron charged losses of \$16.3 million and \$23.8 million for the three and six months ended June 30, 2003, respectively, and \$5.4 million and \$22.9 million for the three and six months ended June 30, 2002, respectively, to "Accumulated deficit" in the Condensed Consolidated Balance Sheets.

*New Accounting Standards*

In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity." This Statement establishes new standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). This Statement is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. The adoption of SFAS No. 150 is not expected to have a material impact on the Consolidated Financial Statements.

In April 2003, the FASB issued SFAS No. 149, "Amendment of Statement 133 on Derivative Instruments and Hedging Activities," which amends and clarifies the accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts, and for hedging activities under SFAS No. 133. It requires, among other things, that contracts with comparable characteristics be accounted for similarly and clarifies under what circumstances a contract with an initial net investment meets the characteristic of a derivative and when a derivative contains a financing component that warrants special reporting in the statement of cash flows. SFAS No. 149 is effective generally for contracts entered into and modified after June 30, 2003. The adoption of SFAS No. 149 is not expected to have a material impact on the Consolidated Financial Statements.

In January 2003, the FASB issued Interpretation No. 46 (referred to as FIN No. 46), "Consolidation of Variable Interest Entities" which address the accounting for certain off-balance sheet lease financing. The recognition provisions of FIN No. 46 will be effective for Chiron for the interim period ended September 30, 2003. The adoption of FIN No. 46 is not expected to have a material impact on the Consolidated Financial Statements.

In November 2002, the FASB issued EITF Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables." EITF Issue No. 00-21 addresses certain aspects of the accounting by a company for arrangements under which it will perform multiple revenue-generating activities. EITF Issue No. 00-21 addresses when and how an arrangement involving multiple deliverables should be divided into separate units of accounting. EITF Issue No. 00-21 provides guidance with respect to the effect of certain customer rights due to company nonperformance on the recognition of revenue allocated to delivered units of accounting. EITF Issue No. 00-21 also addresses the impact on the measurement and/or allocation of arrangement consideration of customer cancellation provisions and consideration that varies as a result of future actions of the customer or the company. Finally, EITF Issue No. 00-21 provides guidance with respect to the recognition of the cost of certain deliverables that are excluded from the revenue accounting for an arrangement. The provisions of EITF Issue No. 00-21 apply to revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The adoption of EITF Issue No. 00-21 is not expected to have a material impact on the Consolidated Financial Statements.

**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

Edgar Filing: CHIRON CORP - Form 10-Q

if-converted method. Due to rounding, quarterly amounts may not sum fully to yearly amounts.

13

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2003	2002	2003	2002
<b>Income (Numerator):</b>				
Income from continuing operations	\$ 61,459	\$ 50,444	\$ 122,528	\$ 31,507
<b>Shares (Denominator):</b>				
Weighted-average common shares outstanding	186,408	189,579	186,584	189,536
<b>Effect of dilutive securities:</b>				
Stock options and equivalents	3,550	3,346	3,294	3,668
Put options	5		3	5
Weighted-average common shares outstanding, plus assumed issuances	189,963	192,925	189,881	193,209
Basic earnings per share	\$ 0.33	\$ 0.27	\$ 0.66	\$ 0.17
Diluted earnings per share	\$ 0.32	\$ 0.26	\$ 0.65	\$ 0.16

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2003	2002	2003	2002
<b>Income (Numerator):</b>				
Net income	\$ 61,997	\$ 50,444	\$ 124,492	\$ 31,507
<b>Shares (Denominator):</b>				
Weighted-average common shares outstanding	186,408	189,579	186,584	189,536
<b>Effect of dilutive securities:</b>				
Stock options and equivalents	3,550	3,346	3,294	3,668
Put options	5		3	5
Weighted-average common shares outstanding, plus assumed issuances	189,963	192,925	189,881	193,209
Basic earnings per share	\$ 0.33	\$ 0.27	\$ 0.67	\$ 0.17
Diluted earnings per share	\$ 0.33	\$ 0.26	\$ 0.66	\$ 0.16

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

For the three months ended June 30, 2003 and 2002, stock options to purchase 16.8 million and 14.1 million shares, respectively, and for the six months ended June 30, 2003 and 2002, stock options to purchase 17.1 million and 13.8 million, 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.

14

---

Also excluded from the computations of diluted earnings per share for each of the three and six months ended June 30, 2003 and June 30, 2002 were 5.2 million shares of common stock issuable upon conversion of the Liquid Yield Option Notes, as their inclusion would be antidilutive.

### **Note 3 Put Options**

In May 2003, Chiron entered into a contract with a third party to sell put options on Chiron stock, entitling the holder to sell to Chiron 0.5 million shares at \$43.89 per share. The option expired June 30, 2003. On June 30, 2003, Chiron's closing stock price was \$43.86. The third party elected to exercise a portion of the options. As a result, Chiron repurchased 0.2 million shares.

In February 2003, Chiron entered into a contract with a third party to sell put options on Chiron stock, entitling the holder to sell to Chiron 0.5 million shares at \$36.79 per share. The option expired unexercised on May 5, 2003.

As of December 31, 2002, Chiron had an outstanding put option contract with a third party entitling the holder to sell to Chiron 0.5 million shares at \$38.11 per share. The option expired unexercised on January 29, 2003. This put option contract was initially classified as equity. However, because the settlement options available to Chiron could require Chiron to deliver cash if the put option was exercised by the counter-party, the cash redemption value, totaling \$19.1 million, was reclassified from "Additional paid-in capital" to "Put options" in temporary equity in the Condensed Consolidated Balance Sheet at December 31, 2002. Upon expiration, the options were not exercised and the temporary equity of \$19.1 million was reclassified to permanent equity in the first quarter 2003.

### **Note 4 Discontinued Operations**

In a strategic effort to focus on its core businesses of biopharmaceuticals, vaccines and blood testing, Chiron completed the sale of Chiron Diagnostics and Chiron Vision in 1998 and 1997, respectively. Discontinued operations had no impact on basic earnings per share for the three months ended June 30, 2003. Diluted earnings per share from discontinued operations was \$0.01 for the three months ended June 30, 2003. Basic and diluted earnings per share from discontinued operations were \$0.01 for the six months ended June 30, 2003. There was no activity related to discontinued operations during the three and six months ended June 30, 2002.

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

In the first quarter 2003, Chiron and Bayer Corporation reached a settlement agreement relating to certain claims raised by Bayer under the Stock Purchase Agreement dated September 17, 1998, between Chiron and Bayer for Chiron Diagnostics. Under this settlement agreement, Chiron was required to make a payment to Bayer during the first quarter 2003. Chiron utilized an amount previously reserved for indemnity obligations, based upon the settlement agreement with Bayer. These amounts resulted in a net charge 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 recorded as a "Gain on disposal of discontinued operations" for the six months ended June 30, 2003.

15

---

### *Income Taxes*

In connection with the sale of Chiron Diagnostics and Chiron Vision, Chiron recorded cumulative net deferred tax assets of \$0.2 million and \$8.5 million at June 30, 2003 and December 31, 2002, respectively, principally attributable to the timing of the deduction of certain expenses associated with these sales. Chiron also recorded corresponding valuation allowances of \$0.2 million and \$8.5 million at June 30, 2003 and December 31, 2002, respectively, to offset these deferred tax assets, as management believes that it is more likely than not that the deferred tax assets to which the valuation allowance relates will not be realized. The future recognition of these deferred tax assets will be reported as a component of "Gain (loss) on disposal of discontinued operations."

**Note 5 Acquisitions**

**Pulmopharm GmbH** On July 1, 2002, Chiron completed its acquisition of Pulmopharm GmbH, a distributor of TOBI® products in Germany and Austria by purchasing the remaining 80.1% ownership that Chiron did not previously own. Previously, Chiron owned 19.9% of Pulmopharm and accounted for the investment under the equity method. Chiron's acquisition of all of the remaining outstanding shares of common stock of Pulmopharm, including estimated acquisition costs, resulted in a total purchase price of approximately \$3.7 million. The acquisition resulted in the recognition of \$3.8 million of intangible assets relating to the distribution rights, \$1.2 million of goodwill, \$0.3 million of tangible assets and \$1.6 million of deferred tax liabilities on the acquisition date. In addition, on the acquisition date, the carrying value of the original investment in Pulmopharm, which totaled \$0.3 million, was reclassified to goodwill. Chiron accounted for the acquisition using the purchase method of accounting and included Pulmopharm's operating results in its consolidated operating results beginning on July 1, 2002. Pulmopharm is part of Chiron's biopharmaceuticals segment.

**Matrix Pharmaceutical, Inc.** On February 20, 2002, Chiron acquired Matrix Pharmaceutical, Inc., a company that was developing tezacitabine, a drug to treat cancer. Chiron acquired all of the outstanding shares of common stock of Matrix Pharmaceutical at \$2.21 per share, which, including acquisition costs, resulted in a total purchase price of approximately \$67.0 million. Matrix Pharmaceutical is part of Chiron's biopharmaceuticals segment. Tezacitabine expanded Chiron's portfolio of cancer therapeutics.

Chiron accounted for the acquisition as an asset purchase and included Matrix Pharmaceutical's operating results, including the seven business days from February 20 to 28, 2002, in its consolidated operating results beginning on March 1, 2002. The components and allocation of the purchase price, based on their fair values, consisted of the following (in thousands):

Consideration and acquisition costs:	
Cash paid for common stock	\$ 58,737
Cash paid for options on common stock	2,231
Acquisition costs	6,078
	<hr/>
Total purchase price	\$ 67,046
	<hr/>

16

Allocation of purchase price:	
Cash and cash equivalents	\$ 17,337
Assets held for sale	2,300
Deferred tax assets	10,000
Other assets	1,469
Write-off of purchased in-process research and development	45,181
Accounts payable	(2,898)
Reduction of income taxes payable	1,739
Accrued liabilities	(8,082)
	<hr/>
Total purchase price	\$ 67,046
	<hr/>

Acquisition costs included contractual severance and involuntary termination costs, as well as other direct acquisition costs. Approximately \$5.1 million represented severance payments, assumed by Chiron, to eligible employees as defined by their employment agreements.

Chiron allocated the purchase price based on the fair value of the assets acquired and liabilities assumed. Once value was allocated to tangible assets, the residual amount (which was less than the estimated fair value of the in-process research and development discussed below) was allocated to the identifiable intangible assets, including in-process research and development. Chiron allocated a portion of the purchase price to purchased in-process research and development and wrote off \$54.8 million in the first quarter 2002. Chiron allocated a portion of the purchase price to a liability for asset disposal and lease cancellation for the San Diego, California facility closed during the third quarter 2002. In the fourth quarter 2002, Chiron found an assignee for the manufacturing facility lease and revised the allocation of the purchase price resulting

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

in a \$9.6 million decrease to the liabilities relating to the expected exit of the facility. As a result, the revised aggregate fair value of the assets acquired and liabilities assumed, including purchased in-process research and development, exceeded the purchase price by \$9.6 million. Accordingly, this excess credit of \$9.6 million was allocated to purchased in-process research and development, as an excess credit allocated to any other acquired asset would have resulted in the recording of assets below fair value and would have required a gain to be recognized as current assets were realized. Chiron does not anticipate that there will be any alternative future use for the in-process research and development that was written off. The write-off of purchased in-process research and development represented the fair value, calculated using probability-of-success-adjusted cash flows and a 20% discount rate, at the acquisition date. Chiron assumed cash flows from tezacitabine to commence after 2005. As with all pharmaceutical products, the probability of commercial success for any research and development project is highly uncertain.

As indicated in the above table, a portion of the purchase price was allocated to assets held for sale. In March 2002, Chiron sold the leasehold improvements and assigned the lease related to a facility located in Fremont, California. Chiron received an amount equivalent to the fair value of the assets at the date of acquisition.

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

17

---

as a component of "Cash paid for acquisitions, net of cash acquired" for the six months ended June 30, 2003.

In March 2002, Chiron paid \$6.0 million related to a bank loan assumed during the purchase of Matrix Pharmaceutical. This payment is reflected on the Condensed Consolidated Statement of Cash Flows as a component of "Cash paid for acquisitions, net of cash acquired" for the six months ended June 30, 2002.

The deferred tax assets primarily related to future utilization of net operating loss carryforwards. Chiron acquired federal and state net operating loss carryforwards and business credits attributed to Matrix Pharmaceutical of approximately \$288.7 million and \$9.5 million, respectively. The available utilization of such net operating loss and business tax credit carryforwards is limited in any one year to approximately \$2.8 million per annum over the next twenty years under provisions of the Internal Revenue Code. As such, a significant portion of Matrix Pharmaceutical's net operating loss carryforwards is expected to expire unutilized.

### **Note 6 Restructuring and Reorganization**

For the six months ended June 30, 2003, Chiron recorded restructuring and reorganization charges of \$0.7 million. The charges, included in "Restructuring and reorganization charges" in the condensed consolidated statement of operations, consisted of termination and other employee-related costs recognized in connection with the elimination of 7 positions in its Amsterdam manufacturing facility. Termination notice has been provided. However, of the 7 positions for elimination, none were terminated as of June 30, 2003. For the six months ended June 30, 2002, Chiron had no restructuring and reorganization adjustments.

Previously, Chiron recorded restructuring and reorganization charges related to (i) the integration of its worldwide vaccines operations, (ii) the closure of its Puerto Rico and St. Louis, Missouri facilities and (iii) the ongoing restructuring of its business operations. The integration of its worldwide vaccines operations consisted of termination and other employee-related costs recognized in connection with the elimination of 28 positions, all of which had terminated as of December 31, 2000, in Chiron's Italian manufacturing facility and facility-related costs. The closure of its Puerto Rico and St. Louis facilities and the ongoing restructuring of its business operations consisted of termination and other employee-related costs recognized in connection with the elimination of 371 positions in manufacturing, research, development, sales, marketing and other administrative functions, and facility-related costs. Employee termination costs included wage continuation, advance notice pay and medical and other benefits. Facility-related costs included losses on disposal of property, plant and equipment, lease payments and other related costs. For the six months ended June 30, 2003 and 2002, Chiron had no restructuring and reorganization adjustments related to these items. Of the 371 positions for elimination, 366 were terminated as of June 30, 2003 and 363 had been terminated as of June 30, 2002.

Chiron expects to substantially settle the restructuring and reorganization accruals within one to six years of accruing the related charges. As of June 30, 2003, \$0.9 million was included in "Other current liabilities" in the Condensed Consolidated Balance Sheet. As of December 31, 2002, \$0.2 million and \$0.1 million were included in "Other current liabilities" and "Other noncurrent liabilities," respectively, in the Condensed Consolidated Balance Sheet.

18

Edgar Filing: CHIRON CORP - Form 10-Q

The activity in accrued restructuring and reorganization for the six months ended June 30, 2003 and 2002 is summarized as follows (in thousands):

	Accrual at December 31, 2002	Amount of Total Restructuring Charge	Amount Utilized Through June 30, 2003	Amount to Be Utilized In Future Periods
Employee-related costs and Other facility-related costs	\$ 334	\$ 675	\$ (150)	\$ 859
	Accrual at December 31, 2001	Amount of Total Restructuring Charge	Amount Utilized Through June 30, 2002	Amount to Be Utilized In Future Periods
Employee-related costs and Other facility-related costs	\$ 693	\$	\$ (201)	\$ 492

**Note 7 Intangible Assets**

In July 2001, the FASB issued SFAS No. 141, "Business Combinations," and SFAS No. 142, "Goodwill and Other Intangible Assets." Chiron adopted the provisions of SFAS No. 141 immediately, and SFAS No. 142 effective January 1, 2002.

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

	June 30, 2003			December 31, 2002		
	Gross Carrying Value	Accumulated Amortization	Net Carrying Value	Gross Carrying Value	Accumulated Amortization	Net Carrying Value
Purchased technologies	\$ 331,975	\$ 85,026	\$ 246,949	\$ 331,941	\$ 74,328	\$ 257,613
Patents	\$ 112,711	\$ 56,915	\$ 55,796	\$ 106,723	\$ 52,136	\$ 54,587
Trademarks	56,966	17,547	39,419	53,394	14,928	38,466
Licenses and technology rights	37,202	19,927	17,275	35,243	16,063	19,180
Customer relationships	26,298	8,392	17,906	24,082	7,054	17,028
Know how(1)	11,943	5,066	6,877	10,935	4,245	6,690
Databases	7,100	1,301	5,799	7,100	1,065	6,035
Other	15,356	11,926	3,430	15,274	10,171	5,103
Total other intangible assets	\$ 267,576	\$ 121,074	\$ 146,502	\$ 252,751	\$ 105,662	\$ 147,089
Total intangible assets subject to amortization	\$ 599,551	\$ 206,100	\$ 393,451	\$ 584,692	\$ 179,990	\$ 404,702



(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.

19

Aggregate amortization expense is as follows (in thousands):

For the six months ended June 30, 2003 (reported)	\$ 27,399
For the remaining six months in the year ended December 31, 2003 (estimated)	27,461
	<u>54,860</u>
For the year ended December 31, 2003 (estimated)	\$ 54,860
For the year ended December 31, 2004 (estimated)	\$ 51,909
For the year ended December 31, 2005 (estimated)	\$ 47,467
For the year ended December 31, 2006 (estimated)	\$ 45,862
For the year ended December 31, 2007 (estimated)	\$ 44,662
For the year ended December 31, 2008 (estimated)	\$ 43,846

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

	<u>Biopharmaceuticals</u>	<u>Vaccines</u>	<u>Total</u>
<b>Goodwill (including assembled workforce):</b>			
Balance as of December 31, 2002	\$ 199,225	\$ 40,521	\$ 239,746
Effect of exchange rate changes		3,730	3,730
	<u>199,225</u>	<u>44,251</u>	<u>243,476</u>
Balance as of June 30, 2003	\$ 199,225	\$ 44,251	\$ 243,476

#### Note 8 Segment Information

Chiron is organized based on the products and services that it offers. Under this organizational structure, there are three reportable segments: (i) biopharmaceuticals, (ii) vaccines and (iii) blood testing. 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. The vaccines segment consists principally of adult and pediatric vaccines for viral and bacterial infections. Chiron sells these vaccines primarily in 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 blood testing segment consists of an alliance with Gen-Probe Incorporated and Chiron's one-half interest in the pretax operating earnings of its 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.

20

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.

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

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.

For the three and six months ended June 30, 2002, expenses of approximately \$2.5 million and \$4.4 million, respectively, previously allocated to the biopharmaceuticals segment, have been allocated to the vaccines segment to conform with the current period presentation.

The accounting policies of Chiron's reportable segments are the same as those described in Note 1 The Company and Summary of Significant Accounting Policies above and in Chiron's Annual Report on Form 10-K for the year ended December 31, 2002. Chiron evaluates the performance of its segments based on each segment's income (loss) from continuing operations, excluding certain special items, such as restructuring and reorganization charges and the write-off of purchased in-process research and development, which are shown as reconciling items in the table below.

21

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2003	2002	2003	2002
<i>Revenues</i>				
Biopharmaceuticals:				
Product sales, net	\$ 107,267	\$ 104,065	\$ 208,952	\$ 194,501
Collaborative agreement revenues	1,118	3,428	3,282	7,015
Royalty and license fee revenues	20,758	16,424	38,574	33,737
Other revenues	3,151	1,907	18,785	6,644
<b>Total biopharmaceuticals revenues</b>	<b>\$ 132,294</b>	<b>\$ 125,824</b>	<b>\$ 269,593</b>	<b>\$ 241,897</b>
Vaccines:				
Product sales, net	\$ 85,557	\$ 72,602	\$ 153,961	\$ 130,600
Collaborative agreement revenues	166	333	167	333
Royalty and license fee revenues	3,343	2,791	6,529	5,434
Other revenues	3,218	5,218	6,009	9,098
<b>Total vaccines revenues</b>	<b>\$ 92,284</b>	<b>\$ 80,944</b>	<b>\$ 166,666</b>	<b>\$ 145,465</b>
Blood testing:				
Product sales, net	\$ 53,104	\$ 34,626	\$ 101,635	\$ 59,776
Earnings of unconsolidated joint business	27,475	27,394	53,927	46,192
Collaborative agreement revenues	2,340	2,841	4,289	5,461
Royalty and license fee revenues	23,160	12,573	38,796	22,762
Other revenues		41		41
<b>Total blood testing revenues</b>	<b>\$ 106,079</b>	<b>\$ 77,475</b>	<b>\$ 198,647</b>	<b>\$ 134,232</b>
Other:				
Royalty and license fee revenues	\$ 19,615	\$ 13,706	\$ 36,401	\$ 28,439
Other revenues		1,329		1,442

Edgar Filing: CHIRON CORP - Form 10-Q

	Three Months Ended June 30,		Six Months Ended June 30,	
Total other revenues	\$ 19,615	\$ 15,035	\$ 36,401	\$ 29,881
Total revenues	\$ 350,272	\$ 299,278	\$ 671,307	\$ 551,475

22

*Income (loss) from  
continuing operations*

Biopharmaceuticals	\$ 8,872	\$ 4,745	\$ 33,971	\$ 12,979
Vaccines	794	13,281	(4,508)	8,978
Blood testing	62,441	43,630	113,003	73,113
Other	2,163	(1,571)	2,930	(2,458)
Segment income from operations	74,270	60,085	145,396	92,612
Operating expense reconciling items:				
Write-off of purchased in-process research and development				(54,781)
Restructuring and reorganization charges	(519)		(675)	
Income from operations	73,751	60,085	144,721	37,831
Interest expense	(2,839)	(3,133)	(6,301)	(6,288)
Interest and other income, net	11,613	12,613	25,931	32,760
Minority interest	(581)	(464)	(981)	(883)
Income from continuing operations before income taxes	\$ 81,944	\$ 69,101	\$ 163,370	\$ 63,420

**Note 9 Commitments and Contingencies**

Effective June 2003, Chiron and SynCo Bio Partners B.V., a related party, executed a seven and a half-year contract manufacturing agreement. Under this agreement, SynCo agreed to provide services related to the production of certain of Chiron's vaccine products for the European and U.S. markets. Chiron has a firm binding order for products to be delivered by SynCo in 2004, 2005 and 2006 under this agreement. Chiron's minimum purchase obligation under this agreement, subject to adjustment depending on the quantities purchased by Chiron in years 2007 through 2010, inflation and movement in the Euro to U.S. Dollar exchange rate, is expected to be approximately \$34.0 million over the term of the agreement.

Simultaneously in June 2003, Chiron and SynCo Bio Partners B.V. executed an FDA compliance agreement. Under this agreement, Chiron will fund certain costs required to bring SynCo's Amsterdam manufacturing facility into compliance to support approval by the U.S. Food and Drug Administration to manufacture certain vaccine products for the U.S. market. Chiron's funding commitment under this agreement is expected to be approximately \$10.0 million through the first quarter 2005.

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

In July 2003, Chiron entered into a new six-year lease to rent a research and development facility in Emeryville, California following the expiration of the existing lease. Effective July 1, 2003, Chiron accounted for this new lease as a capital lease and, as a result, recorded the leased facility and the corresponding liability on its balance sheet. The amount recorded on the balance sheet for the leased facility is \$157.5 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

23

---

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 Chiron to the lessors in the event of property value declines. Consequently, Chiron's maximum payment obligation is \$156.0 million upon termination of the lease on or before July 1, 2009. On or before July 1, 2009, Chiron can choose to either purchase the facility from the lessors or sell the facility to a third party. This option accelerates if Chiron defaults on its 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.

Chiron is limited partner of several venture capital funds, as discussed in Note 1 "The Company and Summary of Significant Accounting Policies." In the second quarter 2003, Chiron became a limited partner of two additional venture capital funds. Chiron is obligated to pay \$15.0 million over ten years in equity contributions to these two new venture capital funds, of which \$1.0 million was paid through June 30, 2003.

In April 2003, Chiron entered into a 15-year lease to rent an office building in Uxbridge, United Kingdom. The total minimum lease payments over the term of the lease are approximately 9.8 million British Pounds (\$16.4 million at June 30, 2003). After 10 years, Chiron has the option to terminate or continue the lease, with one-year prior notice. This lease is accounted for as an operating lease.

There were no amounts drawn against any outstanding letters of credit at June 30, 2003. Effective April 1, 2003, the amount of insurance-related letters of credit was increased by \$4.8 million.

Effective February 2003, Chiron and Baxter Pharmaceutical Solutions LLC executed an eight-year manufacturing and supply agreement. Under this agreement, Baxter agreed to perform certain manufacturing procedures and supply Chiron with a key component for a certain biopharmaceutical product. Chiron has certain minimum purchase obligations under this agreement and is required to pay the difference, if any, between the actual quantity purchased and the minimum purchase obligation. Chiron's minimum purchase obligation is effective once regulatory approval is obtained. Chiron can terminate this agreement in the fifth year with prior notice. Chiron's minimum purchase obligation under this agreement is expected to be approximately \$36.0 million over the next four years.

In April 2001, Chiron, Rhein Biotech N.V. (now part of Berna Biotech) and GreenCross Vaccine Corporation entered into a collaboration 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 (\$30.2 million at June 30, 2003) for the expansion of Chiron's Italian manufacturing facilities, of which Chiron had incurred costs of 4.6 million Euro (\$5.4 million), as of June 30, 2003. This agreement began in the fourth quarter 2001 and is expected to continue through 2008.

In February 2001, Chiron's Board of Directors approved a \$235.0 million capital expansion project, which includes the construction of a research and development facility (including a supporting central utility facility) and a parking structure in Emeryville, California. Chiron has committed to \$37.6 million in design and construction services, of which Chiron had incurred costs of \$28.4 million, as of June 30,

24

---

2003. Chiron may cancel these commitments at any time. Related to the research and development facility, Chiron is evaluating various financing alternatives to fund this expansion. Construction was completed on the parking structure in December 2002.

Chiron enters into indemnification provisions under its agreements with other companies in its ordinary course of business, typically with business partners, contractors, clinical sites, insurers and customers. Under these provisions Chiron generally indemnifies and holds harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of Chiron's activities. These indemnification provisions generally survive termination of the underlying agreement. In some cases, the maximum potential amount of future payments Chiron could be

required to make under these indemnification provisions is unlimited. The estimated fair value of the indemnity obligations of these agreements is minimal. Accordingly, Chiron has no liabilities recorded for these agreements as of June 30, 2003. 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.

#### **Note 10 Subsequent Events**

On May 19, 2003, Chiron announced the commencement of an all cash offer to acquire all issued and to be issued share capital of PowderJect Pharmaceuticals plc for 550 pence per ordinary share. PowderJect, which is based in Oxford, United Kingdom, develops and commercializes vaccines. PowderJect's portfolio of vaccine products includes vaccines for influenza, yellow fever, travel diarrhea and cholera, tuberculosis, polio and tetanus. PowderJect will be part of Chiron's vaccines segment. As of June 30, 2003, Chiron had purchased 3.8 million shares of PowderJect for \$33.7 million, representing approximately 4.1% of the existing issued share capital of PowderJect as of that date. These shares were included in "Investments in equity securities and affiliated companies" as of June 30, 2003. On July 8, 2003, Chiron's cash offer became unconditional. As of July 8, 2003, Chiron had acquired or agreed to acquire or had received valid acceptances of the offer in respect of, in aggregate, 83,069,483 PowderJect shares representing 90.07% of the existing issued share capital of PowderJect. As part of the acquisition of PowderJect, Chiron will assume the debt of PowderJect including convertible notes with a face value of 35.0 million British Pounds (\$57.0 million at July 8, 2003). As of August 11, 2003,

25

---

Chiron had acquired or agreed to acquire or had received valid acceptances of the offer in respect of, in aggregate, 97,735,800 PowderJect shares, representing 99.14% of the issued share capital of PowderJect as of that date. Chiron has implemented the statutory procedures under the laws of the United Kingdom to acquire all remaining PowderJect shares outstanding. Chiron expects to pay the acquisition consideration from its available cash and cash equivalents and through liquidation of certain of its long-term investments in marketable debt securities.

On July 30, 2003, Chiron raised \$450.0 million through an offering of convertible debentures, referred to as the "Offering", and an additional \$50.0 million from the exercise of an option, granted to the underwriters, to purchase additional convertible debentures in connection with the Offering. The convertible debentures bear a coupon rate of 1.625% per annum and interest is payable semiannually. The debentures are convertible into shares of Chiron common stock and the terms include an initial conversion price of approximately \$68.44 per share. The debentures may not be called for redemption by Chiron for five years. Holders of the debentures will have the option to require Chiron to purchase their debentures at par value in years five, 10, 15, 20 and 25. Chiron may choose to pay the redemption purchase price in cash and / or shares of common stock. The debentures mature on August 1, 2033.

26

---

## **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, 2002. 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, nor 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: biopharmaceuticals, vaccines and blood testing. Our revenues consist of product sales, earnings of unconsolidated joint business, collaborative agreement revenues, royalty and license fee revenues and other revenues. The biopharmaceuticals segment consists of therapeutic products and services, with an emphasis on the treatment of cancer and infectious disease, using the development and acquisition of technologies related to therapeutic proteins and small molecules. The biopharmaceuticals segment also includes collaborations with Berlex Laboratories, Inc. and its parent company, Schering AG of Germany, related to Betaseron®. The vaccines segment consists of a meningococcal vaccine, flu vaccines, travel vaccines, which include rabies and tick-borne encephalitis vaccines and pediatric vaccines. We sell these vaccines primarily in Germany, Italy, the United Kingdom and other international markets. Our vaccines segment is also involved in the development of other novel vaccines and vaccination technology. The blood testing segment consists of an alliance with Gen-Probe Incorporated and our one-half interest in the pretax operating earnings of our 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. 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.

### ***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; intangible assets; 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 consists of our one-half interest in the pretax operating earnings of our joint business contractual arrangement with Ortho-Clinical Diagnostics, Inc., a Johnson & Johnson company. 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. Prior to the first quarter 2003, we had accounted for revenues from 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 in the first quarter 2003, and as a result, we are able to recognize revenues from 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 earnings of unconsolidated joint business for the six months ended June 30, 2003.

We recognize a portion of revenue for product sales of Betaseron® upon shipment to our marketing partner, and the remainder based on a contractual percentage of sales by our marketing partner. We also earn royalties on our marketing partner's European sales of Betaferon® in those cases where we do not supply the product. Prior to the first quarter 2002, we had accounted for revenues from non-U.S. product sales on a one-quarter lag and royalties as a percentage of forecast received from our marketing partner, with an adjustment of the estimate to actual in the subsequent quarter. More current information of non-U.S. Betaseron® sales became available in 2002, and as a result, we were able to recognize

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

revenues from Betaseron® product sales and Betaferon® royalties on a current basis beginning in the first quarter 2002. The effect of this change, net of tax, was an increase in net income for the six months ended June 30, 2002 by \$3.1 million for product sales and \$2.8 million for royalties.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our Condensed Consolidated Financial Statements:

**Purchased in-process research and development** We allocate the purchase price of acquisitions based on the fair value of the assets acquired and liabilities assumed. To assist in determining the value of the in-process research and development and certain other intangibles, a third party valuation is typically obtained as of the acquisition date. For previous acquisitions, the income approach has been used to value in-process research and development. The income approach 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. We performed a discounted cash flow analysis, utilizing anticipated revenues, expenses and net cash flow forecasts related to the technology. Given the high risk associated with the development of new drugs, we probability adjust the revenue and expense forecasts to reflect the risk of advancement through the regulatory approval process based on the stage of development

28

---

in the regulatory process. Such a valuation requires significant estimates and assumptions. We believe the fair value assigned to the 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. Additionally, estimates for the purchase price allocation may change as subsequent information becomes available. For the Matrix Pharmaceutical acquisition, we allocated a portion of the purchase price to purchased in-process research and development and wrote off \$54.8 million in the first quarter 2002. We do not anticipate that there will be any alternative future use for the in-process research and development that were written off. We allocated a portion of the purchase price to a liability for asset disposal and lease cancellation for the San Diego, California facility closed during the third quarter 2002. In the fourth quarter 2002, we found an assignee for the manufacturing facility lease and revised the allocation of the purchase price resulting in a \$9.6 million decrease to purchased in-process research and development (as the residual amount allocated to in-process research and development was less than the estimated fair value of the in-process research and development).

**Investments** We invest in marketable debt and equity securities. The prices of some of our marketable securities are subject to considerable volatility. We record an impairment charge when we believe that an investment in a marketable security has experienced a decline in fair value, as measured by quoted market prices, that is other-than-temporary. We believe that an investment in a marketable security is impaired if its quoted market price has been below its carrying value for each trading day in a six-month period, at which point we write down the investment. In addition, in determining whether impairment of a marketable equity security is considered to be other-than-temporary, we consider all available factors in the evaluation. These factors may include, but are not limited to, (i) whether the issuer of the securities is experiencing depressed and declining earnings in relation to competitors, erosion of market share, and deteriorating financial position, (ii) whether the issuer is experiencing financial difficulties and its market is experiencing difficulties, (iii) ongoing activity in our collaborations with the issuer, if any and (iv) the issuer's prospects for favorable clinical trial results, new product initiatives and new collaborative agreements. Decreases in the fair value of these securities may impact our profitability. To reduce this risk, we hedge a portion of our exposure through forward sales contracts.

**Inventories** We maintain inventory reserves primarily for product failures, recalls and obsolescence. The manufacturing processes for many of our products are complex. Slight deviations anywhere in the manufacturing process may result in unacceptable changes in the products that may result in failures or recalls and, therefore, additional inventory reserves. Obsolete inventory, due to the expiration of shelf life, and the seasonal nature of some of our products, may result in additional product reserves. In estimating inventory obsolescence reserves, we analyze on a product-by-product basis (i) the shelf life and the expiration date, (ii) sales forecasts and (iii) inventory levels compared to forecasted usage obtained from the production planning department. Judgment is required in determining whether the forecasted sales and usage information is sufficiently reliable to enable us to estimate an inventory obsolescence reserve. In addition, we operate in a highly competitive environment, with rapidly changing technologies. New technology or changes in production processes may result in product obsolescence. As a result, we may be required to record additional inventory reserves.

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

**Product returns and rebates** In estimating returns, we analyze (i) historical returns and sales patterns, (ii) our experience with similar products, (iii) current inventory on hand at the distributors and in the distribution channel and the remaining shelf life of that inventory, (iv) current economic trends, (v) distributors practices, (vi) changes in demand, particularly due to the seasonality of certain of our products and (vii) introduction of new competing products.

29

---

In arriving at the accrual for product returns we use one of the following four methodologies depending on the product: (i) we calculate the average actual returns percentage for the previous rolling twelve months on a product-by-product basis and apply it to gross sales on a product-by-product basis for the last twelve months to arrive at the reserve balance required at the balance sheet date. The change in the reserve balance is recognized as a charge against revenue for the period, (ii) we match the actual returns to the actual sale on a product-by-product basis to assess the historical trend for returns. Based on an analysis of the historical trend, the appropriate return percentage for the current period is then applied to current period sales to arrive at the product returns charge against revenue for the period, (iii) we calculate the average returns percentage for the previous rolling twelve months on a product-by-product basis and apply it to inventory on hand at the distributors on a product-by-product basis or (iv) for seasonal products we analyze our actual returns over the previous seasons to arrive at the average actual returns percentage, which is then applied to the current season's sales to arrive at the charge against revenue for the current period. In estimating rebates, we match the actual rebate to the actual sale on a product-by-product basis, to arrive at an actual rebate percentage. This actual rebate percentage is applied to current period sales to arrive at the rebates expense for the period. In addition, we consider allowable prices by Medicaid and Medicare. If actual product returns and rebates are greater than our estimates, additional product return and rebates accruals may be required.

**Collaborative, royalty and license arrangements** We recognize up-front refundable fees as revenues upon the later of when they become nonrefundable or when performance obligations are completed. In situations where continuing performance obligations exist, we defer and amortize up-front nonrefundable fees ratably over the performance period, which is typically stipulated by the contract; otherwise, we recognize them as revenues when collection is reasonably assured. In arrangements with multiple deliverables, there may be significant judgment in separating the different revenue generating activities and in determining whether each is a separate earnings process. Milestones, if any, related to scientific or technical achievements are recognized in income when the milestone is accomplished. The terms of such arrangements may cause our operating results to vary considerably from period to period. We estimate royalty revenues based on previous period royalties received or on product sales forecast information provided by the third party licensee. In the subsequent quarter, we record an adjustment equal to the difference between those estimated royalty revenues recorded in the previous quarter and the contractual percentage of the third party's actual product sales for that period. We exercise judgment in determining whether the forecast information provided by licensees is sufficiently reliable for us to base our royalty revenue recognition thereon.

**Income taxes** Significant management judgment is required in developing our provision for income taxes, including the determination of deferred tax assets and liabilities and any valuation allowances that might be required against the deferred tax assets. We record valuation allowances to reduce deferred tax assets to the amounts that are more likely than not to be realized. We have considered future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for valuation allowances. If we determined that we would be able to realize our deferred tax assets in the future in excess of our net deferred tax assets, adjustments to the deferred tax assets would increase income by reducing tax expense in the period that we made such determination. Likewise, if we determined that we would not be able to realize all or part of our net deferred tax assets in the future, adjustments to the deferred tax assets would decrease income by increasing tax expense in the period that we made such determination.

**Litigation and other contingencies** We establish and maintain accruals for litigation and other contingencies when we believe a loss to be probable and reasonably estimable, as required by

30

---

SFAS No. 5, "Accounting for Contingencies." We base our accruals on information available internally within the company at the time of such determination and after management has consulted with and obtained advice from external professional advisors. Judgment is required in both the determination of probability and as to whether such an exposure is reasonably estimable. Information may become available to us after that time, for which adjustments to accruals may be required.



Goodwill and intangible assets The valuation in connection with the initial purchase price allocation and the ongoing evaluation for impairment of goodwill and intangible assets requires significant management estimates and judgment. The purchase price allocation process requires management estimates and judgment as to expectations for various products and business strategies. If any of the significant assumptions differ from the estimates and judgments used in the purchase price allocation, this could result in different valuations for goodwill and intangible assets. Once it is established, we must test goodwill annually for impairment using a two-step process as required by SFAS No. 142 "Goodwill and Other Intangible Assets." In addition, in certain circumstances, we must assess if goodwill should be tested for impairment between annual tests. Intangible assets with definite useful lives must be tested for impairment in accordance with SFAS No. 144 "Accounting for the Impairment or Disposal of Long-Lived Assets." When we conduct our impairment tests for goodwill and intangibles, factors that are considered important in determining whether impairment might exist include significant continued under-performance compared to peers, significant changes in the underlying business and products of our reporting units, or other factors specific to each asset or reporting unit being evaluated. Any changes in key assumptions about the business and its prospects, or changes in market conditions or other externalities, could result in an impairment charge and such a charge could have a material adverse effect on our consolidated results of operations.

The accounting policies of our reportable segments are the same as those described in Note 1, "The Company and Summary of Significant Accounting Policies," in the Notes to Condensed Consolidated Financial Statements above and in our Annual Report on Form 10-K for the year ended December 31, 2002.

On July 1, 2002, we completed our acquisition of Pulmopharm GmbH, a distributor of TOBI® products in Germany and Austria by purchasing the remaining 80.1% ownership that we did not previously own. Previously, we owned 19.9% of Pulmopharm and accounted for the investment under the equity method. We accounted for the acquisition of this business under the purchase method of accounting and included Pulmopharm's operating results in our consolidated operating results beginning on July 1, 2002. Pulmopharm is part of our biopharmaceuticals segment.

On February 20, 2002, we acquired Matrix Pharmaceutical, Inc., a company that was developing tezacitabine, a drug to treat cancer. We accounted for the acquisition as an asset purchase and included Matrix Pharmaceutical's operating results, including the seven business days from February 20 to 28, 2002, in our consolidated operating results beginning on March 1, 2002. Matrix Pharmaceutical is part of our biopharmaceuticals segment.

Certain minor arithmetical variances between the following narrative and the Condensed Consolidated Financial Statements may arise due to rounding.

## Results of Operations

### *Biopharmaceuticals*

**Product sales** Biopharmaceutical product sales were \$107.3 million and \$104.0 million for the three months ended June 30, 2003 and 2002, respectively, and \$209.0 million and \$194.5 million for the

---

six months ended June 30, 2003 and 2002, respectively. Biopharmaceutical product sales in 2003 and 2002 consisted principally of Betaseron®, TOBI® and Proleukin®.

*Betaseron®* 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 Chiron, 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 supply costs, which we record in royalty and license fee revenues. The amount we record as product sales, based on a percentage of sales by Schering, and Betaferon® royalties will decline by five percentage points pursuant to our contractual agreement with Schering. As a result, we estimate that the percentage of sales on which our payments are based will decrease in the fourth quarter 2003, reducing our per unit revenue by approximately 18% (for sales of Chiron product) and approximately 34% (for royalties from sales of Boehringer Ingelheim product). However, there are a number of mitigating considerations, including (i) the transitional supply agreement, (ii) the volume mix of Chiron product and Boehringer Ingelheim product and (iii) the launch of product upgrades with ease-of-use features that will somewhat offset this contractual change and impact the ultimate contribution of Betaseron®

to Chiron's profit.

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 \$30.5 million and \$34.2 million for the three months ended June 30, 2003 and 2002, respectively, and \$59.8 million and \$56.0 million for the six months ended June 30, 2003 and 2002, respectively. The decrease in Betaseron® product sales in the second quarter 2003 as compared with the second quarter 2002 primarily related to Berlex Laboratories and Schering ordering patterns, as well as wholesaler ordering patterns in the second quarter 2002. Wholesalers built inventory in the second quarter 2002, to support the mid-2002 launch of our new room-temperature formulation, which positively influenced sales in that quarter. This impact was partially offset by (i) increased patient demand, (ii) price increases and (iii) the benefit of the movement in the Euro to U.S. Dollar exchange rate in the second quarter 2003 as compared with the second quarter 2002.

The increase in Betaseron® product sales year-to-date 2003 as compared with year-to-date 2002 primarily related to (i) increased patient demand attributed to a favorable response in the market place to the new room-temperature formulation and key marketing programs, (ii) an overall increase in the market for interferon beta-1b products for multiple sclerosis, (iii) price increases and (iv) the benefit of the movement in the Euro to U.S. Dollar exchange rate. These increases were partially offset by (i) incremental revenues recognized in the first quarter 2002 related to the effect of recording revenue based on more current information available from Schering and (ii) Berlex Laboratories and Schering ordering patterns as wholesalers built inventory to support the mid-2002 launch of our new room-temperature formulation. Prior to the first quarter 2002, we accounted for revenues from non-U.S. product sales based on information provided by Schering on a one-quarter lag. More current information of non-U.S. Betaseron® sales became available in 2002, and as a result, we were able to begin recognizing revenues from Betaseron® product sales on a current basis. This change resulted in incremental revenues recognized during the first quarter 2002 of \$4.3 million. Inventory ordering patterns as well as foreign currency exchange rates may influence future Betaseron® sales.

32

**TOBI®** We sell TOBI® directly in the U.S. and certain international markets. We recognized TOBI® sales of \$39.0 million and \$33.6 million for the three months ended June 30, 2003 and 2002, respectively, and \$79.7 million and \$69.4 million for the six months ended June 30, 2003 and 2002, respectively. Increased TOBI® sales in the second quarter 2003 as compared with the second quarter 2002, as well as year-to-date 2003 compared with year-to-date 2002, primarily related to (i) greater product penetration in various European countries, (ii) increased use and improved compliance in the U.S. by patients with cystic fibrosis, (iii) price increases and (iv) the benefit of the movement in the Euro to U.S. Dollar exchange rate. These increases were partially offset by wholesale ordering patterns. In addition, the first quarter 2003 was negatively impacted by a change in sales adjustments. We continue to pursue the use of TOBI® to treat other serious lung infections and to seek approval in other countries. Wholesale ordering patterns as well as reimbursement and government pressures, competition, foreign currency exchange rates and the level of rebates may influence future TOBI® sales. In December 2002, the U.S. Food and Drug Administration tentatively approved an abbreviated new drug application for an inhaled tobramycin for sale in the U.S. following expiration of the orphan drug status of TOBI® in December 2004. We have a patent in the U.S. covering the formulation of TOBI® that extends until 2014.

**Proleukin®** Sales of Proleukin® were \$29.4 million and \$27.6 million for the three months ended June 30, 2003 and 2002, respectively, and \$55.4 million and \$51.6 million for the six months ended June 30, 2003 and 2002, respectively. Proleukin® product sales in the second quarter 2003 as compared with the second quarter 2002, as well as year-to-date 2003 compared with year-to-date 2002, increased primarily as a result of (i) price increases, (ii) wholesaler ordering patterns and (iii) the benefit of the movement in the Euro to U.S. Dollar exchange rate. Wholesale ordering patterns, reimbursement pressures, government legislation 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, 2002.

**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 \$1.1 million and \$3.5 million for the three months ended June 30, 2003 and 2002, respectively, and \$3.3 million and \$7.1 million for the six months ended June 30, 2003 and 2002, respectively.

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

Collaborative agreement revenues for the three months ended June 30, 2003, primarily consisted of our fourth quarter 2002 collaboration agreement and license agreement with GlaxoSmithKline plc related to certain of our MC-4R compound patents. Collaborative agreement revenues for the six months ended June 30, 2003, consisted of our fourth quarter 2002 collaboration agreement and license agreement with GlaxoSmithKline plc and our first quarter 2001 collaboration agreement with Taisho Pharmaceutical Co., Ltd. to target macrolide mediated gene discovery. Collaborative agreement revenues for the three and six months ended June 30, 2002, primarily consisted of our second quarter 2000 agreement with S\*BIO (discussed below) and our first quarter 2001 collaboration agreement with Taisho Pharmaceutical Co., Ltd.

*S\*BIO* In the second quarter 2000, we invested in a Singapore-based venture, S\*BIO Pte Ltd, to research and develop therapeutic, diagnostic, vaccine and antibody products. We also granted S\*BIO certain rights to our gene expression and combinatorial chemistry technology. Under this arrangement,

33

---

we received approximately \$23.7 million for technology transfer and research services. We recognized collaborative agreement revenues of \$3.0 million and \$6.1 million for the three and six months ended June 30, 2002, respectively, under this arrangement. The technology transfer period and related revenue recognition period ended in the third quarter 2002.

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

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. However, we have no assurance that the collaborative partners will meet their development objectives or 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. We have no assurance that new relationships will be established or that current collaborative agreement revenues will not decline.

**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 \$20.8 million and \$16.4 million for the three months ended June 30, 2003 and 2002, respectively, and \$38.6 million and \$33.7 million for the six months ended June 30, 2003 and 2002, respectively.

*Betaferon®* 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. As discussed in "Product sales - Betaseron®" above, under our contractual agreement with Schering, our royalty will decline by five percentage points. For the three months ended June 30, 2003 and 2002, we recognized \$17.2 million and \$10.6 million, respectively, and for the six months ended June 30, 2003 and 2002, we recognized \$31.2 million and \$24.2 million, respectively, under this arrangement. Betaferon® royalties increased in the second quarter 2003 as compared with the second quarter 2002 primarily as the result of (i) a positive true-up of estimate to actual in the subsequent quarter, (ii) an increase in Chiron's effective royalty rate under an agreement with Schering and (iii) the benefit of the movement in the Euro to U.S. Dollar exchange rate. The increase in Chiron's effective royalty rate is due to a reduction of the allocated cost under a three-year limited cost sharing arrangement with Schering.

Betaferon® royalties increased year-to-date 2003 as compared with year-to-date 2002 primarily as the result of (i) positive true-ups in the first and second quarters of 2003 of estimate to actual in the subsequent quarter, (ii) an increase in Chiron's effective royalty rate under an agreement with Schering, as discussed above, and (iii) the benefit of the movement in the Euro to U.S. Dollar exchange rate. These increases were offset by incremental revenues recognized during the first quarter 2002 of \$3.9 million related to a change in our methodology of recognizing these royalties. Prior to 2002, we accounted for Betaferon® royalties as a percentage of forecast received from Schering, with an adjustment of the estimate to actual in the subsequent quarter. More current information of European Betaseron® sales was available in 2002, and as a result, we were able to recognize Betaferon® royalties

34

---

on a current basis beginning in the first quarter 2002. Foreign currency exchange rates may influence future Betaferon® royalties.

*Novo Nordisk* We earn royalty revenues on insulin and glucagon product sales by Novo Nordisk AS. We recognized \$1.9 million and \$1.3 million for the three months ended June 30, 2003 and 2002, respectively, and \$3.9 million and \$3.3 million for the six months ended June 30, 2003 and 2002, respectively, under this arrangement. Patents related to the production of insulin and glucagon expire beginning 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. The balance of royalty and license fee revenues for the three and six months ended June 30, 2003, primarily consisted of our fourth quarter 2002 agreement with GlaxoSmithKline plc where we granted rights under certain of our MC-4R compound patents for which we recognized a portion of the license fee in the second quarter 2003. The balance of royalty and license fee revenues for the three months ended June 30, 2002, primarily consisted of our second quarter 2002 agreement with Merck & Co., Inc. where we granted rights under certain of our hepatitis C virus-related patents for which we recognized a license fee in the second quarter 2002. The balance of royalty and license fee revenues for the six months ended June 30, 2002, consisted of our second quarter 2002 agreement with Merck & Co., Inc. and our first quarter 2002 agreement with Abbott Laboratories where we granted rights under certain of our hepatitis C virus-related patents for which we recognized a license fee in the first quarter 2002.

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 \$3.2 million and \$2.0 million for the three months ended June 30, 2003 and 2002, respectively, and \$18.8 million and \$6.7 million for the six months ended June 30, 2003 and 2002, respectively.

*Contract manufacturing revenues* Our biopharmaceuticals segment recognized contract manufacturing revenues of \$3.0 million and \$1.9 million for the three months ended June 30, 2003 and 2002, respectively, and \$3.1 million and \$6.3 million for the six months ended June 30, 2003 and 2002, respectively. The fluctuation resulted from the level of activity and the timing of contract manufacturing activities.

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

*Depocyt®* In the fourth quarter 2002, we sold U.S. sales and marketing rights for Depocyt® to SkyePharma plc. For the six months ended June 30, 2003, we recognized \$1.0 million related to transition services provided to SkyePharma under the acquisition agreement.

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 71% and 72% for the three months ended June 30, 2003 and 2002, respectively, and 75% and 74% for the six months ended June 30, 2003 and 2002, respectively. The decrease in biopharmaceutical gross profit margins for the second quarter 2003 as compared with the second quarter 2002 primarily resulted from costs due to a reserve taken against certain manufactured components held in inventory. The increase in the biopharmaceutical gross profit margins

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

year-to-date 2003 as compared with year-to-date 2002 primarily resulted from price increases and the benefit of the movement in the Euro to U.S. Dollar exchange rate, partially offset by costs due to a reserve taken against certain manufactured components held in inventory.

Biopharmaceutical gross profit percentages may fluctuate significantly in future periods due to production yields and as the biopharmaceutical product and customer mix changes.

**Research and development** Our biopharmaceuticals segment recognized research and development expenses of \$57.4 million and \$61.1 million for the three months ended June 30, 2003 and 2002, respectively, and \$113.7 million and \$118.6 million for the six months ended June 30, 2003 and 2002, respectively.

In the fourth quarter 2002, we reached an agreement in principle to transfer responsibility for the SILCAAT (referred to also as Proleukin® for HIV) trial, a Phase III study for recombinant human interleukin-2 (IL-2, aldeseleukin), to the investigators, as managed by a Scientific Committee comprised of researchers affiliated with the Hospital Henri Mondor in Paris, the National Institutes Allergy and Infectious Disease (NIAID), the University of Minnesota, and other research institutions. 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 2003 as a result of transferring responsibility for the trial. However, 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 \$3.0 million has been paid through June 30, 2003.

In April 2003, we acquired exclusive worldwide development and commercial rights from Novartis for aerosolized cyclosporine (ACSA), a therapy under evaluation for treatment of acute rejections in lung transplant recipients.

The decrease in research and development spending year-to-date 2003 as compared with year-to-date 2002 primarily related to the timing of various clinical trials, including (i) transfer of the responsibility of the SILCAAT trial, to the investigators in the fourth quarter 2002 (discussed above) and (ii) termination of our trials for fibroblast growth factor (FGF), a compound for treatment of patients with peripheral arterial disease, HBV-MF59, an immunotherapy for patients with chronic hepatitis B infection, and PA-1806, a compound for gram negative infections in cystic fibrosis patients. These decreases were partially offset by the investment in other development projects, including those activities related to the development of (i) tezacitabine, obtained as a part of the acquisition of Matrix Pharmaceutical in the first quarter 2002, (ii) interleukin-2 in combination with various monoclonal antibodies and (iii) a dry powder formulation of our inhaled TOBI® product for the treatment of *pseudomonas aeruginosa* in cystic fibrosis patients. In addition, we are required to make capital

36

---

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 the installed equipment.

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 \$28.2 million and \$23.9 million for the three months ended June 30, 2003 and 2002, respectively, and \$54.4 million and \$43.9 million for the six months ended June 30, 2003 and 2002, respectively. The increase in selling, general and administrative expenses for the second quarter 2003 as compared with the second quarter 2002, as well as year-to-date 2003 compared with year-to-date 2002, related to (i) sales and marketing costs for various biopharmaceutical post-market approval commitments, (ii) support for continued market penetration of TOBI® in Europe, (iii) costs following the acquisition of Pulmopharm in the third quarter 2002, (iv) additional costs associated with the enhancement of current business processes and (v) the Euro to U.S. Dollar exchange rate fluctuation.

**Amortization expense** Our biopharmaceuticals segment recognized amortization expense of \$6.2 million and \$5.9 million for the three months ended June 30, 2003 and 2002, respectively, and \$12.4 million and \$11.8 million for the six months ended June 30, 2003 and 2002, respectively. The increase in amortization expense in the three and six months ended June 30, 2003 as compared with the three and six months ended June 30, 2002 related to the distribution rights acquired in the acquisition of Pulmopharm in the third quarter 2002.

### **Vaccines**

**Product sales** We sell meningococcal, flu, travel and pediatric vaccines in Germany, Italy, the United Kingdom and other international markets. Vaccine product sales were \$85.6 million and \$72.7 million for the three months ended June 30, 2003 and 2002, respectively, and \$154.0 million and \$130.6 million for the six months ended June 30, 2003 and 2002, respectively.

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

Menjugate, our conjugate vaccine against meningococcal infection caused by the bacterium *N. meningitidis* serogroup C, sales were \$13.7 million and \$9.9 million for the three months ended June 30, 2003 and 2002, respectively, and \$21.2 million and \$15.7 million for the six months ended June 30, 2003 and 2002, respectively. The increase in Menjugate sales in the second quarter 2003 as compared with the second quarter 2002 primarily related to an Australian tender in the state of New South Wales and the benefit of the movement in the Euro to U.S. Dollar exchange rate. The increase in Menjugate sales year-to-date 2003 as compared with year-to-date 2002 primarily related to the Australian tender, as discussed above, increased sales to the Italian market and the benefit of the movement in the Euro to U.S. Dollar exchange rate.

Sales of our flu vaccines were \$3.8 million and \$1.8 million for the three months ended June 30, 2003 and 2002, respectively, and \$8.1 million and \$4.1 million for the six months ended June 30, 2003 and 2002, respectively. The increase in flu vaccine sales in the second quarter 2003 as compared with the second quarter 2002, as well as year-to-date 2003 compared with year-to-date 2002, primarily resulted from increased sales to The Netherlands and the benefit of the movement in the Euro to U.S. Dollar exchange rate.

Sales of our travel vaccines, comprised of tick-borne encephalitis and rabies vaccines, were \$23.1 million and \$23.4 million for the three months ended June 30, 2003 and 2002, respectively, and \$48.8 million and \$41.8 million for the six months ended June 30, 2003 and 2002, respectively. The increase in travel vaccine sales year-to-date 2003 compared with year-to-date 2002, primarily related to increased tick-borne encephalitis vaccine sales in the German market, driven by the new adult and

37

---

pediatric formulations launched in the first quarter 2002, and the benefit of the movement in the Euro to U.S. Dollar exchange rate.

Sales of our pediatric vaccines were \$45.0 million and \$37.6 million for the three months ended June 30, 2003 and 2002, respectively, and \$75.9 million and \$69.0 million for the six months ended June 30, 2003 and 2002, respectively. The increase in pediatric vaccine sales for the second quarter 2003 as compared with the second quarter 2002, as well as year-to-date 2003 compared with year-to-date 2002, primarily was due to tender sales and the benefit of the movement in the Euro to U.S. Dollar exchange rate. These increases were partially offset by decreased sales of our polio vaccines.

Certain of our vaccine products, particularly our flu vaccines, are seasonal and typically have higher sales in the third and fourth quarters of the year. In addition, we expect Menjugate sales to continue to fluctuate as public health authorities consider adoption of broad vaccination programs. We have initiated a Phase III trial in the U.S. for Menjugate. The study, which is being conducted in conjunction with the Northern California Kaiser Permanente Vaccines Research Center, will expand the vaccine's safety database for a U.S. population relative to the safety profile of the current U.S.-licensed meningococcal polysaccharide vaccine Menomune® (A, C, Y, W-135). We are exploring opportunities for additional Menjugate sales in other countries.

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, 2002.

**Royalty and license fee revenues** Our vaccines segment earns royalties on third party sales of, and license fees on, several products. The vaccines segment recognized royalty and license fee revenues of \$3.3 million and \$2.8 million for the three months ended June 30, 2003 and 2002, respectively, and \$6.5 million and \$5.4 million for the six months ended June 30, 2003 and 2002, respectively.

*GlaxoSmithKline* An agreement with GlaxoSmithKline plc provides for royalties on sales of certain vaccine products. Under this agreement, we recognized \$1.6 million and \$1.7 million of such royalties for the three months ended June 30, 2003 and 2002, respectively, and \$3.4 million and \$3.6 million of such royalties for the six months ended June 30, 2003 and 2002, respectively.

*Other* We recognized \$1.7 million and \$1.1 million for the three months ended June 30, 2003 and 2002, respectively, and \$3.1 million and \$1.8 million for the six months ended June 30, 2003 and 2002, respectively, of royalty revenues primarily on third party sales of hepatitis B virus vaccine products. The increase in 2003 as compared with 2002 primarily resulted from increased availability of the pediatric formulation in Germany, partially offset by increased competition from multivalent hepatitis B virus vaccine products. Certain patents related to the production of hepatitis B vaccine products expire beginning in 2004, which will result in reductions in royalty revenues recognized under one arrangement.

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. 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 vaccines segment recognized other revenues of \$3.2 million and \$5.1 million for the three months ended June 30, 2003 and 2002, respectively, and \$6.0 million and \$9.1 million for the six months ended June 30, 2003 and 2002, respectively.

38

---

**Grant and contract revenues** Our vaccines segment other revenues included grant and contract revenues of \$2.5 million and \$4.0 million for the three months ended June 30, 2003 and 2002, respectively, and \$4.7 million and \$7.1 million for the six months ended June 30, 2003 and 2002, respectively. In the second quarter 2000, we entered into an agreement with the U.S. National Institutes of Health to advance our HIV vaccine program into human clinical trials. Under this arrangement, we could receive \$23.2 million over five years. Under supplemental arrangements, we may perform other work related to the National Institutes of Health's HIV vaccine program on a grant or contract-by-contract basis. A majority of the grant and contract revenues, \$2.3 million and \$2.6 million for the three months ended June 30, 2003 and 2002, respectively, and \$4.1 million and \$4.7 million for the six months ended June 30, 2003 and 2002, respectively, were recognized under these arrangements.

The balance of other revenues recognized in our vaccines segment consisted of various other arrangements, 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. We have no assurance that we will be successful in obtaining additional revenues or that these revenues will not decline.

**Gross profit** Vaccines gross profit as a percentage of net product sales was 56% and 61% for the three months ended June 30, 2003 and 2002, respectively, and 52% and 55% for the six months ended June 30, 2003 and 2002, respectively. The vaccine gross profit margin in the second quarter 2003 was negatively impacted by foreign exchange rates. In addition, vaccine gross profit margin year-to-date 2003 as compared with year-to-date 2002 was negatively impacted by an expected temporary shutdown of certain facilities, in the first quarter 2003, to ensure compliance with regulatory requirements.

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 \$26.8 million and \$17.5 million for the three months ended June 30, 2003 and 2002, respectively, and \$47.4 million and \$34.6 million for the six months ended June 30, 2003 and 2002, respectively. The increase in research and development spending for the three months ended June 30, 2003 as compared with the three months ended June 20, 2002, as well as year-to-date 2003 compared with year-to-date 2002, primarily related to the advancement of several programs in our meningococcal franchise.

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 \$24.7 million and \$19.8 million for the three months ended June 30, 2003 and 2002, respectively, and \$46.9 million and \$39.8 million for the six months ended June 30, 2003 and 2002, respectively. The increase in selling, general and administrative expenses in the second quarter 2003 as compared with the second quarter 2002, as well as year-to-date 2003 compared with year-to-date 2002, primarily resulted from additional costs associated with the enhancement of current business processes and headcount and the impact of the movement in the Euro to U.S. Dollar exchange rate. For the year-to-date comparison, these increases were partially offset by (i) a payment made in the first quarter 2002 to the German government in lieu of statutory price reductions on prescription drugs that are reimbursed under the German government's healthcare program that was expensed in the first quarter 2002 and (ii) increased sales and marketing costs associated with the 2002 launch of our newly formulated tick-borne encephalitis vaccine.

**Amortization expense** Our vaccines segment recognized amortization expense of \$1.5 million for each of the three months ended June 30, 2003 and 2002, and \$2.9 million for each of the six months ended June 30, 2003 and 2002.

39

---

**Blood testing**

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

**Product sales** Our blood testing segment recognized product sales of \$53.1 million and \$34.6 million for the three months ended June 30, 2003 and 2002, respectively, and \$101.6 million and \$59.8 million for the six months ended June 30, 2003 and 2002, respectively.

*Procleix®* On February 27, 2002, the U.S. Food and Drug Administration approved the Procleix® HIV-1/ HCV Assay. Under a collaboration agreement with Gen-Probe Incorporated, we market and sell the Procleix® HIV-1/ HCV Assay and the related instrument system. In addition to selling directly in the U.S., we also sell in various European and Asia / Pacific markets, directly and through distributors. We recognize product revenues based on the details of each contract.

Worldwide product sales related to tests, instruments and the provision of services were \$46.0 million and \$29.5 million for the three months ended June 30, 2003 and 2002, respectively, and \$88.1 million and \$47.5 million for the six months ended June 30, 2003 and 2002, respectively. The three months ended June 30, 2003 include a full quarter of commercial pricing for the Procleix® HIV-1/ HCV Assay in the U.S. following the U.S. Food and Drug Administration approval in February 2002, and the subsequent commercial pricing commencing May 1, 2002. Also contributing to the increase in product sales in the second quarter 2003 as compared with the second quarter 2002 were market share gains in the U.S. and continued penetration into several markets abroad.

Subsequent to the first quarter 2002, we signed new commercial contracts including those with existing America's Blood Centers customers, the American Red Cross, the U.S. military and the Association of Independent Blood Centers to provide the Procleix® HIV-1/ HCV Assay. In addition, we experienced market share gains in the U.S. and increased sales to several markets abroad in 2003 as compared with 2002. Slightly offsetting the increase in product sales related to tests, instruments and the provision of services in 2003 as compared with 2002, was a one-time positive adjustment recognized in the first quarter 2002 under contracts with all our U.S. customers for increased donations exceeding contractual minimums.

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 will run on the same instrumentation platform as the currently approved Procleix® HIV-1/HCV assay.

*Ortho-Clinical Diagnostics* Under the Ortho-Clinical Diagnostics, Inc. contract, we manufacture bulk reagents and antigens and confirmatory test kits for immunodiagnostic products. We recognized product sales under this contract of \$7.1 million and \$5.1 million for the three months ended June 30, 2003 and 2002, respectively, and \$13.5 million and \$12.3 million for the six months ended June 30, 2003 and 2002, respectively. The increase in the second quarter 2003 as compared with the second quarter 2002, primarily related to an increase in products manufactured for Ortho-Clinical Diagnostics. In addition, the timing of manufacturing services under the arrangement contributed to the increase in year-to-date 2003 sales as compared with year-to-date 2002 sales. Chiron also supplies bulk antigens for Ortho-Clinical Diagnostics to be included in products to be sold by Bayer under a June 2001 agreement among Chiron, 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 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, 2002.

**Earnings of unconsolidated joint business** Our share of earnings from our joint business contractual arrangement with Ortho-Clinical Diagnostics, Inc. was \$27.5 million and \$27.4 million for the three months ended June 30, 2003 and 2002, respectively, and \$54.0 million and \$46.2 million for

the six months ended June 30, 2003 and 2002, respectively. The increase in year-to-date 2003 as compared with year-to-date 2002 primarily resulted from (i) a one-time benefit in the first quarter 2003 due to a change in estimate relating to revenues from Ortho-Clinical Diagnostics' non-U.S. affiliate sales, (ii) the timing of Ortho-Clinical Diagnostics' shipments to third parties and (iii) increased profitability of Ortho-Clinical Diagnostics' foreign affiliates. Prior to the first quarter 2003, we had accounted for revenues from non-U.S. affiliate sales on a one-quarter lag. More current information is now available to us and as such, we now recognize revenues from non-U.S. affiliate sales on a one-month lag, consistent with the method of how we recognize revenues from Ortho-Clinical Diagnostics' sales for the U.S. portion of Ortho-Clinical Diagnostics' business.

**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. contract, we conduct research and development services related to immunodiagnostic products. Our blood testing segment recognized total collaborative agreement revenues of \$2.3 million and \$2.8 million for the three months ended June 30, 2003 and 2002, respectively, and \$4.2 million and \$5.4 million for the six months ended June 30, 2003 and 2002, respectively. The majority of collaborative agreement revenues recognized by our blood testing segment related to immunodiagnostic



products. The fluctuations between 2003 and 2002 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. We have no assurance that new relationships will be established or that current collaborative agreement revenues will not decline.

**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 \$23.2 million and \$12.6 million for the three months ended June 30, 2003 and 2002, respectively, and \$38.8 million and \$22.8 million for the six months ended June 30, 2003 and 2002, respectively.

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

*F. Hoffmann-La Roche settlement* In October 2000, we entered into three license agreements with F. Hoffmann-La Roche Limited and several of its affiliated companies related to the settlement of certain litigation in the U.S. and certain other countries for the use of our hepatitis C virus and HIV intellectual property. Two agreements relate to *in vitro* diagnostic products. See "Other Royalty and license fee revenues" below. The third agreement for blood screening was superseded in May 2001 by two new agreements, one for each of hepatitis C virus and HIV. Revenues under these agreements were \$14.2 million and \$11.3 million for the three months ended June 30, 2003 and 2002, respectively, and \$28.6 million and \$20.2 million for the six months ended June 30, 2003 and 2002, respectively. The increase in 2003 as compared with 2002 related to a contractual increase in the royalty rates and increased donations. Royalties will continue under these new agreements 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 2008 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 Chiron 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 46% and 41% for the three months ended June 30, 2003 and 2002, respectively, and 44% and 39% for the six months ended June 30, 2003 and 2002, respectively. The increase in blood testing gross profit margins in the second quarter 2003 as compared with the second quarter 2002, primarily related to an adjustment to cost of goods sold pursuant to our collaboration agreement with Gen-Probe Incorporated. In addition, the increase in blood testing gross profit margin year-to-date 2003 as compared with year-to-date 2002 related to (i) the increase in Procleix® HIV-1/ HCV product sales as a percentage of total blood testing product sales and (ii) the timing of manufacturing services under the Ortho-Clinical Diagnostics contract.

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 \$5.6 million and \$5.2 million for the three months ended June 30, 2003 and 2002, respectively, and \$10.8 million and \$9.4 million for the six months ended June 30, 2003 and 2002, respectively. The increase in research and development spending in 2003 as compared with 2002 primarily related to the continued development of nucleic acid testing products.

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 \$9.6 million and \$8.0 million for the three months ended June 30, 2003 and 2002, respectively, and \$17.4 million and \$15.2 million for the six months ended June 30, 2003 and 2002, respectively. The increased selling, general and administrative expenses in the second quarter 2003 as compared with the second quarter 2002, as well as year-to-date 2003 compared with year-to-date 2002, related to the expansion of our customer base for the Procleix® HIV-1/HCV Assay in the U.S., Europe and other international markets and to the preparation and roll-out of the West Nile virus assay under IND testing. We expect continued growth in selling, general and administrative expenses related to nucleic acid testing technology and products as we expand our sales opportunities in new markets through anticipated additional nucleic acid testing adoption.

42

---

### **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 \$19.6 million and \$13.7 million for the three months ended June 30, 2003 and 2002, respectively, and \$36.4 million and \$28.5 million for the six months ended June 30, 2003 and 2002, 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 year-to-date 2003 as compared with year-to-date 2002, primarily as a result of increased sales recognized by F. Hoffmann-La Roche.

The HIV agreement provides for royalties on future sales related to F. Hoffmann-La Roche's use of our HIV-related patent in its *in vitro* diagnostic products, which commenced in the first quarter 2001 when the European Patent Office Board of Technical Appeals upheld our HIV-related patent. Royalty revenues recognized under this agreement year-to-date 2003 were consistent with year-to-date 2002.

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 2008 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 June 30, 2003. 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 year-to-date 2003 as compared with year-to-date 2002.

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

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

Royalty and license fee revenues may fluctuate based on the nature of the related agreements, the timing of receipt of license fees and the expiration of patents. Results in any one period are not necessarily indicative of results to be achieved in the future. In addition, our ability to generate additional royalty and license fee revenues may depend, in part, on our ability to market and capitalize on our technologies. We have no assurance that we will be able to do so or that future royalty and license fee revenues will not decline.

**Selling, general, and administrative** Our other segment recognized selling, general and administrative expenses of \$17.2 million and \$19.4 million for the three months ended June, 2003 and 2002, respectively, and \$34.0 million and \$35.0 million for the six months ended June, 2003 and 2002, respectively. The decrease in selling, general and administrative expenses in 2003 as compared with 2002 primarily resulted from lower litigation costs in the first and second quarters of 2003 related to our investment in and defense of our patents and technology, partially offset by increased consulting, severance and employee-related expenses.

**Write-off of purchased in-process research and development** The write-off of purchased in-process research and development was \$54.8 million for the six months ended June 30, 2002. There was no write-off of purchased in-process research and development for the six months ended June 30, 2003.

On February 20, 2002, we acquired Matrix Pharmaceutical, Inc. and accounted for the acquisition as an asset purchase. We allocated the purchase price based on the fair value of the assets acquired and liabilities assumed. We allocated a portion of the purchase price to purchased in-process research and development and wrote off \$54.8 million in the first quarter 2002. We allocated a portion of the purchase price to a liability for asset disposal and lease cancellation for the San Diego, California facility closed during the third quarter 2002. In the fourth quarter 2002, we found an assignee for the manufacturing facility lease and revised the allocation of the purchase price resulting in a \$9.6 million decrease to purchased in-process research and development. We do not anticipate that there will be any alternative future use for the in-process research and development that were written off. In valuing the purchased in-process research and development, we used probability-of-success-adjusted cash flows and a 20% discount rate. We assumed revenue from tezacitabine to commence after 2005. As with all pharmaceutical products, the probability of commercial success for any research and development project is highly uncertain.

**Restructuring and reorganization** For the three and six months ended June 30, 2003, we recorded restructuring and reorganization charges of \$0.5 million and \$0.7 million, respectively. The charges consisted of termination and other employee-related costs recognized in connection with the elimination of 7 positions in our Amsterdam manufacturing facility.

**Interest expense** We recognized interest expense of \$2.8 million and \$3.1 million for the three months ended June 30, 2003 and 2002, respectively, and \$6.3 million for each of the six months ended June 30, 2003 and 2002. The decrease in the second quarter 2003 as compared with the second quarter 2002 primarily was related to lower interest rates.

**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 \$6.3 million and \$9.3 million for the three months ended June 30, 2003 and 2002, respectively, and \$13.3 million and \$19.1 million for the six months ended June 30, 2003 and 2002, respectively. The decrease in interest income in 2003 as compared with 2002 primarily was due to lower average interest rates and lower average cash and investment balances.

We recognized gains of \$4.8 million and \$7.8 million for the three months ended June 30, 2003 and 2002, respectively, and \$9.4 and \$14.3 million for the six months ended June 30, 2003 and 2002, respectively, related to the sale of certain equity securities.

We did not recognize any losses attributable to the other-than-temporary impairment of equity securities for the three and six months ended June 30, 2003. For the three and six months ended June 30, 2002, we recognized losses attributable to the other-than-temporary impairment of certain equity securities of \$2.8 million and \$4.6 million, respectively.

In the second quarter 2001, we recorded a charge of \$1.5 million to write-down debt securities with a face value of \$5.0 million due to the decline in the credit rating of the issuer. On March 1, 2002, the issuer paid us \$5.1 million the full principal plus interest. As a result, we recorded

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

\$1.5 million in "Interest and other income, net," for the six months ended June 30, 2002.

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 \$2.0 million for 2002 and \$5.4 million for 2001 during the six months ended June 30, 2003 and 2002, respectively.

**Income taxes** The reported effective tax rate for 2003 is 25% of pretax income from continuing operations. The reported effective tax rate for the six months ended June 30, 2002 was 27% of pretax income from continuing operations, excluding the write-off of purchased in-process research and development related to the Matrix Pharmaceutical acquisition. The write-off of purchased in-process research and development in 2002 is not tax deductible. The 2003 effective tax rate is lower than the 2002 effective tax rate due to increased benefits associated with Chiron's research and development activities and tax planning initiatives. The effective tax rate may be affected in future periods by changes in management's estimates with respect to our deferred tax assets, acquisitions and other items affecting the overall tax rate.

The reported effective tax rate for 2003 of 25% excludes any anticipated impact associated with our July 2003 acquisition of PowderJect Pharmaceuticals plc. PowderJect operates primarily in the United Kingdom and Sweden, where the marginal tax rates are in excess of our current effective tax rate of 25%. Management is currently reviewing and is considering implementing tax strategies that mitigate these tax rate disparities.

**Discontinued Operations** In a strategic effort to focus on our core businesses of biopharmaceuticals, vaccines and blood testing, we completed the sale of Chiron Diagnostics and Chiron Vision in 1998 and 1997, respectively.

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

In the first quarter 2003, Chiron and Bayer Corporation reached a settlement agreement relating to certain claims raised by Bayer under the Stock Purchase Agreement dated September 17, 1998, between Chiron and Bayer for Chiron Diagnostics. Under this settlement agreement, we made a payment to Bayer during the first quarter 2003. We utilized an amount previously reserved for indemnity obligations, based upon the settlement agreement with Bayer. These amounts resulted in a net charge 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 recorded as a "Gain on disposal of discontinued operations" for the six months ended June 30, 2003.

In connection with the sale of Chiron Diagnostics and Chiron Vision, we recorded cumulative net deferred tax assets of \$0.2 million and \$8.5 million at June 30, 2003 and December 31, 2002, respectively, principally attributable to the timing of the deduction of certain expenses associated with these sales. We also recorded corresponding valuation allowances of \$0.2 million and \$8.5 million at June 30, 2003 and December 31, 2002, respectively, to offset these deferred tax assets, as management

believes that it is more likely than not that the deferred tax assets to which the valuation allowance relates will not be realized. The future recognition of these deferred tax assets will be reported as a component of "Gain (loss) on disposal of discontinued operations."

### New Accounting Standards

In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity." This Statement establishes new standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). This Statement is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. The adoption of SFAS No. 150 is not expected to have a material impact on our Consolidated Financial Statements.

In April 2003, the FASB issued SFAS No. 149, "Amendment of Statement 133 on Derivative Instruments and Hedging Activities," which amends and clarifies the accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts, and for hedging activities under SFAS No. 133. It requires, among other things, that contracts with comparable characteristics be accounted for similarly and clarifies under what circumstances a contract with an initial net investment meets the characteristic of a derivative and when a derivative contains a financing component that warrants special reporting in the statement of cash flows. SFAS No. 149 is effective generally for contracts entered into and modified after June 30, 2003. The adoption of SFAS No. 149 is not expected to have a material impact

on our Consolidated Financial Statements.

In January 2003, the FASB issued Interpretation No. 46 (referred to as FIN No. 46), "Consolidation of Variable Interest Entities" which address the accounting for certain off-balance sheet lease financing. The recognition provisions of FIN No. 46 will be effective for Chiron for the interim period ended September 30, 2003. The adoption of FIN No. 46 is not expected to have a material impact on our Consolidated Financial Statements.

In November 2002, the FASB issued EITF Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables." EITF Issue No. 00-21 addresses certain aspects of the accounting by a company for arrangements under which it will perform multiple revenue-generating activities. EITF Issue No. 00-21 addresses when and how an arrangement involving multiple deliverables should be divided into separate units of accounting. EITF Issue No. 00-21 provides guidance with respect to the effect of certain customer rights due to company nonperformance on the recognition of revenue allocated to delivered units of accounting. EITF Issue No. 00-21 also addresses the impact on the measurement and/or allocation of arrangement consideration of customer cancellation provisions and consideration that varies as a result of future actions of the customer or the company. Finally, EITF Issue No. 00-21 provides guidance with respect to the recognition of the cost of certain deliverables that are excluded from the revenue accounting for an arrangement. The provisions of EITF Issue No. 00-21 apply to revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The adoption of EITF Issue No. 00-21 is not expected to have a material impact on our Consolidated Financial Statements.

### Liquidity and Capital Resources

Our capital requirements have generally been funded from operations, cash and investments on hand, debt borrowings and issuance of common stock. Our cash and investments in marketable debt securities, which totaled \$1,266.5 million at June 30, 2003, are invested in a diversified portfolio of financial instruments, including money market instruments, corporate notes and bonds, government or government agency securities and other debt securities issued by financial institutions and other issuers

46

---

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.

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

On May 19, 2003, we announced the commencement of an all cash offer to acquire all issued and to be issued share capital of PowderJect Pharmaceuticals plc for 550 pence per ordinary share. On July 8, 2003, our cash offer became unconditional. As part of the acquisition of PowderJect, we will assume the debt of PowderJect including convertible notes with a face value of 35.0 million British Pounds (\$57.0 million at July 8, 2003). As of August 11, 2003, we had acquired or agreed to acquire or had received valid acceptances of the offer in respect of, in aggregate, 97,735,800 PowderJect shares, representing 99.14% of the issued share capital of PowderJect as of that date.

On July 30, 2003, we raised \$450.0 million through an offering of convertible debentures, referred to as the "Offering", and an additional \$50.0 million from the exercise of an option, granted to the underwriters, to purchase additional convertible debentures in connection with the Offering. The convertible debentures bear a coupon rate of 1.625% per annum and interest is payable semiannually. The debentures are convertible into shares of our common stock and the terms include an initial conversion price of approximately \$68.44 per share. The debentures may not be called for redemption by us for five years. Holders of the debentures will have the option to require us to purchase their debentures at par value in years five, 10, 15, 20 and 25. We may choose to pay the redemption purchase price in cash and / or shares of common stock. The debentures mature on August 1, 2033.

**Sources and uses of cash** We had cash and cash equivalents of \$876.0 million and \$268.3 million at June 30, 2003 and 2002, respectively.

*Operating activities* For the six months ended June 30, 2003, net cash provided by operating activities was \$113.2 million as compared with \$82.6 million for the six months ended June 30, 2002. The increase in cash provided by operating activities primarily was due to higher income from continuing operations before depreciation and amortization and other non-cash charges. The net cash provided by operating activities increased as a result of (i) higher royalty payments received under the Roche royalty arrangements, (ii) \$14.4 million of cash received as a result of the Biogen and Serono settlements in connection with the McCormick patents (see "Biopharmaceuticals Other revenues" above), (iii) higher royalty payments received under the Betaferon® royalty arrangement and (iv) larger increases in accounts receivable at June 30,

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

2002 as compared to June 30, 2003. Partially offsetting these increases were (i) larger increases in inventory at June 30, 2003 and (ii) payments in 2003 including a payment made to Bayer Corporation as a result of a settlement agreement relating to certain claims raised by Bayer in connection under the Stock Purchase Agreement dated September 17, 1998 and higher tax payments. We made approximately \$29.0 million in federal tax payments during the first half of 2003 as compared with approximately \$17.0 million in the first half of 2002.

At June 30, 2003, we had foreign net operating loss carryforwards of approximately \$13.2 million, of which approximately \$3.6 million begin expiring over the period 2008 to 2018. The remaining foreign net operating loss carryforwards of \$9.6 million are available to offset future taxable income without limitation.

At June 30, 2003, we had unutilized federal net operating loss carryforwards attributable to the acquisition of Matrix Pharmaceutical of approximately \$56.7 million, which are available to offset future domestic taxable income ratably through 2022.

47

---

At June 30, 2003, we had \$34.0 million of state net operating loss carryforwards, which expire between 2003 and 2022, and state net operating loss carryforwards attributable to the acquisition of Matrix Pharmaceutical, Inc. of approximately \$28.4 million, which are available to offset taxable income ratably through 2012.

At June 30, 2003, we had \$2.2 million of federal business tax credit carryforwards attributed to the acquisition of PathoGenesis Corporation, which expire in 2012. At June 30, 2003, we had \$3.6 million of federal business tax credit carryovers, which expire in 2007, and state business tax credit carryovers of \$23.0 million, which are available to offset future state tax liabilities without limitation.

We anticipate that research and development expenditures in 2003 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 and a dry powder inhaleable erythromyclamine product targeted for the treatment of acute exacerbations of chronic bronchitis, (ii) those activities related to the development of tezacitabine, obtained as a part of the acquisition of Matrix Pharmaceutical in the first quarter 2002, (iii) those activities related to the development of interleukin-2 in combination with various monoclonal antibodies, (iv) expansion of our meningococcal franchise, (v) development of a flu cell culture system and (vi) research activities focused on identifying several novel vaccines and therapeutics for clinical development in the areas of oncology and infectious disease. 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 six months ended June 30, 2003, net cash provided by investing activities consisted of proceeds from sales and maturities of investments in marketable debt securities of \$917.8 million and proceeds from the sale of equity securities and interests in affiliates companies of \$7.4 million. Cash provided by investing activities was offset by purchases of investments in marketable debt securities of \$277.5 million, capital expenditures of \$52.4 million, purchases of equity securities and interests in affiliated companies of \$36.9 million, cash paid for acquisitions, net of cash acquired of \$1.2 million and other uses of cash of \$0.8 million.

In April 2001, we 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. Our commitment is approximately 26.4 million Euro (\$30.2 million at June 30, 2003) for the expansion of our Italian manufacturing facilities, of which we paid 4.6 million Euro (\$5.4 million), as of June 30, 2003. This agreement began in the fourth quarter 2001 and is expected to continue through 2008. We currently are evaluating various financing alternatives to fund this expansion.

In February 2001, our Board of Directors approved a \$235.0 million capital expansion project, which includes the construction of a research and development facility (including a supporting central utility facility) and a parking structure in Emeryville, California. We had committed to \$37.6 million in design and construction services, under which we had incurred costs of \$28.4 million, as of June 30, 2003. We may cancel these remaining commitments at any time. Related to the research and development facility, we are evaluating various financing alternatives to fund this expansion.

The purchases of equity securities and interests in affiliated companies consisted of a \$33.7 million payment to purchase 3.8 million shares of PowderJect (discussed above) and equity contributions under several venture capital funds including a \$1.0 million capital contribution under a 2003 limited

partnership agreement, a \$0.1 million capital contribution under a 2002 limited partnership agreement, a \$0.6 million capital contribution under a 2001 limited partnership agreement and a \$1.4 million capital contribution under a 2000 limited partnership agreement. We are obligated to pay \$60.0 million over ten years in equity contributions to these venture capital funds, of which \$28.7 million was paid through June 30, 2003.

For the six months ended June 30, 2002, net cash used in investing activities consisted of purchases of investments in marketable debt securities of \$320.7 million, net cash paid to acquire Matrix Pharmaceutical, Inc. of \$54.9 million, capital expenditures of \$54.3 million, purchases of equity securities and interests in affiliated companies of \$3.1 million, other uses of cash of \$0.9 million, and cash paid for acquisition costs related to the acquisition of PathoGenesis of \$0.4 million. Cash used in investing activities was offset by proceeds from sales and maturities of investments in marketable debt securities of \$311.1 million, proceeds from the sale of equity securities and interests in affiliated companies of \$13.4 and proceeds from the sale of assets of \$0.2 million.

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

Our Board of Directors has authorized the repurchase of our common stock on the open market. In December 2002, our Board of Directors approved an additional 5.0 million share increase and authorized such repurchases through December 31, 2003. As of June 30, 2003, we may repurchase up to an additional 3.0 million shares of our common stock.

In January 2001, we initiated a put option program to reduce the effective costs of repurchasing our common stock. Under this program, we have entered into contracts with third parties to sell put options on Chiron stock, entitling the holders to sell to us a specified number of shares at a specified price on a specified date. In May 2003, we entered into a contract with a third party to sell put options on Chiron stock, entitling the holder to sell to us 0.5 million shares at \$43.89 per share. In connection with the sale, we collected a \$0.7 million premium. The option expired June 30, 2003. On June 30, 2003, our closing stock price was \$43.86. The third party elected to exercise a portion of the options. As a result, we repurchased 0.2 million shares.

As of March 31, 2003, we had an outstanding put option contract with a third party, entitling the holder to sell to us 0.5 million shares at \$36.79 per share. In connection with the sale, we collected a \$1.4 million premium. The option expired unexercised on May 5, 2003.

As of December 31, 2002, we had an outstanding put option contract with a third party entitling the holder to sell to us 0.5 million shares at \$38.11 per share. The option expired unexercised on January 29, 2003.

For the six months ended June 30, 2002, net cash used in financing activities consisted of \$45.1 million for the acquisition of treasury stock and \$0.3 million for the repayment of short-term borrowings. Cash used in financing activities was offset by \$18.0 million of proceeds from the reissuance of treasury stock (related to stock option exercises) and \$2.0 million of proceeds from put options.

We are currently evaluating 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 may cause us to issue Chiron shares.

**Borrowing arrangements** Under a revolving, committed, uncollateralized credit agreement with a major financial institution, we can borrow up to \$100.0 million in the U.S. This credit facility is guaranteed by Novartis AG under a November 1994 Investment Agreement, provides various interest rate options and matures in February 2006. There were no borrowings outstanding under this credit facility at June 30, 2003 and December 31, 2002. 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.

We also have various credit facilities available outside the U.S. There were no outstanding borrowings under these facilities at June 30, 2003. Borrowings under these facilities totaled \$0.1 million at December 31, 2002. One facility is maintained for our 51%-owned Indian subsidiary, and allows for total borrowings of 200 million Indian Rupee (\$4.3 million at June 30, 2003). There were no outstanding borrowings

under this facility at June 30, 2003. At December 31, 2002, \$0.1 million was outstanding under this facility. Our Italian subsidiary also has various facilities, related to its receivables, which allow for total borrowings of 10.9 million Euro (\$12.4 million at June 30, 2003). There were no outstanding borrowings under these facilities at June 30, 2003 and December 31, 2002.

**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 our existing 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 our balance sheet for the leased facility is \$157.5 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 ultimately result in the creation of commercial products, our business could be adversely affected.*

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.

*We collaborate with third parties to develop and commercialize new products; conflicts with or decisions by these third parties 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 corporate 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 corporate partners as to how best to realize the value associated with a current product or a product in development. In some cases, the corporate 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 corporate partners, causing them to reprioritize their efforts related to 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. See Part I, Item 1. "Business-Government Regulation" in our Annual Report on Form 10-K for the year ended December 31, 2002. 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, including those 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 actions, 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. Great care is taken 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 adversely affected.*

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.

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

We purchase bulk powdered tobramycin, the primary basic raw material in TOBI®, 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.

52

---

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 its flu vaccine product, PowderJect must purchase large quantities of chicken eggs. Currently, PowderJect purchases those eggs and incubation services from a single supplier and, pursuant to the contract with that supplier, PowderJect is required to make specified minimum purchases from that supplier through 2007. All of the chickens that produce those eggs are located in the United Kingdom. If PowderJect's 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, PowderJect's 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 Procleix® HIV-1/ HCV Assay. We currently source the related instrument system from third party suppliers. Currently, Gen-Probe is the only manufacturer of nucleic acid testing products using Transcription-Mediated Amplification technology. In immunodiagnostics, under the Ortho-Clinical Diagnostics, Inc. contract, we manufacture bulk reagents and antigens and confirmatory test kits sold in the clinical diagnostics and blood screening fields. While we and our partners work to mitigate the risks associated with being a key provider, there can be no assurance that our partner, Gen-Probe, will be able to provide sufficient quantities of the Procleix® HIV-1/ HCV Assay or that we will be able to manufacture sufficient bulk reagents and antigens and confirmatory test kits for immunodiagnostic products. Our difficulties or delays or those of our partners' could cause a public health concern for the blood supply, as well as increase costs and cause loss of revenue or market share.

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

Third parties, including competitors, have patents and patent applications in the U.S. and other significant markets that may be useful or necessary for the manufacture, use or sale of certain products and products in development by us and our corporate partners. 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 corporate 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 it's

53

---

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.*

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

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

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

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

We operate in a highly competitive environment, and the competition is expected to increase. Competitors include large pharmaceutical, chemical and blood testing companies, and biotechnology companies. Some of these competitors, particularly large pharmaceutical and blood testing companies, have greater resources than ours. 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; or

the competitive product may have therapeutic or other advantages.

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. Specific to one product, TOBI®, a generic form of this product may be available from our competitors, which may cause loss of revenue or market share. In December 2002, the U.S. Food and Drug Administration tentatively approved an abbreviated new drug application for an inhaled tobramycin for sale in the U.S. following expiration of the orphan drug status of TOBI® in December 2004. We have a patent in the U.S. covering the formulation of TOBI® that extends until 2014. We have therefore filed a suit claiming that this new generic form of tobramycin violates our patent. If our patent is found invalid or if this new product is found not to infringe upon our patent, sales of TOBI® could be adversely affected.

*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

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

patent litigation against one party may place significant royalty revenues received or to be received from other parties at risk. Even if we are successful in obtaining and defending patents, there can be no assurance that these patents will provide substantial protection. The length of time necessary to resolve patent litigation successfully may allow infringers to gain significant market advantage. Third parties may be able to design around the patents and develop competitive products that do not use the inventions covered by our patents. Many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties (for example, the third party's product is needed to meet a threat to public health or safety in that country, or the patent owner has failed to "work" the invention in that country, or the third party has patented improvements). In addition, most countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may be limited to monetary relief and may be unable to enjoin infringement, which could materially diminish the value of the patent. In addition, royalty revenues will 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. Certain of our products could be subject to re-importation from other countries. 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 our acquisition of PowderJect. The failure to adequately address the financial, operational or legal risks raised by such transactions, including our acquisition 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.

55

---

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

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;

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

the assumption of known and unknown liabilities of the acquired company, including intellectual property claims; and subsequent loss of key personnel of the acquired company.

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 have no assurance that we will establish such other sources of revenue.

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

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

*Our 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 43% as of June 30, 2003. 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. For more information on our relationship with

Novartis, see Note 9 "Related Party Transactions," in our Annual Report on Form 10-K for the year ended December 31, 2002.

*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;

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

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 corporate 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 corporate partners. The price of these securities also is subject to significant volatility and may be affected by, among other things, the types of events that affect our stock. Changes in the market price of these securities may impact our profitability.

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

We pay taxes principally in the U.S., Germany, Italy and The Netherlands. 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.

57

---

*Volatility of earnings could negatively impact our business.*

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

inventory management practices, including wholesale ordering patterns;

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

seasonality of certain vaccine products;

the tender driven nature of certain vaccine products, in particular Menjugate ;

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, interest rates, the fair value of equity securities held and our stock price. We attempt to limit our exposure to some or all of these market risks through the use of various financial instruments. There were no significant changes in our market risk exposures during the first half of 2003. These activities are discussed in further detail in Part II, Item 7A., "Quantitative and Qualitative Disclosures About Market Risk" of our Annual Report on Form 10-K for the year ended December 31, 2002.

### 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)

58

---

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, 2002. 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, 2002.

#### *Average Wholesale Pricing*

In December 2001, Citizens for Consumer Justice and 13 other named plaintiffs filed a class action lawsuit in the United States District Court for the District of Massachusetts against 29 biotechnology and pharmaceutical companies, including Chiron, in connection with setting average wholesale prices for various products, including DepoCyt®, which are reimbursed by Medicare. Plaintiffs alleged that defendants violated federal antitrust and racketeering laws by devising and implementing a fraudulent pricing scheme against Medicare and Medicaid beneficiaries, and sought declaratory relief, as well as compensatory and punitive damages. In March 2002, Plaintiffs filed an amended complaint that eliminated the antitrust allegations and changed the subject drug from DepoCyt® to Mitomycin®, a generic oncology drug sold by the Cetus-Ben Venue Therapeutics partnership. In September 2002, plaintiffs filed a Master Consolidated Class Action Complaint, which did not name Chiron as a defendant.

In February 2002, the State of Montana through its Attorney General filed a complaint in the First Judicial District Court in Lewis and Clark County against 18 biotechnology and pharmaceutical companies, including Chiron, in connection with setting average wholesale prices for various products, including DepoCyt®, that are reimbursed by Medicare and Medicaid. The Attorney General alleged that the Defendants violated Montana state and common laws on unfair trade practices and consumer protection, deceptive trade practices, Medicaid fraud, breach of contract and false claims, and seeks both compensatory and punitive damages.

In March 2002, the State of Nevada through its Attorney General filed a complaint in the Second Judicial District Court in Washoe County against 10 biotechnology and pharmaceutical companies, including Chiron, concerning setting average wholesale prices for various products, including DepoCyt®, that are reimbursed by Medicare and Medicaid. The Attorney General alleged that Defendants violated Nevada state and common laws on unfair and deceptive trade practices and consumer protection, Medicaid fraud, racketeering, and seeks both compensatory and punitive damages.

Between July and September 2002, three separate class action lawsuits were filed in two California Superior Courts against Chiron, Cetus Oncology, and numerous other biotechnology and pharmaceutical companies. Plaintiff's claims are based upon alleged violations of the California Business and Professions Codes. These matters seek compensatory and punitive damages, plus injunctive relief, against Chiron in connection with setting the average wholesale prices for various oncology drugs, including DepoCyt®.

In October 2002 and February 2003, the Montana, Nevada and California actions were coordinated and consolidated to the In re Pharmaceutical Industry Average Wholesale Price Litigation pre-trial proceedings. In August 2003, the States of Montana and Nevada both filed amended complaints, which did not name Chiron as a defendant.

In January 2003, the County of Suffolk filed a complaint in the United States District Court for the Eastern District of New York against 29 biotechnology and pharmaceutical companies, including Chiron, in connection with setting average wholesale prices for various products, including TOBI@,

---

which are reimbursed by Medicaid. Plaintiffs allege that defendants violated federal racketeering laws, federal and state laws on Medicaid fraud, and state laws on unfair trade practice, breach of contract, fraud and unjust enrichment by devising and implementing a fraudulent pricing scheme against Medicaid beneficiaries, and seeks declaratory relief, as well as compensatory and punitive damages. In August 2003, plaintiffs filed an Amended Complaint, which did not name Chiron as a defendant.



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

Currently, the California actions are the only remaining matters pending in the In re Pharmaceutical Industry Average Wholesale Price Litigation pre-trial proceedings which name Chiron as a party defendant.

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

### *F. Hoffmann-La Roche Ltd. and Roche Molecular Systems, Inc. HIV*

On March 11, 2003, the U.S. Patent and Trademark Office issued Chiron's U.S. Patent No. 6,531,276 (addressed to Methods For Detecting Human Immunodeficiency Virus Nucleic Acid) (the "'276 Patent"). Chiron has concluded that under an October 2000 HIV Probe License Agreement (the "Roche HIV Agreement") between Chiron, F. Hoffmann-La Roche Ltd. and Roche Molecular Systems (collectively, "Roche"), Roche is obligated to pay certain licensing fees and ongoing royalties for the sale of certain Roche HIV nucleic acid tests which infringe the '276 Patent. Roche disputes these obligations on a variety of grounds including non-infringement. Roche further contests the rate at which royalties must be paid if in fact its products are covered by the Roche HIV Agreement. In April 2003, the parties initiated alternative dispute resolution procedures (the "ADR procedures"), mandated by the Roche HIV agreement, to address these and, potentially other, disputes. The parties have been unable to resolve the matter, and in July 2003, Chiron initiated the final meet and confer process required under the ADR procedures. If this process fails to produce a resolution, the matter will be decided in a formal arbitration conducted under the rules of the CPR Institute for Dispute Resolution.

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

### *F. Hoffmann-La Roche A.G. HCV*

Chiron initiated an action in July 2000 against Roche Diagnostics GmbH in the German Federal Court ("Landgericht") in Dusseldorf, asserting that Roche's manufacture and sale of hepatitis C virus immunoassay products infringe Chiron's German Patent Nos. DD 298 527, DD 298 524, DD 287 104, DD 297 446 (collectively, the "German patents") and Chiron's European Patent No. EP 0 450 931 (the "'931 patent"). The Landgericht subsequently separated the matter into individual actions and then stayed oral hearings pending results of the nullity proceedings initiated by Roche in December 2000 in the German Federal Patent court ("Bundespatentgericht") against the same patents. In August 2002, the Bundespatentgericht upheld the validity of the German patents, but nullified the German portion of the '931 patent. In November 2002, Chiron filed appeals in the Federal Supreme Court to the nullity decisions with respect to the '931 and '527 patents, and Roche likewise appealed the nullity decisions regarding the German patents. In July 2003, the Landgericht determined that Roche's HCV immunoassay kits containing a certain antigen infringe Chiron's '524 patent. Accordingly, the Landgericht granted Chiron the right to enjoin Roche from the import, use, possession and sale of such kits in Germany, and ordered Roche to provide information about its commercial activities related to such kits since 1998 and to destroy any such kits in its possession in Germany. This judgment is subject to appeal. Furthermore, the Landgericht has stayed proceedings based on the '104, '527 and '931 patents pending the appeal of the Bundespatentgericht's judgment in the respective nullity suits.

In January 1997, Chiron and Ortho-Clinical Diagnostics, Inc. filed suit against F. Hoffmann-La Roche AG in the Regional Court of Dusseldorf, Germany, asserting that Roche's manufacture and sale of hepatitis C virus immunoassay products infringed Chiron's EP 0 318 216 (the "'216 patent"). The

61

---

suit sought damages and injunctive relief. In April 1999, the Court granted Chiron's application and entered an injunction. In September 1999, Roche appealed the decision to the Court of Appeals in Dusseldorf. Following withdrawal of certain claims from the '216 patent, Chiron rescinded the injunction and substituted the aforementioned '931 and German patents in the appellate proceeding. Oral hearings before the Court of Appeals on the German patents were held in May 2003, and the Court is expected to render judgment in September 2003. Oral hearings on the '931 patent are stayed pending the appeal of the Bundespatentgericht's judgment in the '931 nullity suit.

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

### *German Red Cross Donation Service and Working Society of Physicians*

In October 2001, the German Red Cross Donation Service and Working Society of Physicians brought a complaint against Chiron and Roche before the Commission of the European Communities (the "Commission"). These matters generally alleged that Chiron and Roche have engaged in certain anticompetitive actions that violate Articles 81 and 82 of the Treaty Establishing the European Community (the "EC Treaty") in connection with HIV and hepatitis C virus nucleic acid tests in blood screening. The complainants sought a determination that Roche pricing for its blood screening kits based upon the number of donations tested is unreasonable and should be prohibited through interim measures to be ordered by the Commission prior to final resolution of the action. Chiron filed its initial response with the Commission in January 2002. In

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

February 2002, the Sanquin Blood Services Foundation in The Netherlands also filed a complaint against Chiron and Roche before the Commission. The Sanquin complaint, filed in support of the German complaint, similarly alleged anticompetitive practices in violation of Articles 81 and 82 of the EC Treaty. The National Blood Authority of England also filed a related complaint with the Commission against Chiron and Roche in February 2002. The National Blood Authority complaint focused exclusively on hepatitis C virus licensing. Chiron was also informed that blood banking entities from Finland and Luxembourg filed similar complaints with the Commission.

In July 2002, the Directorate General for Competition provided its provisional assessment concerning both the October 2000 hepatitis C virus and HIV nucleic acid testing licensing agreements for clinical diagnostics and the May 2001 hepatitis C virus and HIV nucleic acid testing licensing agreements for blood screening between Chiron and Roche which had been notified to the European Commission in May 2001 and September 2001, respectively, and the complaints referenced above. The provisional assessment indicated that certain field of use restrictions and most favored nation license provisions appeared to give rise to competition restrictions incompatible with Article 81(1) of the EC Treaty, and were unlikely to qualify for exemption under Article 81(3) of the EC Treaty. The provisional assessment did not indicate that the per donation pricing was incompatible with the EC Treaty.

In July 2003, the European Commission accepted a joint settlement proposal made by Chiron and Roche, thereby resolving all related complaints. As part of the settlement, Chiron and Roche agreed to modify certain terms of their agreements under which Roche has licensed Chiron's hepatitis C virus and HIV-1 intellectual property for use in nucleic acid testing products in Europe. In resolving their inquiry, the European Commission concluded that the modified agreements satisfy the criteria for an individual exemption under Article 81(3) of the Treaty. Additionally, Chiron will extend a time-limited license offer to blood banks using "home brew" testing throughout Europe, allowing them to continue to use their own "in-house" technology to screen their own donations and the donations of other blood banks. As part of this offer, Chiron will provide relief from liability for past infringements to all blood banks that choose to take such a license.

62

---

### *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 also 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 seek dismissal of that action. This decision is subject to appeal.

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") ("Methods for Detecting Human Immunodeficiency Virus Nucleic Acid").

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

### *Roxane Laboratories, Inc.*

In June 2003, Chiron and Children's Hospital and Regional Medical Center (collectively, the "Plaintiffs"), filed a complaint in the United States District Court for the District of Delaware against Roxane Laboratories, Inc. ("Roxane") seeking damages and an injunction against Roxane's manufacture, use and sale or importation of an alleged generic version of Chiron's tobramycin solution for inhalation (TOBI®) described in Roxane's Abbreviated New Drug Application No. 65-105, for infringing Chiron's U.S. Patent No. 5,508,269 (the "'269 patent") ("Aminoglycoside Formulation for Aerosolization"). Plaintiffs also seek a judgment providing that the effective date of any U.S. Food and Drug Administration approval for Roxane to make, use, sell or import said generic be no earlier than the date on which the '269 patent expires. In August 2003, Roxane filed a counterclaim seeking to invalidate the '269 patent, and a declaration of non-infringement.

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

### *Sorin Biomedica/Snia*

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

In June 1994, Sorin Biomedica S.p.A. ("Sorin") filed a lawsuit with the Court of Milan, Italy against Chiron and Ortho Diagnostic Systems S.p.A. seeking a declaration of nullity and non-infringement of the Italian counterpart to Chiron's European Patent 0 318 216 (the "'216 patent") claiming hepatitis C virus immunodiagnostic technology. Chiron denied Sorin's allegations and filed a counterclaim seeking a declaration of infringement. In February 1997, the Court enjoined Sorin from manufacturing or selling hepatitis C virus immunoassay kits in Italy. After Sorin made further objections, the Court ruled in October 1999 that certain '216 patent claims were valid and that Sorin's hepatitis C virus immunoassay infringed the '216 patent. In June 2000, the European Patent Office Technical Board Of Appeals upheld the validity of the '216 patent in an amended form which deleted claims that Chiron alleged to have been infringed by Sorin. In December 2000, Snia S.p.A., Sorin's parent company, filed an appeal in the Court of Milan asking the Court to declare the Italian portion of the '216 patent null and void and to award Snia damages. In March 2001, Chiron denied Snia's allegations and asked the Court to dismiss the case. In May 2002, the Court of Appeal of Milan

63

declared that Snia's claims were inadmissible and dismissed Snia's appeal. In July 2003, Snia filed an appeal before the Supreme Court.

In January 2002, Chiron filed a complaint against Snia in the Court of Milan asserting that Snia's manufacture and sale of certain hepatitis C virus immunodiagnostics infringe the '931 patent. Chiron seeks a declaration of infringement based on the '931 patent, as well as damages. Trial is currently scheduled for December 1, 2004.

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

### *Sysmex Corporation*

In March 2001, Chiron filed a complaint and petition for preliminary injunction with the Osaka District Court in Japan against Sysmex Corporation ("Sysmex") seeking damages and an injunction against Sysmex's manufacture and sale of the Ranream HCV II Ex kit for infringing Chiron's Japanese Patent No. 2733138 (the "'138 patent") claiming hepatitis C virus immunodiagnostic technology. Sysmex denied the infringement allegations and filed two invalidation appeals with the Japanese Patent Office Board of Appeals against the '138 patent. In February 2003, the Japanese Patent Office Board of Appeals, ruling on one of the invalidation appeals, found that the '138 patent was invalid. In May 2003, Chiron filed an appeal of the invalidation judgment before the Tokyo High Court. Furthermore, the second invalidation appeal has been stayed pending Chiron's appeal to the Tokyo High Court.

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**

- (a) Chiron held its Annual Meeting of Stockholders on May 15, 2003.
- (b) Omitted pursuant to Instruction 3 to Item 4 of Form 10-Q.
- (c) The two matters voted upon at the meeting were: (i) election of six directors to hold office for the terms indicated; and (ii) ratification of the appointment of Ernst & Young LLP as Chiron's independent auditors for the year ending December 31, 2003. Two recently-appointed directors, Mr. J. Richard Fredericks and Mr. Howard H. Pien, were nominated for election to hold office for a two-year term expiring in 2005. The remaining four directors, Dr. Raymund Breu, Ms. Denise O'Leary, Mr. Seán Lance and Dr. Pieter Strijkert were currently serving as directors and were nominated for election to the Board for a three-year term expiring in 2006.
- (i) The following votes were cast for or were withheld with respect to each of the nominees for director:

<b>DIRECTORS</b>	<b>FOR</b>	<b>WITHHELD</b>
Class of 2005		

Edgar Filing: CHIRON CORP - Form 10-Q

DIRECTORS	FOR	WITHHELD
J. Richard Fredericks	166,099,732	1,490,167
Howard H. Pien	165,301,325	2,288,574
Class of 2006		
Raymund Breu	160,906,114	6,683,785
Seán P. Lance	165,616,588	1,973,311
Denise M. O'Leary	164,553,029	3,036,870
Pieter J. Strijkert	161,432,140	6,157,759

All nominees were declared to have been elected as directors to hold their respective offices until the Annual Meeting of Stockholders in the years 2005 and 2006 as noted above. No abstentions or broker non-votes were cast for the election of directors.

64

The following directors shall continue in office after Chiron's Annual Meeting of Stockholders held on May 15, 2003: Vaughn D. Bryson, Pierre E. Douaze and Edward E. Penhoet shall continue in office until the Annual Meeting of Stockholders in the year 2004; and Lewis W. Coleman, Paul L. Herrling and William J. Rutter until the Annual Meeting of Stockholders in the year 2005.

(ii) With respect to the proposal to ratify the appointment of Ernst & Young LLP as Chiron's independent auditors, 163,368,164 votes were cast for the proposal, 3,279,821 votes were cast against the proposal, and 941,914 votes abstained. No broker non-votes were cast in connection with the proposal. The selection of Ernst & Young LLP as the Chiron's independent auditors for the year ending December 31, 2003 was declared to have been ratified.

**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, incorporated by reference to Exhibit 3.04 to Chiron's report on Form 10-K for fiscal year 2000.
4.01	Indenture between Chiron and State Street Bank and Trust Company, dated as of June 12, 2001, incorporated by reference to Exhibit 4.01 of Chiron's report on Form 10-Q for the period ended June 30, 2001.
4.02	Registration Rights Agreement between Chiron and Merrill Lynch & Co., Inc., and Merrill Lynch, Pierce, Fenner & Smith, Incorporated, incorporated by reference to Exhibit 4.02 of

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

**Exhibit  
Number**

**Exhibit**

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 above), incorporated by reference to Exhibit 4.03 of Chiron's report on Form 10-Q for the period ended June 30, 2001.                                  |
| 4.04   | Reserved.  |
| 10.004 | Second Amendment between BNP Paribas Leasing Corporation, a Delaware corporation (as successor in interest to BNP Leasing Corporation) ("BNPLC"), and Chiron, dated July 1, 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. |

65

- |        |   |
|--------|---|
| 10.212 | Contract Manufacturing Agreement dated as of June 12, 2003 between Chiron S.r.l., Chiron Behring GmbH & Co., and SynCo Bio Partners B.V. (We have omitted certain information from the Agreement and filed it separately with the Securities and Exchange Commission pursuant to our request for confidential treatment under Rule 24b-2. We have identified the omitted confidential information by the following statement: "Confidential Treatment Requested".)                                    |
| 10.213 | FDA Compliance Agreement dated as of June 12, 2003 between Chiron S.r.l, Chiron Behring GmbH & Co and SynCo Bio Partners B.V. (We have omitted certain information from the Agreement and filed it separately with the Securities and Exchange Commission pursuant to our request for confidential treatment under Rule 24b-2. We have identified the omitted confidential information by the following statement: "Confidential Treatment Requested".)   |
| 10.321 | Blood Screening HCV Probe License Agreement European Union dated effective as of July 1, 2003, between Chiron, F. Hoffmann-La Roche Ltd., and Roche Molecular Systems, Inc. (We have omitted certain information from the Agreement and filed it separately with the Securities and Exchange Commission pursuant to our request for confidential treatment under Rule 24b-2. We have identified the omitted confidential information by the following statement: "Confidential Treatment Requested".) |
| 10.322 | Blood Screening HIV Probe License Agreement European Union dated effective as of July 1, 2003, between Chiron, F. Hoffmann-La Roche Ltd., and Roche Molecular Systems, Inc. (We have omitted certain information from the Agreement and filed it separately with the Securities and Exchange Commission pursuant to our request for confidential treatment under Rule 24b-2. We have identified the omitted confidential information by the following statement: "Confidential Treatment Requested".) |
| 10.323 | HCV Probe License and Option Agreement European Union dated effective as of July 1, 2003, between Chiron, F. Hoffmann-La Roche Ltd., and Roche Molecular Systems, Inc. (We have omitted certain information from the Agreement and filed it separately with the Securities and Exchange Commission pursuant to our request for confidential treatment under Rule 24b-2. We have identified the omitted confidential information by the following statement: "Confidential Treatment Requested".)      |
| 10.324 | HIV Probe License and Option Agreement European Union dated effective as of July 1,   |

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

2003, between Chiron, F. Hoffmann-La Roche Ltd., and Roche Molecular Systems, Inc. (We have omitted certain information from the Agreement and filed it separately with the Securities and Exchange Commission pursuant to our request for confidential treatment under Rule 24b-2. We have identified the omitted confidential information by the following statement: "Confidential Treatment Requested".)

- 10.501 Chiron 1991 Stock Option Plan, as amended August 14, 1993, April 11, 1994, February 24, 1995, March 8, 1996, February 28, 1997, August 7, 1998, August 20, 1999, February 25, 2000, September 21, 2000, February 16, 2001 and June 30 2003. \*
- 10.518 Nominating and Corporate Governance Committee Charter.
- 10.528 Amendment dated May 16, 2003 to Governance Agreement dated as of November 20, 1994, between Chiron and Novartis AG as successor-in-interest to Ciba-Gigy Limited.
- 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.

66

- 31.2 Certification of the Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
- 32.1 Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2 Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

\*

Management contract, compensatory plan or arrangement.

(b)

### Reports on Form 8-K

On April 23, 2003, Chiron filed a Current Report on Form 8-K, furnishing under Item 9, Chiron's preliminary results for its first quarter ended March 31, 2003, via a press release.

On May 19, 2003, Chiron filed a Current Report on Form 8-K, reporting under Item 5, that its indirect wholly-owned subsidiary, Chiron UK-1 Limited, had announced a cash tender offer to acquire all of the issued and to be issued share capital of PowderJect Pharmaceuticals plc for 550 pence per share subject to certain conditions.

67

## CHIRON CORPORATION

June 30, 2003

### 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.

Edgar Filing: CHIRON CORP - Form 10-Q

CHIRON CORPORATION

DATE: August 12, 2003

BY: /s/ HOWARD H. PIEN

---

Howard H. Pien  
President and Chief Executive Officer

DATE: August 12, 2003

BY: /s/ DAVID V. SMITH

---

David V. Smith  
Vice President, Finance and Acting Chief Financial Officer  
68

---

QuickLinks

CHIRON CORPORATION TABLE OF CONTENTS

Item 1. Financial Statements

CHIRON CORPORATION CONDENSED CONSOLIDATED BALANCE SHEETS (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, except per share data)

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

CHIRON CORPORATION NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS June 30, 2003 (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

CHIRON CORPORATION June 30, 2003 SIGNATURES