

CHIRON CORP  
Form 10-Q  
November 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 September 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.

<b>Title of Class</b>	<b>Outstanding at October 31, 2003</b>
Common Stock, \$0.01 par value	187,717,396

**CHIRON CORPORATION  
TABLE OF CONTENTS**

	<b>Page No.</b>
<b>PART I. FINANCIAL INFORMATION</b>	
<b>ITEM 1. Financial Statements (Unaudited)</b>	
Condensed Consolidated Balance Sheets at September 30, 2003 and December 31, 2002	3
Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2003 and 2002	5
Condensed Consolidated Statements of Comprehensive Income for the three and nine months ended September 30, 2003 and 2002	6
Condensed Consolidated Statements of Cash Flows for the nine months ended September 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>	33
<b>ITEM 3. Quantitative and Qualitative Disclosures About Market Risk</b>	67
<b>ITEM 4. Controls and Procedures</b>	67
<b>PART II. OTHER INFORMATION</b>	
<b>ITEM 1. Legal Proceedings</b>	68
<b>ITEM 4. Submission of Matters to a Vote of Security Holders</b>	71
<b>ITEM 6. Exhibits and Reports on Form 8-K</b>	71
<b>SIGNATURES</b>	74

Item 1. Financial Statements

**CHIRON CORPORATION  
CONDENSED CONSOLIDATED BALANCE SHEETS**

(Unaudited)

(In thousands, except share data)

	September 30, 2003	December 31, 2002
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 499,907	\$ 247,950
Short-term investments in marketable debt securities	197,759	626,130
	<u>697,666</u>	<u>874,080</u>
Total cash and short-term investments	697,666	874,080
Accounts receivable, net	427,749	278,625
Current portion of notes receivable	1,469	718
Inventories, net of reserves	247,641	146,005
Current net deferred income tax assets	61,977	38,450
Derivative financial instruments	10,485	12,006
Other current assets	77,579	35,838
	<u>1,524,566</u>	<u>1,385,722</u>
Total current assets	1,524,566	1,385,722
Noncurrent investments in marketable debt securities	340,308	414,447
Property, plant, equipment and leasehold improvements, at cost:		
Land and buildings	360,281	168,144
Laboratory, production and office equipment	586,763	418,255
Leasehold improvements	109,680	93,463
Construction-in-progress	105,730	74,717
	<u>1,162,454</u>	<u>754,579</u>
Less accumulated depreciation and amortization	(520,136)	(381,021)
	<u>642,318</u>	<u>373,558</u>
Property, plant, equipment and leasehold improvements, net	642,318	373,558
Purchased technologies, net	241,791	257,613
Goodwill	709,765	239,746
Other intangible assets, net	477,247	147,089
Investments in equity securities and affiliated companies	99,920	87,167
Noncurrent notes receivable	7,500	8,939
Noncurrent derivative financial instruments	10,177	9,007
Other noncurrent assets	38,821	37,056
	<u>\$ 4,092,413</u>	<u>\$ 2,960,344</u>

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

## CONDENSED CONSOLIDATED BALANCE SHEETS (Continued)

(Unaudited)

(In thousands, except share data)

	September 30, 2003	December 31, 2002
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 92,319	\$ 59,022
Accrued compensation and related expenses	69,399	59,498
Short-term borrowings		71
Current portion of unearned revenue	91,455	26,610
Income taxes payable	18,102	21,883
Other current liabilities	205,924	131,552
<b>Total current liabilities</b>	<b>477,199</b>	<b>298,636</b>
Long-term debt	923,725	416,954
Capital lease	157,756	
Noncurrent derivative financial instruments		253
Noncurrent net deferred income tax liabilities	147,130	45,743
Noncurrent unearned revenue	49,696	62,580
Other noncurrent liabilities	70,436	35,813
Minority interest	6,633	5,355
<b>Total liabilities</b>	<b>1,832,575</b>	<b>865,334</b>
Commitments and contingencies		
Put options		19,054
Stockholders' equity:		
Common stock	1,917	1,917
Additional paid-in capital	2,494,733	2,445,208
Deferred stock compensation	(15,202)	(11,349)
Accumulated deficit	(155,994)	(221,236)
Accumulated other comprehensive income	122,257	54,861
Treasury stock, at cost (4,385,000 shares at September 30, 2003 and 4,830,000 shares at December 31, 2002)	(187,873)	(193,445)
<b>Total stockholders' equity</b>	<b>2,259,838</b>	<b>2,075,956</b>
	<b>\$ 4,092,413</b>	<b>\$ 2,960,344</b>

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

## CHIRON CORPORATION

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
<b>Revenues:</b>				
Product sales, net	\$ 432,674	\$ 272,190	\$ 897,222	\$ 657,067
Revenues from joint business arrangement	26,058	32,356	79,985	78,548
Collaborative agreement revenues	7,816	4,977	15,554	17,786
Royalty and license fee revenues	66,237	48,047	186,537	138,419
Other revenues	7,688	10,911	32,482	28,136
<b>Total revenues</b>	<b>540,473</b>	<b>368,481</b>	<b>1,211,780</b>	<b>919,956</b>
<b>Operating expenses:</b>				
Cost of sales	174,380	97,432	357,389	239,823
Research and development	97,519	81,635	269,564	243,938
Selling, general and administrative	104,736	68,159	257,485	202,022
Amortization expense	19,821	7,504	35,135	22,328
Write-off of purchased in-process research and development	122,700		122,700	54,781
Restructuring and reorganization charges	1,082		1,757	
Other operating expenses	4,779	5,694	7,573	11,176
<b>Total operating expenses</b>	<b>525,017</b>	<b>260,424</b>	<b>1,051,603</b>	<b>774,068</b>
<b>Income from operations</b>	<b>15,456</b>	<b>108,057</b>	<b>160,177</b>	<b>145,888</b>
Interest expense	(6,222)	(3,210)	(12,523)	(9,498)
Interest and other income, net	5,239	8,696	31,170	41,456
Minority interest	(443)	(477)	(1,424)	(1,360)
<b>Income from continuing operations before income taxes</b>	<b>14,030</b>	<b>113,066</b>	<b>177,400</b>	<b>176,486</b>
Provision for income taxes	34,183	30,530	75,025	62,443
<b>(Loss) income from continuing operations</b>	<b>(20,153)</b>	<b>82,536</b>	<b>102,375</b>	<b>114,043</b>
Gain (loss) from discontinued operations	1,174	(320)	3,138	(320)
<b>Net (loss) income</b>	<b>\$ (18,979)</b>	<b>\$ 82,216</b>	<b>\$ 105,513</b>	<b>\$ 113,723</b>
<b>Basic (loss) earnings per share:</b>				
(Loss) income from continuing operations	\$ (0.11)	\$ 0.44	\$ 0.55	\$ 0.60

Edgar Filing: CHIRON CORP - Form 10-Q

	Three Months Ended September 30,		Nine Months Ended September 30,	
Net (loss) income	\$ (0.10)	\$ 0.44	\$ 0.57	\$ 0.60
<b>Diluted (loss) earnings per share:</b>				
(Loss) income from continuing operations	\$ (0.11)	\$ 0.43	\$ 0.54	\$ 0.59
Net (loss) income	\$ (0.10)	\$ 0.43	\$ 0.55	\$ 0.59

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)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
Net (loss) income	\$ (18,979)	\$ 82,216	\$ 105,513	\$ 113,723
Other comprehensive income (loss):				
Change in foreign currency translation adjustment during the period, net of tax benefit (provision) of \$295 for the three months ended September 30, 2002 and (\$6,154) for the nine months ended September 30, 2002	21,182	(6,926)	66,300	48,307
Unrealized gains (losses) from investments:				
Net unrealized holding gains (losses) arising during the period, net of tax benefit (provision) of (\$1,984) and \$1,625 for the three months ended September 30, 2003 and 2002, respectively, and (\$3,268) and \$5,157 for the nine months ended September 30, 2003 and 2002, respectively	4,200	(2,610)	6,840	(8,233)
Reclassification adjustment for net losses (gains) included in net income, net of tax (benefit) provision of (\$37) for the three months ended September 30, 2002 and \$3,626 and \$3,550 for the nine months ended September 30, 2003 and 2002, respectively		60	(5,744)	(5,742)
Net unrealized gains (losses) from investments	4,200	(2,550)	1,096	(13,975)
Other comprehensive income (loss)	25,382	(9,476)	67,396	34,332

Edgar Filing: CHIRON CORP - Form 10-Q

	Three Months Ended September 30,		Nine Months Ended September 30,	
Comprehensive income	\$ 6,403	\$ 72,740	\$ 172,909	\$ 148,055

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)

	Nine Months Ended September 30,	
	2003	2002
Net cash provided by operating activities	\$ 260,588	\$ 191,829
Cash flows from investing activities:		
Purchases of investments in marketable debt securities	(622,650)	(581,162)
Proceeds from sales and maturities of investments in marketable debt securities	1,112,778	568,549
Proceeds from notes receivable	750	5,150
Capital expenditures	(81,372)	(74,111)
Proceeds equity forward contracts		5,989
Proceeds from sales of assets		429
Purchases of equity securities and interests in affiliated companies	(4,270)	(5,508)
Proceeds from sale of equity securities and interests in affiliated companies	12,545	18,869
Cash paid for acquisitions, net of cash acquired	(804,728)	(58,176)
Other, net	(12,999)	(3,954)
Net cash used in investing activities	(399,946)	(123,925)
Cash flows from financing activities:		
Net repayment of short-term borrowings	(2,344)	(630)
Net repayment of debt and capital lease	(62,341)	
Payments to acquire treasury stock	(132,675)	(96,683)
Proceeds from reissuance of treasury stock	85,995	21,968
Proceeds from issuance of convertible debentures	500,000	
Proceeds from issuance of debt	536	
Proceeds from put options	2,144	3,713

Edgar Filing: CHIRON CORP - Form 10-Q

	<b>Nine Months Ended September 30,</b>	
	<b>_____</b>	<b>_____</b>
Net cash provided by (used in) financing activities	391,315	(71,632)
	<b>_____</b>	<b>_____</b>
Net increase (decrease) in cash and cash equivalents	251,957	(3,728)
Cash and cash equivalents at beginning of the period	247,950	320,673
	<b>_____</b>	<b>_____</b>
Cash and cash equivalents at end of the period	\$ 499,907	\$ 316,945
	<b>_____</b>	<b>_____</b>

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

7

**CHIRON CORPORATION**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**September 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 September 30, 2003, and for the three and nine months ended September 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 8, 2003, Chiron acquired PowderJect Pharmaceuticals plc, a company based in Oxford, United Kingdom that develops and commercializes vaccines. Chiron accounted for the acquisition using the purchase method of accounting and included PowderJect Pharmaceuticals' operating results in its consolidated operating results beginning July 8, 2003 (see Note 5). PowderJect Pharmaceuticals is part of Chiron's vaccines segment.



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

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).

8

---

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 \$29.8 million was paid through September 30, 2003. Chiron accounts for these investments under the equity method of accounting.

### *Use of Estimates and Reclassifications*

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

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

9

---

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 nine months ended September 30, 2002 by \$3.1 million for product sales and \$2.8 million for royalties.

Chiron currently owns a facility in London, England for international operations. Chiron has definite plans to vacate this facility and move to a new facility. The existing facility is not available for immediate sale and is classified as held for use. Accordingly, the remaining estimated useful life of the existing facility has been revised. This has resulted in an additional \$0.7 million of depreciation expense for the three months

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

ended September 30, 2003.

Chiron, prior to filing its financial statements on Form 10-Q, publicly releases an unaudited condensed balance sheet and statement of operations. Between the date of Chiron's earnings release and the filing of Form 10-Q, reclassifications may be required. These reclassifications, when made, have no effect on income from continuing operations, net income or earnings per share. In the Condensed Consolidated Balance Sheet at September 30, 2003, cash and cash equivalents is reduced by \$0.03 million due to the reclassification of short-term borrowings.

### *Revenue Recognition*

"Revenues from joint business arrangement" represents Chiron's one-half share in the pretax operating earnings generated by the joint business contractual arrangement with Ortho-Clinical Diagnostics, Inc., a Johnson & Johnson company. The arrangement was established in 1989, based largely on the screening, using immunodiagnostic technology, of blood in blood banks and other similar settings for the presence of HIV and hepatitis viruses. Through this arrangement, Ortho-Clinical Diagnostics sells a full line of tests required to screen for hepatitis viruses and retroviruses and provides supplemental tests and microplate-based instrument systems to automate test performance and data collection. In addition, Chiron and Ortho-Clinical Diagnostics jointly hold the immunodiagnostic rights to Chiron's hepatitis and retrovirus technology and receive royalties from the sales of hepatitis C virus and HIV tests by licensees.

Chiron manufactures viral antigens and supplemental hepatitis tests and sells these tests to Ortho-Clinical Diagnostics, while Ortho-Clinical Diagnostics manufactures and sells assays and instrument systems. The revenue from the sale of these antigens and tests, from Chiron to Ortho-Clinical Diagnostics, are recorded in product sales, with the corresponding costs recorded in cost of sales. Reimbursements from Ortho-Clinical Diagnostics for research costs incurred by Chiron and the related research expenses are separately recorded. In addition to these product revenues and reimbursements, Chiron shares in the defined pre-tax operating earnings of the Ortho-Clinical Diagnostics joint business activity at a pre-determined percentage (50%), as defined in the agreement, rather than from an ownership interest in an entity. Chiron receives contractually defined profit sharing payments from Ortho-Clinical Diagnostics on a quarterly basis.

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 sale, lease or rental of equipment and revenue from providing field service for the instruments. Revenue is recorded based upon the reported results obtained from the customer from the use of

10

---

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, respectively. For the provision of service on the instruments, revenue is recognized ratably over the life of the service agreement.

### *Inventories*

Inventories, net of reserves 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):

	September 30, 2003	December 31, 2002
Finished goods	\$ 83,180	\$ 32,697
Work-in-process	104,952	77,232
Raw materials	59,509	36,076
	\$ 247,641	\$ 146,005

In connection with the acquisition of PowderJect Pharmaceuticals, on July 8, 2003 (see Note 5), there was a step up in the value of inventory of \$24.4 million. For the three months ended September 30, 2003, \$10.9 million of this step up was included in cost of sales. Approximately \$13.5 million of this step up remains in inventory at September 30, 2003 and will be charged to cost of sales as the related product is sold.

### *Impairment of Long-Lived Assets*

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

Chiron evaluates the recoverability of long-lived assets when indicators of impairment are present. Impairment, if any, is based on the excess of the carrying value of such assets over their respective fair values, calculated based upon the projected discounted net cash flows associated with such assets.

Chiron had capitalized building design costs of \$1.6 million for a biologics pilot plant in Emeryville, California related to construction of a research and development facility for a capital expansion project (see Note 10). Chiron has abandoned plans to construct this building and accordingly wrote off \$1.6 million of building design costs in the third quarter of 2003.

### *Income Taxes*

The reported effective tax rate for 2003 is 25% of pretax income from continuing operations, excluding the write-off of purchased in-process research and development related to the acquisition of PowderJect Pharmaceuticals (see Note 5). 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 nine months ended September 30, 2002, was based on an estimated annual effective tax rate on pretax income from continuing operations of

11

---

approximately 27%, excluding the write-off of purchased in-process research and development related to the acquisition of Matrix Pharmaceutical, Inc. (see Note 5).

### *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.

### *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

12

---

in measuring compensation expense for all periods presented. Due to rounding, quarterly amounts may not sum fully to yearly amounts.

Three Months Ended September 30,		Nine Months Ended September 30,	
2003	2002	2003	2002

Edgar Filing: CHIRON CORP - Form 10-Q

	Three Months Ended September 30,		Nine Months Ended September 30,	
	(in thousands, except per share data)			
<b>Net (loss) income:</b>				
As reported	\$ (18,979)	\$ 82,216	\$ 105,513	\$ 113,723
Add: Stock-based employee compensation expense included in reported net (loss) income, net of related tax effects	1,091	757	3,743	2,268
Less: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	20,741	17,578	58,786	47,308
<b>Pro forma</b>	<b>\$ (38,629)</b>	<b>\$ 65,395</b>	<b>\$ 50,470</b>	<b>\$ 68,683</b>
<b>Basic net (loss) income per share:</b>				
As reported	\$ (0.10)	\$ 0.44	\$ 0.57	\$ 0.60
Pro forma	\$ (0.21)	\$ 0.35	\$ 0.27	\$ 0.36
<b>Diluted net (loss) income per share:</b>				
As reported	\$ (0.10)	\$ 0.43	\$ 0.55	\$ 0.59
Pro forma	\$ (0.21)	\$ 0.33	\$ 0.27	\$ 0.36

*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 \$8.9 million and \$40.3 million for the three and nine months ended September 30, 2003, respectively, and \$8.2 million and \$31.1 million for the three and nine months ended September 30, 2002, respectively, to "Accumulated deficit" in the Condensed Consolidated Balance Sheets.

*New Accounting Standards*

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 at the end of the first reporting period ending after December 15, 2003. The adoption of FIN No. 46 is not expected to have a material impact on the Consolidated Financial Statements.

**Note 2 Earnings (Loss) Per Share**

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

Edgar Filing: CHIRON CORP - Form 10-Q

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
<b>Income (loss) (Numerator):</b>				
(Loss) income from continuing operations	\$ (20,153)	\$ 82,536	\$ 102,375	\$ 114,043
Plus: Interest on convertible Liquid Yield Option Notes, net of tax		1,787		
(Loss) income from continuing operations, plus assumed issuances	\$ (20,153)	\$ 84,323	\$ 102,375	\$ 114,043
<b>Shares (Denominator):</b>				
Weighted-average common shares outstanding	186,685	188,493	186,658	189,175
Effect of dilutive securities:				
Stock options and equivalents		2,826	3,828	3,387
Put options			2	3
Convertible Liquid Yield Option Notes		5,228		
Weighted-average common shares outstanding, plus assumed issuances	186,685	196,547	190,488	192,565
Basic (loss) earnings per share	\$ (0.11)	\$ 0.44	\$ 0.55	\$ 0.60
Diluted (loss) earnings per share	\$ (0.11)	\$ 0.43	\$ 0.54	\$ 0.59

14

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
<b>Income (loss) (Numerator):</b>				
Net (loss) income	\$ (18,979)	\$ 82,216	\$ 105,513	\$ 113,723
Plus: Interest on convertible Liquid Yield Option Notes, net of taxes		1,787		
Net (loss) income, plus assumed issuances	\$ (18,979)	\$ 84,003	\$ 105,513	\$ 113,723
<b>Shares (Denominator):</b>				
Weighted-average common shares outstanding	186,685	188,493	186,658	189,175
Effect of dilutive securities:				
Stock options and equivalents		2,826	3,828	3,387
Put options			2	3
Convertible Liquid Yield Option Notes		5,228		

Edgar Filing: CHIRON CORP - Form 10-Q

	Three Months Ended September 30,		Nine Months Ended September 30,	
Weighted-average common shares outstanding, plus assumed issuances	186,685	196,547	190,488	192,565
Basic (loss) earnings per share	\$ (0.10)	\$ 0.44	\$ 0.57	\$ 0.60
Diluted (loss) earnings per share	\$ (0.10)	\$ 0.43	\$ 0.55	\$ 0.59

For the three months ended September 30, 2003 and 2002, stock options to purchase 4.2 million and 16.5 million shares, respectively, and for the nine months ended September 30, 2003 and 2002, stock options to purchase 10.7 million and 13.9 million, respectively, with exercise prices greater than the average market prices of common stock, were excluded from the respective computations of diluted (loss) earnings per share as their inclusion would be antidilutive.

Also excluded from the computations of diluted (loss) earnings per share for each of the three and nine months ended September 30, 2003 were 5.2 million shares of common stock issuable upon conversion of the Liquid Yield Option Notes and 7.3 million shares of common stock issuable upon conversion of the Convertible Debentures as their inclusion would be antidilutive. For the nine months ended September 30, 2002, 5.2 million shares of common stock issuable upon conversion of the Liquid Yield Option Notes were excluded from the computation of diluted earnings per share as their inclusion would be antidilutive.

All potential common shares have been excluded from the computation of diluted loss per share for the three months ended September 30, 2003, as their inclusion would be antidilutive due to the net loss. These potential common shares included stock options to purchase 23.3 million shares of common stock, 5.2 million shares of common stock issuable upon conversion of the Liquid Yield Option Notes and 7.3 million shares issuable upon conversion of the Convertible Debentures.

15

### 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. For the third quarter 2003, Chiron had no outstanding put option contracts.

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. Basic earnings per share from discontinued operations was \$0.01 and \$0.02 for the three and nine months ended September 30, 2003, respectively. Diluted earnings per share from discontinued operations was \$0.01 for each of the three and nine months ended September 30, 2003. Discontinued operations had no impact on basic and diluted earnings per share for the three and nine months ended September 30, 2002.

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

The "Gain (loss) from discontinued operations" for the three and nine months ended September 30, 2003 and 2002, consisted of the following (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
Reversal of reserves (net charge) for indemnity obligations	\$ 1,833	\$	\$ (5,222)	\$
Employee settlement		(438)		(438)
Income tax (provision) benefit	(659)	118	8,360	118
	<u>\$ 1,174</u>	<u>\$ (320)</u>	<u>\$ 3,138</u>	<u>\$ (320)</u>

In the third quarter 2003, Chiron reversed approximately \$1.2 million, net of tax, related to unutilized reserves for Chiron Diagnostics, which was recorded as a "Gain from discontinued operations" for the three and nine months ended September 30, 2003.

16

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 from discontinued operations" for the nine months ended September 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 from discontinued operations" for the nine months ended September 30, 2003.

In the third quarter 2002, Chiron recognized a charge of \$0.4 million related to a settlement with a former employee arising out of the sale of Chiron Diagnostics. This amount was recorded as a "Loss from discontinued operations" for the three and nine months ended September 30, 2002.

### *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 September 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 September 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) from discontinued operations."

### **Note 5 Acquisitions**

**PowderJect Pharmaceuticals plc** On July 8, 2003, Chiron acquired PowderJect Pharmaceuticals, a company based in Oxford, United Kingdom that develops and commercializes vaccines. Chiron acquired all of the outstanding shares of common stock of PowderJect Pharmaceuticals for 550 pence per ordinary share, which, including estimated acquisition costs, resulted in a total preliminary purchase price of approximately \$945.6 million. PowderJect Pharmaceuticals is part of Chiron's vaccines segment. PowderJect Pharmaceuticals' products, including vaccines for influenza, expand Chiron's portfolio of vaccine products.

Chiron accounted for the acquisition using the purchase method of accounting and included PowderJect Pharmaceuticals' operating results in its consolidated operating results beginning July 8, 2003. The components and initial allocation of the preliminary purchase price, based on their estimated fair values is summarized in the following table (in thousands). Chiron is in the process of finalizing

17

certain estimates including those for lease exit costs, other exit activities and certain liabilities including a guarantee and therefore the initial allocation of the purchase price is subject to change.

<b>Consideration and acquisition costs:</b>	
Cash paid for common stock	\$ 831,026
Cash paid for options on common stock	59,153
Acquisition costs paid as of September 30, 2003	5,547
Acquisition costs not yet paid as of September 30, 2003	49,920
	<hr/>
Total preliminary purchase price	\$ 945,646
	<hr/>
<b>Allocation of preliminary purchase price:</b>	
Cash and cash equivalents	\$ 92,178
Short-term marketable securities	8,840
Accounts receivable, net	42,732
Inventories	68,375
Property, plant and equipment	70,199
Goodwill	451,823
Acquired intangible assets	335,500
Other assets	6,461
Income taxes payable	(17,741)
Current liabilities	(76,981)
Net deferred tax liability	(68,664)
Long-term liabilities	(89,776)
Write-off of purchased in-process research and development	122,700
	<hr/>
Total preliminary purchase price	\$ 945,646
	<hr/>

Acquisition costs included involuntary termination costs of \$16.8 million, as well as other direct acquisition costs.

Chiron allocated the preliminary purchase price based on the fair value of the assets acquired and liabilities assumed. A portion of the purchase price was allocated to purchased in-process research and development, which was written off entirely in the third quarter 2003 because Chiron does not anticipate that there will be any alternative future use for the in-process research and development. The write-off of purchased in-process research and development represented the valuation of acquired, to-be-completed research projects. Purchased in-process research and development was determined using the income approach, which is based on the premise that the value of a security or asset is the present value of the future earning capacity that is available for distribution to the subject investors in the security or asset. In valuing the purchased in-process research and development, Chiron used probability-of-success-adjusted cash flows and a 14% discount rate. Cash flows from projects including those relating to (i) viral infectious disease, (ii) certain travel vaccines and (iii) vaccines for allergies were assumed to commence between 2004 and 2012. Given the high risk associated with the development of new drugs, Chiron probability adjusted the revenue and expense forecasts to reflect the risk of advancement through the regulatory approval process based on the stage of development in the

regulatory process. Such a valuation requires significant estimates and assumptions. Chiron believes that fair value assigned to purchased in-process research and development is based on reasonable assumptions. However, these assumptions may be incomplete or inaccurate, and unanticipated events and circumstances may occur. To assist in determining the value of the purchased in-process research and development, a third-party valuation was obtained as of the acquisition date.



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

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

Income taxes payable of \$17.7 million relates to current tax liabilities associated with PowderJect Pharmaceuticals at the date of acquisition. The net deferred tax liability of \$68.7 million is comprised of current and non-current deferred tax assets of \$32.0 million primarily related to net operating losses incurred from April 1, 2003 through the acquisition date and depreciation timing differences and a non-current deferred tax liability of \$100.7 million related to acquired intangibles.

At the date of acquisition, PowderJect Pharmaceuticals had \$150.0 million of tax loss carryforwards in the U.S., Sweden and the United Kingdom, which would give rise to a deferred tax asset of \$46.0 million and \$63.0 million of other temporary differences in Sweden, which would give rise to a deferred tax asset of \$17.6 million. A full valuation allowance has been established for these deferred tax assets, as it is more likely than not, at the date of acquisition, that all of these deferred tax assets will not be realized.

The following unaudited pro forma information presents the results of continuing operations and net income of Chiron and PowderJect Pharmaceuticals for the nine months ended September 30, 2003 and 2002 as if Chiron's acquisition of PowderJect Pharmaceuticals had been consummated as of January 1, 2003 and 2002, respectively. The pro forma results exclude the nonrecurring charge for the write-off of purchased in-process research and development, which resulted directly from the transaction. The unaudited pro forma condensed combined financial information does not reflect any incremental direct costs, including any restructuring charges to be recorded in connection with the acquisition, or potential cost savings, which may result from the consolidation of certain operations of Chiron and PowderJect Pharmaceuticals. Accordingly, the unaudited pro forma financial information is presented for illustrative purposes and not necessarily indicative of the results of operations of the combined company that would have occurred had the acquisition occurred at the beginning of each

19

period presented, nor is it necessarily indicative of future operating results. The unaudited pro forma information is as follows (in thousands, except per share data):

	Nine Months Ended September 30,	
	2003	2002
Total revenues	\$ 1,279,363	\$ 1,065,487
Income from continuing operations	\$ 188,985	\$ 92,941
Net income	\$ 192,123	\$ 92,621
Pro forma earnings per share from continuing operations:		
Basic	\$ 1.01	\$ 0.49
Diluted	\$ 0.99	\$ 0.48
Pro forma earnings per share from net income:		
Basic	\$ 1.03	\$ 0.49
Diluted	\$ 1.01	\$ 0.48

**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.

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

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

20

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):

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

21

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.

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

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 nine months ended September 30, 2003. These payments are reflected in the Condensed Consolidated Statement of Cash Flows as a component of "Cash paid for acquisitions, net of cash acquired" for the nine months ended September 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 nine months ended September 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 \$2.7 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 nine months ended September 30, 2003, Chiron recorded restructuring and reorganization charges of \$1.8 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 15 positions in its Amsterdam manufacturing facility. Termination notice has been provided. Of the 15 positions for elimination, one was terminated as of September 30, 2003. For the nine months ended September 30, 2002, Chiron had no restructuring and reorganization adjustments related to these items.

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

22

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 nine months ended September 30, 2003 and 2002, Chiron had no restructuring and reorganization adjustments related to these items. Of the 371 positions for elimination, 367 were terminated as of September 30, 2003.

Chiron expects to substantially settle the restructuring and reorganization accruals within one to six years of accruing the related charges. As of September 30, 2003, \$1.8 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.

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

	<u>Accrual at December 31, 2002</u>	<u>Amount of Total Restructuring Charge</u>	<u>Amount Utilized Through September 30, 2003</u>	<u>Amount to Be Utilized In Future Periods</u>
Employee-related costs and Other facility-related costs	\$ 334	\$ 1,757	\$ (316)	\$ 1,775
	<u>Accrual at December 31, 2001</u>	<u>Amount of Total Restructuring Charge</u>	<u>Amount Utilized Through September 30, 2002</u>	<u>Amount to Be Utilized In Future Periods</u>

Employee-related costs and Other facility-related costs	\$	693	\$	\$	(298)	\$	395
--	----	-----	----	----	-------	----	-----

23

**Note 7 Intangible Assets**

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

	September 30, 2003			December 31, 2002		
	Gross Carrying Value	Accumulated Amortization	Net Carrying Value	Gross Carrying Value	Accumulated Amortization	Net Carrying Value
Purchased technologies	\$ 332,054	\$ 90,263	\$ 241,791	\$ 331,941	\$ 74,328	\$ 257,613
Patents	\$ 115,638	\$ 59,128	\$ 56,510	\$ 106,723	\$ 52,136	\$ 54,587
Trademarks	57,663	18,540	39,123	53,394	14,928	38,466
Licenses and technology rights(1)	46,573	23,117	23,456	35,243	16,063	19,180
Developed product technologies(2)	324,924	10,805	314,119			
Customer relationships	26,655	8,854	17,801	24,082	7,054	17,028
Know how(3)	12,105	5,352	6,753	10,935	4,245	6,690
Databases	7,100	1,420	5,680	7,100	1,065	6,035
Other	26,229	12,424	13,805	15,274	10,171	5,103
Total other intangible assets	\$ 616,887	\$ 139,640	\$ 477,247	\$ 252,751	\$ 105,662	\$ 147,089
Total intangible assets subject to amortization	\$ 948,941	\$ 229,903	\$ 719,038	\$ 584,692	\$ 179,990	\$ 404,702

- (1) Intangible assets related to distribution rights and a contract manufacturing agreement with a gross carrying value of \$9.1 million and accumulated amortization of \$1.7 million acquired in the acquisition of PowderJect Pharmaceuticals during the third quarter 2003 (see Note 5) were included in Licenses and technology rights at September 30, 2003. The gross carrying value of these intangible assets has decreased approximately \$0.04 million due to exchange rate fluctuations between the acquisition date and September 30, 2003.
- (2) Intangible assets with a gross carrying value of \$324.9 million and accumulated amortization of \$10.8 million acquired in the acquisition of PowderJect Pharmaceuticals during the third quarter 2003 (see Note 5) were included in Developed product technologies at September 30, 2003. The gross carrying value of these intangible assets has decreased approximately \$1.46 million due to exchange rate fluctuations between the acquisition date and September 30, 2003.
- (3) 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.

24

Aggregate amortization expense is as follows (in thousands):

For the nine months ended September 30, 2003 (reported)	\$ 51,367
For the remaining three months in the year ended December 31, 2003 (estimated)	25,684
	<u>77,051</u>
For the year ended December 31, 2003 (estimated)	\$ 77,051
For the year ended December 31, 2004 (estimated)	\$ 96,954
For the year ended December 31, 2005 (estimated)	\$ 94,229
For the year ended December 31, 2006 (estimated)	\$ 99,916
For the year ended December 31, 2007 (estimated)	\$ 101,804
For the year ended December 31, 2008 (estimated)	\$ 95,374

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

	<u>Biopharmaceuticals</u>	<u>Vaccines</u>	<u>Total</u>
Balance as of December 31, 2002	\$ 199,225	\$ 40,521	\$ 239,746
Goodwill acquired (Note 5)		451,823	451,823
Effect of exchange rate changes		18,196	18,196
	<u>199,225</u>	<u>510,540</u>	<u>709,765</u>
Balance as of September 30, 2003	\$ 199,225	\$ 510,540	\$ 709,765

Chiron performed its annual impairment test for goodwill as of June 30, 2003. Based on this analysis, Chiron has no indication of an impairment loss.

#### 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 in the U.S., Germany, Italy, the United Kingdom and other international markets. The vaccines segment is also involved in the development of novel vaccines and vaccination technology. The blood testing segment consists of an alliance with Gen-Probe Incorporated and Chiron's one-half share in the pretax operating earnings generated by the joint business contractual arrangement with Ortho-Clinical Diagnostics, Inc., a Johnson & Johnson company. Chiron's alliance with Gen-Probe is focused on developing and commercializing nucleic acid testing products using Transcription-Mediated Amplification technology to screen donated blood and plasma products for viral infection. Chiron's joint business arrangement with Ortho-Clinical Diagnostics is operated under a contractual arrangement and is not a separate and distinct legal entity. Through Chiron's joint business contractual arrangement with Ortho-Clinical Diagnostics, Chiron sells a line of immunodiagnostic tests to detect

25

hepatitis viruses and retroviruses and provides supplemental tests and microplate and chemiluminescent instrument systems to automate test performance and data collection.

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 nine months ended September 30, 2002, expenses of approximately \$0.4 million and \$1.2 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
<b>Revenues</b>				
Biopharmaceuticals:				
Product sales, net:				
Betaseron®	\$ 29,010	\$ 28,533	\$ 88,788	\$ 84,593
TOBI®	43,022	38,971	122,740	108,308
Proleukin®	29,859	32,088	85,223	83,693
Other	8,166	6,319	22,258	23,818
Total product sales, net	110,057	105,911	319,009	300,412
Collaborative agreement revenues	1,364	3,270	4,645	10,285
Royalty and license fee revenues	23,523	12,494	62,098	46,231
Other revenues	5,009	6,378	23,794	13,022
Total biopharmaceuticals revenues	139,953	128,053	409,546	369,950

26

### Vaccines:

Product sales, net:				
Influenza vaccines	183,250	66,907	191,286	71,047
Menjugate	10,642	6,193	31,876	21,819
Travel vaccines	11,229	16,621	59,981	58,512
Pediatric and other vaccines	57,598	35,771	133,537	104,714
Total product sales, net	262,719	125,492	416,680	256,092
Collaborative agreement revenues	4,349	111	4,516	444
Royalty and license fee revenues	3,023	3,721	9,550	9,155
Other revenues	2,679	4,289	8,688	13,387

Edgar Filing: CHIRON CORP - Form 10-Q

Total vaccines revenues	272,770	133,613	439,434	279,078
Blood testing:				
Product sales, net:				
Procleix®	53,663	35,961	141,767	83,424
Ortho-Clinical Diagnostics	6,235	4,826	19,766	17,139
Total product sales, net	59,898	40,787	161,533	100,563
Revenues from joint business arrangement	26,058	32,356	79,985	78,548
Collaborative agreement revenues	2,103	1,596	6,393	7,057
Royalty and license fee revenues	20,576	14,232	59,372	36,994
Other revenues				41
Total blood testing revenues	108,635	88,971	307,283	223,203
Other:				
Royalty and license fee revenues	19,115	17,600	55,517	46,039
Other revenues		244		1,686
Total other revenues	19,115	17,844	55,517	47,725
Total revenues	\$ 540,473	\$ 368,481	\$ 1,211,780	\$ 919,956

27

*Income (loss) from continuing operations*

Biopharmaceuticals	\$ 16,745	\$ 7,796	\$ 50,716	\$ 20,775
Vaccines	69,848	39,942	65,340	48,920
Blood testing	56,994	54,549	169,997	127,662
Other	(4,349)	5,770	(1,419)	3,312
Segment income from operations	139,238	108,057	284,634	200,669
Operating expense reconciling items:				
Write-off of purchased in-process research and development	(122,700)		(122,700)	(54,781)
Restructuring and reorganization	(1,082)		(1,757)	

Edgar Filing: CHIRON CORP - Form 10-Q

charges				
Income from operations	15,456	108,057	160,177	145,888
Interest expense	(6,222)	(3,210)	(12,523)	(9,498)
Interest and other income, net	5,239	8,696	31,170	41,456
Minority interest	(443)	(477)	(1,424)	(1,360)
Income from continuing operations before income taxes	\$ 14,030	\$ 113,066	\$ 177,400	\$ 176,486

**Note 9 Debt Obligations**

On July 30, 2003, Chiron issued \$500.0 million aggregate principal amount of convertible debentures, which mature on August 1, 2033. The convertible debentures accrue interest at a rate of 1.625% per year and interest is payable on February 1 and August 1 commencing February 1, 2004. The debentures are senior, unsecured obligations of Chiron and rank equal in right of payment with all of Chiron's existing and future unsecured and unsubordinated indebtedness.

The holders of the debentures may convert their debentures into shares of Chiron common stock when certain Chiron common stock price targets have been met at certain times, if the debentures have been called for redemption, if the credit rating assigned to Chiron's long-term senior debt is below specified levels or upon the occurrence and continuance of specified corporate transactions. For each \$1,000 principal amount of debentures surrendered for conversion, the holder will receive 14.6113 shares of Chiron common stock. This is equivalent to an initial conversion price of approximately \$68.44 per share of common stock. Upon conversion, holders will not receive any cash payment for accrued interest. Instead, accrued interest will be deemed paid by the common stock received by holders on conversion.

The holders of the debentures may require Chiron to repurchase the debentures on August 1, 2008, August 1, 2013, August 1, 2018, August 1, 2023 and August 1, 2028. The repurchase price will be

28

equal to the principal and accrued and unpaid interest. Chiron may choose to pay the repurchase price in cash or Chiron common stock or any combination of the two.

On or after August 5, 2008, Chiron may redeem for cash all or part of the debentures at a redemption price of principal plus accrued and unpaid interest.

If Chiron undergoes certain change in control transactions, the holder of the debentures have the option to require Chiron to repurchase all or part of the debentures not previously called for redemption. The repurchase price will be equal to the principal and accrued and unpaid interest. Chiron may choose to pay the repurchase price in cash or Chiron common stock or any combination of the two.

Bond issuance costs amounted to approximately \$10.7 million and are being amortized to interest expense on a straight-line basis, which approximated the effective interest method, over five years, which represents the period from the issue date to the earliest redemption date. Bond issuance costs are recorded in "Other intangible assets, net" in the Condensed Consolidated Balance Sheets.

**Note 10 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.



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

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, of which Chiron had paid 3.2 million Euro (\$3.7 million) as of September 30, 2003.

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 operating 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. The amount of the leased facility less the expected value of the facility at the end of the lease term is being amortized on a straight-line basis over the lease term. Chiron expects the value of the facility at the end of the lease term will be approximately \$151.6 million. At the inception of the lease, the future minimum lease payments, exclusive of a residual value guarantee, are approximately \$15.7 million over the lease term. The interest payments represent variable-rate interest payments indexed to a three-month London interbank offered rate plus 40 basis points. The

29

---

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.

In July 2003, Chiron acquired PowderJect Pharmaceuticals, plc (See Note 5). Associated with this acquisition, Chiron assumed operating leases for manufacturing facilities, office space, laboratory and office and manufacturing equipment. The future minimum lease payments for these leases are \$0.5 million for the fourth quarter 2003, \$1.9 million for 2004, \$1.7 million for 2005, \$1.6 million for 2006, \$1.5 million for 2007 and \$1.3 million after 2007. Also, associated with this acquisition, Chiron has guaranteed a \$7.0 million loan for research and development purposes.

In August 2003, Chiron entered into a \$2.5 million revolving credit agreement with Nektar Therapeutics to support the financing of equipment, facility improvements and other capital expenditures related to the manufacture of clinical supplies in support of a program to develop a dry powder formulation of TOBI®. Each advance made under this revolving line of credit matures on the sixth anniversary of the initial advance. As of September 30, 2003, Nektar Therapeutics has not drawn from the revolving line of credit.

In September 2003, Chiron entered into a 10-year lease agreement with a commencement date of December 5, 2003 for an administrative facility in Emeryville, California. The total minimum lease payments over the term of the lease are approximately \$10.0 million. This lease will be accounted for as an operating lease.

In October 2003, Chiron entered into a 15-year lease extension with a commencement date of January 1, 2005 for a production facility in Marburg, Germany. The additional minimum lease payments over the term of the lease extension are approximately \$7.9 million. This lease extension will be accounted for as an operating lease.

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 \$1.3 million was paid through September 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 (\$16.6 million at September 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 September 30, 2003. Effective April 1, 2003, the amount of insurance-related letters of credit has increased by \$4.8 million.

30

---

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 four years from regulatory approval.

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 (\$30.6 million at September 30, 2003) for the expansion of Chiron's Italian manufacturing facilities, of which Chiron had incurred costs of 7.9 million Euro (\$8.9 million), as of September 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 \$28.5 million, as of September 30, 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 September 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 11 Subsequent Events**

In October 2003, Chiron entered into a license agreement with Cubist Pharmaceuticals, Inc. for the development and commercialization of Cubist's antibiotic daptomycin for injection in Western and Eastern Europe, Australia, New Zealand, India and certain Central American, South American and Middle Eastern countries. In exchange for these development and commercialization rights, Chiron has agreed to pay Cubist up to \$50.0 million. This \$50.0 million includes \$18.0 million, which was paid by Chiron up front in the fourth quarter 2003, \$10.0 million of which was used to purchase restricted Cubist common stock at a 50 percent premium over market price, and up to \$32.0 million of additional payments to Cubist upon the achievement of certain regulatory and sales milestones. Chiron will also pay Cubist a tiered royalty on daptomycin for injection made by Chiron. Chiron expects to record a portion of the up front payment as research and development expense.

In November 2003, Chiron's Board of Directors approved \$51.0 million in expenditures for a 25-year lease for buildings, which is part of a \$97.0 million project for a new flu vaccines manufacturing facility in Liverpool, England. The new manufacturing facility will replace existing

flu vaccines manufacturing facilities in Liverpool, England.

## 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, revenues from joint business arrangement, 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, including Fluvirin®, a product we obtained as part of our third quarter 2003 acquisition of PowderJect Pharmaceuticals (discussed below), travel vaccines, which include rabies and tick-borne encephalitis vaccines and two products we obtained as part of our third quarter 2003 acquisition of PowderJect Pharmaceuticals, Arilvax® and Dukoral®, and pediatric and other vaccines. We sell these vaccines primarily in the U.S., 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 share in the pretax operating earnings generated by the joint business contractual arrangement with Ortho-Clinical Diagnostics, Inc., a Johnson & Johnson company. Our alliance with Gen-Probe is focused on developing and commercializing nucleic acid testing products using Transcription-Mediated Amplification technology to screen donated blood and plasma products for viral infection. Our joint business arrangement with Ortho-Clinical Diagnostics is operated under a contractual arrangement and is not a separate and distinct legal entity. Through our joint business contractual arrangement with Ortho-Clinical Diagnostics, we sell a line of immunodiagnostic tests to detect hepatitis viruses and retroviruses and provide supplemental tests and microplate and chemiluminescent instrument systems to automate test performance and data collection. 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; capital leases; intangible assets; goodwill; purchased in-process research and development; product discounts, rebates and returns; bad debts; collaborative, royalty and license arrangements; restructuring;

pension and other post-retirement benefits; income taxes; and litigation and other contingencies. We base our estimates on historical experience and various other assumptions that we believe to be reasonable under the circumstances, the results of which form our basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from those estimates under different assumptions or conditions.

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

34

---

risk of advancement through the regulatory approval process based on the stage of development in the regulatory process. Such a valuation requires significant estimates and assumptions. 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 PowderJect Pharmaceuticals acquisition, we allocated a portion of the purchase price to purchased in-process research and development and wrote off \$122.7 million in the third quarter 2003. 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 purchased in-process research and development. For the Matrix Pharmaceutical acquisition, we also 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.

**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. 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.

36

---

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

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 \$110.1 million and \$105.9 million for the three months ended September 30, 2003 and 2002, respectively, and \$319.0 million and \$300.4 million for the nine months ended September 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, discussed in "Royalty and license fee revenues Betaferon®" below (ii) the volume mix of Chiron product and Boehringer Ingelheim product and (iii) the launch of product upgrades with ease-of-use features. We believe these considerations will somewhat offset this contractual change and impact the ultimate contribution of Betaseron® to Chiron's profit.

In October 2003, the U.S. Food and Drug Administration approved a new pre-filled diluent syringe for Betaseron®. The pre-filled diluent syringe will enhance the delivery mode and shorten preparation, helping to simplify injections of Betaseron®. In the first quarter 2003, the U.S. Food and Drug Administration approved new labeling for Betaseron®. The labeling expands the indication for Betaseron® to treat all relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations. Relapsing forms of multiple sclerosis include relapsing-remitting, the most common form, and secondary progressive multiple sclerosis with relapses.

Betaseron® product sales were \$29.0 million and \$28.5 million for the three months ended September 30, 2003 and 2002, respectively, and \$88.8 million and \$84.6 million for the nine months ended September 30, 2003 and 2002, respectively. The increase in Betaseron® product sales in the third quarter 2003 as compared with the third quarter 2002 primarily related to (i) increased patient demand, (ii) the benefit of the movement in foreign exchange rates and (iii) price increases. These increases were partially offset by fluctuations in Berlex Laboratories and Schering ordering patterns as they decreased inventories of the current materials in anticipation of the launch of our pre-filled diluent syringe materials, discussed above.

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, key marketing programs and an overall increase in the market for interferon beta-1b products for multiple sclerosis, (ii) the benefit of the movement in foreign exchange rates and (iii) price increases. These increases were partially offset by fluctuations in wholesaler ordering patterns and Berlex Laboratories and Schering ordering patterns. In 2002, wholesalers built inventory to support the mid-2002 launch of our new room-temperature formulation, which positively influenced sales in 2002. At the end of the third quarter 2003, decreased inventory

---

levels, in anticipation of the launch of our pre-filled diluent syringe materials, discussed above, negatively impacted sales in 2003. Also partially offsetting the increases in Betaseron® product sales year-to-date 2003 as compared with year-to-date 2002, were incremental revenues recognized in the first quarter 2002 related to the effect of recording revenue based on more current information available from Schering. 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.

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

**TOBI®** We sell TOBI® directly in the U.S. and certain international markets. We recognized TOBI® sales of \$43.0 million and \$39.0 million for the three months ended September 30, 2003 and 2002, respectively, and \$122.7 million and \$108.3 million for the nine months ended September 30, 2003 and 2002, respectively. Increased TOBI® sales in the third quarter 2003 as compared with the third quarter 2002 primarily related to (i) greater product penetration in various European countries, (ii) price increases and (iii) the benefit of the movement in the Euro to U.S. Dollar exchange rate. The increase was partially offset by wholesaler ordering patterns. In addition to the above factors, year-to-date 2003 TOBI® sales were also positively impacted by increased use and improved compliance in the U.S. by patients with cystic fibrosis when compared with year-to-date 2002 TOBI® sales. The increase in TOBI® sales year-to-date 2003 compared with year-to-date 2002 was partially offset by wholesaler ordering patterns and 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. Wholesaler ordering patterns as well as reimbursement and government pressures, competition, foreign currency exchange rates and the level of rebates may influence future TOBI® sales. 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. Subsequently, the application was withdrawn and under terms of a settlement agreement reached in October 2003, approval will not be sought to market this generic product until the 2014 expiration of our patent in the U.S. covering the formulation of TOBI®.

**Proleukin®** Sales of Proleukin® were \$29.9 million and \$32.1 million for the three months ended September 30, 2003 and 2002, respectively, and \$85.2 million and \$83.7 million for the nine months ended September 30, 2003 and 2002, respectively. Decreased Proleukin® product sales in the third quarter 2003 as compared with the third quarter 2002 primarily related to wholesaler ordering patterns. The decrease was partially offset by price increases and the benefit of the movement in the Euro to U.S. Dollar exchange rate.

The increase in Proleukin® product sales year-to-date 2003 as compared with year-to-date 2002 primarily related to price increases and the benefit of the movement in the Euro to U.S. Dollar exchange rate. These increases were partially offset by wholesaler ordering patterns. Wholesaler 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 \$1.4 million and \$3.3 million for the three months ended September 30, 2003 and 2002, respectively, and \$4.6 million and \$10.3 million for the nine months ended September 30, 2003 and 2002, respectively.

Collaborative agreement revenues for the three months ended September 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 nine months ended September 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 nine months ended September 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, we received approximately \$23.7 million for technology transfer and research services. We recognized collaborative agreement revenues of \$2.8 million and \$8.9 million for the three and nine months ended September 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.



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

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 \$23.5 million and \$12.5 million for the three months ended September 30, 2003 and 2002, respectively, and \$62.1 million and \$46.2 million for the nine months ended September 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

40

---

contractual agreement with Schering, our royalty will decline in the fourth quarter 2003 by five percentage points.

For the three months ended September 30, 2003 and 2002, we recognized Betaferon® royalties of \$16.0 million and \$9.6 million, respectively, and for the nine months ended September 30, 2003 and 2002, we recognized \$47.2 million and \$33.8 million, respectively, under this arrangement. Betaferon® royalties increased in the third quarter 2003 as compared with the third quarter 2002, as well as year-to-date 2003 compared with year-to-date 2002, primarily as the result of (i) a positive impact of the difference between the adjustment of estimate to actual in both periods, (ii) an increase in Chiron's effective royalty rate under an agreement with Schering, (iii) increased patient demand as discussed in "Product sales Betaseron®" above and (iv) 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 under the transitional supply agreement with Schering. The increases year-to-date 2003 as compared with year-to-date 2002 were partially 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 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 \$2.3 million and \$2.5 million for the three months ended September 30, 2003 and 2002, respectively, and \$6.2 million and \$5.8 million for the nine months ended September 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 nine months ended September 30, 2003, primarily consisted of our third quarter 2003 agreement with Gilead Sciences, Inc. where we granted rights under certain of our hepatitis C virus-related patents for which we recognized a license fee in the third quarter 2003 and our fourth quarter 2002 agreement with GlaxoSmithKline plc where we granted rights under certain of our MC-4R compound patents for which we recognized portions of the license fee in the second and third quarters of 2003. The balance of royalty and license fee revenues for the nine months ended September 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 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.

In November 2003, we granted a license to Rigel Pharmaceuticals Inc. for the research, development and commercialization of small molecule therapeutics against certain hepatitis C virus drug targets.

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

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

41

---

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 \$5.0 million and \$6.4 million for the three months ended September 30, 2003 and 2002, respectively, and \$23.8 million and \$13.0 million for the nine months ended September 30, 2003 and 2002, respectively.

*Contract manufacturing revenues* Our biopharmaceuticals segment recognized contract manufacturing revenues of \$4.7 million and \$6.3 million for the three months ended September 30, 2003 and 2002, respectively, and \$7.8 million and \$12.6 million for the nine months ended September 30, 2003 and 2002, respectively. The decrease 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 nine months ended September 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 nine months ended September 30, 2003.

*Depocyt®* In the fourth quarter 2002, we sold U.S. sales and marketing rights for Depocyt® to SkyePharma plc. For the nine months ended September 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 74% and 77% for the three months ended September 30, 2003 and 2002, respectively, and 75% for each of the nine months ended September 30, 2003 and 2002. The decrease in biopharmaceutical gross profit margins for the third quarter 2003 as compared with the third quarter 2002 was primarily the result of higher annual maintenance shutdown costs and product start-up costs for the recently approved pre-filled diluent syringe for Betaseron® by the U.S. Food and Drug Administration.

Biopharmaceutical gross profit margins for the nine months ended September 30, 2003 benefited from price increases and the movement in the Euro to U.S. Dollar exchange rate. However, the increase was offset by costs due to a reserve taken against certain manufactured components held in inventory, higher annual maintenance shutdown costs and product start-up costs for the recently approved pre-filled diluent syringe for Betaseron® by the U.S. Food and Drug Administration.

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 \$56.1 million and \$60.1 million for the three months ended September 30, 2003 and 2002, respectively, and \$169.8 million and \$178.7 million for the nine months ended September 30, 2003 and 2002, respectively.

42

---

The decrease in research and development spending in the third quarter 2003 as compared with the third quarter 2002, as well as year-to-date 2003 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 below, and (ii) termination of our trials for 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, (iii) a dry powder formulation of our inhaled TOBI® product for the treatment of *pseudomonas aeruginosa* in cystic fibrosis patients and (iv) tifacogin, as discussed below. 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 the installed equipment.

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 \$6.0 million has been paid through September 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.

In October 2003, we entered into a license agreement with Cubist Pharmaceuticals, Inc. for the development and commercialization of Cubist's antibiotic daptomycin for injection in Western and Eastern Europe, Australia, New Zealand, India and certain Central American, South American and Middle Eastern countries. In exchange for these development and commercialization rights, we have agreed to pay Cubist up to \$50.0 million. This \$50.0 million includes \$18.0 million, which was paid by Chiron up front in the fourth quarter 2003, \$10.0 million of which was used to purchase restricted Cubist common stock at a 50 percent premium over market price and up to \$32.0 million of additional payments to Cubist upon the achievement of certain regulatory and sales milestones. We will also pay Cubist a tiered royalty on daptomycin for injection made by Chiron. We expect to record a portion of the up front payment as research and development expense.

In October 2003, we acquired all of Pfizer, Inc.'s, formerly Pharmacia Corp.'s, interest in tifacogin, in return for which Pfizer will receive royalties on sales of tifacogin. We are initiating plans for a Phase III trial for tifacogin in patients with severe community-acquired pneumonia.

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

**Selling, general, and administrative** Our biopharmaceuticals segment recognized selling, general and administrative expenses of \$28.7 million and \$24.8 million for the three months ended September 30, 2003 and 2002, respectively, and \$83.1 million and \$68.7 million for the nine months ended September 30, 2003 and 2002, respectively. The increase in selling, general and administrative expenses for the third quarter 2003 as compared with the third quarter 2002 related to (i) ongoing sales

---

and marketing programs to support TOBI® in the U.S. and continued market penetration in Europe, (ii) continued investment in and defense of our patents and technology, (iii) sales and marketing costs for various biopharmaceutical post-market approval commitments, (iv) additional costs associated with the enhancement of current business processes and (v) the Euro to U.S. Dollar exchange rate fluctuation. In addition, the increase year-to-date 2003 as compared with year-to-date 2002 was impacted by increased costs following the acquisition of Pulmopharm in the third quarter 2002.

**Amortization expense** Our biopharmaceuticals segment recognized amortization expense of \$6.2 million for each of the three months ended September 30, 2003 and 2002, and \$18.6 million and \$18.0 million for the nine months ended September 30, 2003 and 2002, respectively. The increase in amortization expense year-to-date 2003 as compared with year-to-date 2002 related to the distribution rights acquired upon acquisition of Pulmopharm in the third quarter 2002.

**Vaccines**

**Product sales** We sell flu, meningococcal, travel, pediatric and other vaccines in the U.S., Germany, Italy, the United Kingdom and other international markets. Vaccine product sales were \$262.7 million and \$125.5 million for the three months ended September 30, 2003 and 2002, respectively, and \$416.7 million and \$256.1 million for the nine months ended September 30, 2003 and 2002, respectively.

Sales of our flu vaccines were \$183.3 million and \$66.9 million for the three months ended September 30, 2003 and 2002, respectively, and \$191.3 million and \$71.0 million for the nine months ended September 30, 2003 and 2002, respectively. Flu vaccines sales increased in the third quarter 2003 as compared with the third quarter 2002, as well as year-to-date 2003 compared with year-to-date 2002, primarily as a result of additional sales of flu vaccine products following our third quarter 2003 acquisition of PowderJect Pharmaceuticals. PowderJect Pharmaceuticals flu vaccine sales were \$103.3 million in the third quarter 2003. Excluding PowderJect Pharmaceuticals, sales of our remaining flu vaccines increased primarily as a result of the benefit of the movement in the Euro to U.S. Dollar exchange rate and price and volume increases in Germany and Italy.

Menjugate, our conjugate vaccine against meningococcal infection caused by the bacterium *N. meningitidis* serogroup C, sales were \$10.6 million and \$6.2 million for the three months ended September 30, 2003 and 2002, respectively, and \$31.9 million and \$21.8 million for the nine months ended September 30, 2003 and 2002, respectively. The increase in Menjugate sales in the third quarter 2003 as compared with the third quarter 2002 primarily related to tender sales to Australia, Spain and France 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 tender business, 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 travel vaccines, comprised of tick-borne encephalitis, rabies vaccines and two products we obtained as part of our third quarter 2003 acquisition of PowderJect Pharmaceuticals, Arilvax® and Dukoral®, were \$11.2 million and \$16.6 million for the three months ended September 30, 2003 and 2002, respectively, and \$60.0 million and \$58.5 million for the nine months ended September 30, 2003 and 2002, respectively. The decrease in travel vaccines sales in the third quarter 2003 as compared with the third quarter 2002 was primarily related to decreased tick-borne encephalitis vaccine sales in the German market. In the third quarter 2002, we had end of season sales and additional sales of the then newly approved adult and pediatric formulations, launched in the first quarter 2002. The decrease in travel vaccines sales in the third quarter 2003 as compared with the third quarter 2002 was partially offset by additional sales of travel vaccine products following our third quarter 2003 acquisition of PowderJect Pharmaceuticals and the benefit of the movement in the Euro to U.S. Dollar exchange rate. The increase in travel vaccines sales year-to-date 2003 as compared with year-to-date 2002

primarily resulted from additional sales of travel vaccine products following our third quarter 2003 acquisition of PowderJect Pharmaceuticals and the benefit of the movement in the Euro to U.S. Dollar exchange rate partially offset by decreased tick-borne encephalitis vaccine sales, as discussed above.

Sales of our pediatric and other vaccines were \$57.6 million and \$35.8 million for the three months ended September 30, 2003 and 2002, respectively, and \$133.5 million and \$104.7 million for the nine months ended September 30, 2003 and 2002, respectively. The increase in pediatric and other vaccines sales for the third quarter 2003 as compared with the third quarter 2002, as well as year-to-date 2003 compared with year-to-date 2002, primarily was due to additional sales of other vaccine products following our third quarter 2003 acquisition of PowderJect Pharmaceuticals, the timing of tender sales and the benefit of the movement in the Euro to U.S. Dollar exchange rate.

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.

**Collaborative agreement revenues** We recognize collaborative agreement revenues for fees received as we perform research services and achieve specified milestones. Our vaccines segment recognized collaborative agreement revenues of \$4.3 million and \$0.1 million for the three months ended September 30, 2003 and 2002, respectively, and \$4.5 million and \$0.4 million for the nine months ended September 30,

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

2003 and 2002, respectively. In the first quarter 2002, we entered into an agreement to supply a vaccine for meningococcal meningitis caused by the bacterium *N. meningitidis* serogroup B to the Ministry of Health in New Zealand. We recognized revenue under this arrangement in the third quarter 2003. In addition, as a result of our third quarter 2003 acquisition of PowderJect Pharmaceuticals, we recognized revenue under a shared services agreement with MedImmune, Inc.

The balance of collaborative agreement revenues recognized in our vaccines segment consisted of various other arrangements, 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 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

45

---

\$3.0 million and \$3.7 million for the three months ended September 30, 2003 and 2002, respectively, and \$9.6 million and \$9.2 million for the nine months ended September 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 \$1.8 million and \$1.6 million of such royalties for the three months ended September 30, 2003 and 2002, respectively, and \$5.2 million of such royalties for each of the nine months ended September 30, 2003 and 2002.

*Other* We recognized \$1.2 million and \$2.1 million for the three months ended September 30, 2003 and 2002, respectively, and \$4.3 million and \$3.9 million for the nine months ended September 30, 2003 and 2002, respectively, of royalty revenues primarily on third party sales of hepatitis B virus vaccine products. The decrease in the third quarter 2003 as compared with the third quarter 2002 primarily resulted from decreased sales of hepatitis B virus vaccine products due to competition from multivalent hepatitis B virus vaccine products. The increase in year-to-date 2003 as compared with year-to-date 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 \$2.7 million and \$4.3 million for the three months ended September 30, 2003 and 2002, respectively, and \$8.7 million and \$13.4 million for the nine months ended September 30, 2003 and 2002, respectively.

*Grant and contract revenues* Our vaccines segment other revenues included grant and contract revenues of \$2.2 million and \$3.1 million for the three months ended September 30, 2003 and 2002, respectively, and \$6.9 million and \$10.2 million for the nine months ended September 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, \$1.8 million and \$2.6 million for the three months ended September 30, 2003 and 2002, respectively, and \$5.9 million and \$7.3 million for the nine months ended September 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 58% and 60% for the three months ended September 30, 2003 and 2002, respectively, and 56% and 57% for the nine months ended September 30, 2003 and 2002, respectively. The vaccine gross profit margin in the third quarter 2003 was negatively impacted by the Euro to U.S. Dollar exchange rate fluctuation and the mix of vaccine products. In addition, vaccine gross profit margin year-to-date 2003 as compared with

46

---

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. In connection with the acquisition of PowderJect Pharmaceuticals on July 8, 2003, there was a step up in the value of inventory of \$24.4 million. Included in cost of sales in the third quarter 2003 was \$10.9 million of this step up. Excluding this step up, vaccine gross profit as a percentage of net product sales for the three months ended September 30, 2003 would have been 62%. Approximately \$13.5 million of this step up remains in inventory at September 30, 2003 and will be charged to cost of sales as the related product is sold.

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 \$35.3 million and \$17.8 million for the three months ended September 30, 2003 and 2002, respectively, and \$82.7 million and \$52.4 million for the nine months ended September 30, 2003 and 2002, respectively. The increase in research and development spending for the third quarter 2003 as compared with the third quarter 2002, as well as year-to-date 2003 compared with year-to-date 2002, was driven by additional costs associated with programs obtained following our third quarter acquisition of PowderJect Pharmaceuticals. Excluding \$7.2 million of additional research and development expenses associated with PowderJect Pharmaceuticals, the increase in research and development spending resulted from the advancement of several programs in our meningococcal franchise and flu cell culture.

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 \$43.4 million and \$23.4 million for the three months ended September 30, 2003 and 2002, respectively, and \$90.3 million and \$63.2 million for the nine months ended September 30, 2003 and 2002, respectively. The increase in selling, general and administrative expenses in the third quarter 2003 as compared with the third quarter 2002, as well as year-to-date 2003 compared with year-to-date 2002, primarily related to additional expenses following our third quarter acquisition of PowderJect Pharmaceuticals. Excluding \$19.4 million of additional selling, general and administrative expenses associated with PowderJect Pharmaceuticals, including integration costs of \$5.3 million, the remaining increase in selling, general and administrative resulted from additional costs associated with the enhancement of current business processes and headcount and the Euro to U.S. Dollar exchange rate fluctuation. 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 \$13.6 million and \$1.3 million for the three months ended September 30, 2003 and 2002, respectively, and \$16.5 million and \$4.2 million for the nine months ended September 30, 2003 and 2002, respectively. The increase in amortization expense for the third quarter 2003 as compared with the third quarter 2002, as well as year-to-date 2003 compared with year-to-date 2002, related to the intangibles acquired following our acquisition of PowderJect Pharmaceuticals in the third quarter 2003.

47

---

*Blood testing*

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

**Product sales** Our blood testing segment recognized product sales of \$59.9 million and \$40.8 million for the three months ended September 30, 2003 and 2002, respectively, and \$161.5 million and \$100.6 million for the nine months ended September 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 record revenue based upon the reported results obtained from the customer from the use of assays to screen donations or upon sale and delivery of the assays, depending on the underlying contract. In the case of equipment sales or leases, we record revenue upon the sale and transfer of the title to the instrument or ratably over the life of the lease term, respectively. For the provision of service on the instruments, we recognize revenue ratably over the life of the service agreement.

Worldwide product sales related to tests, instruments and the provision of services were \$53.7 million and \$36.0 million for the three months ended September 30, 2003 and 2002, respectively, and \$141.8 million and \$83.4 million for the nine months ended September 30, 2003 and 2002, respectively. The increase in product sales in the third quarter 2003 as compared with the third quarter 2002 primarily related to (i) the introduction of the West Nile virus assay on an investigational-use basis in the U.S. and (ii) market share gains in the U.S. and continued penetration into several markets abroad for the Procleix® HIV-1/ HCV Assay. In March 2003, the U.S. Food and Drug Administration accepted an investigational new drug (IND) for the West Nile virus assay. The new assay runs on the same instrumentation platform as the currently approved Procleix® HIV-1/HCV assay.

The increase in product sales year-to-date 2003 as compared with year-to-date 2002 primarily related to commercial pricing in the U.S. commencing May 1, 2002 for the Procleix® HIV-1/ HCV Assay following the U.S. Food and Drug Administration approval in February 2002. In addition, 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. Other factors contributing to the increase in 2003 were (i) the introduction of the West Nile virus assay on an investigational-use basis in the U.S., as discussed above and (ii) market share gains in the U.S. and increased sales to several markets abroad for the Procleix® HIV-1/ HCV Assay. 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.

*Ortho-Clinical Diagnostics* Under our joint business contractual arrangement with Ortho-Clinical Diagnostics, Inc., we manufacture bulk reagents and antigens and confirmatory test kits for immunodiagnostic products. We recognized product sales under this arrangement of \$6.2 million and \$4.8 million for the three months ended September 30, 2003 and 2002, respectively, and \$19.8 million and \$17.1 million for the nine months ended September 30, 2003 and 2002, respectively. The increase in the third quarter 2003 as compared with the third 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 of 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.

**Revenues from joint business arrangement** Our share of revenues from our joint business contractual arrangement with Ortho-Clinical Diagnostics, Inc. was \$26.1 million and \$32.4 million for the three months ended September 30, 2003 and 2002, respectively, and \$80.0 million and \$78.5 million for the nine months ended September 30, 2003 and 2002, respectively. The decrease in revenues from joint business arrangement for the third quarter 2003 as compared with the third quarter 2002 primarily resulted from lower profits from Ortho-Clinical Diagnostics' U.S. operations. 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. Offsetting the increase were lower profits from Ortho-Clinical Diagnostics' U.S. operations in the third quarter 2003, as discussed above. Prior to the first quarter 2003, we had accounted for revenues relating to 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 relating to non-U.S. affiliate sales on a one-month lag, consistent with the method of how we recognize revenues relating to Ortho-Clinical Diagnostics' sales for the U.S. portion of Ortho-Clinical Diagnostics' operations.

**Collaborative agreement revenues** We recognize collaborative agreement revenues for fees received as we perform research services and achieve specified milestones. Under the Ortho-Clinical Diagnostics, Inc. joint business arrangement, we conduct research and development services related to immunodiagnostic products. Our blood testing segment recognized total collaborative agreement revenues of \$2.1 million and \$1.6 million for the three months ended September 30, 2003 and 2002, respectively, and \$6.4 million and \$7.1 million for the nine months ended September 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 IV-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 \$20.6 million and \$14.2 million for the three months ended September 30, 2003 and 2002, respectively, and \$59.4 million and \$37.0 million for the nine months ended September 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 and third quarters of 2003, we recognized royalty revenues under one of these agreements.

*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 \$18.9 million and \$13.0 million for the three months ended September 30, 2003 and 2002, respectively, and \$47.5 million and \$33.2 million for the nine months ended September 30, 2003 and 2002, respectively. The increase in 2003 as compared with 2002 related to (i) a \$4.0 million one-time payment estimated using an alternative methodology under an agreement with F. Hoffmann-La Roche relating to back royalties, (ii) a contractual increase in the royalty rates and (iii) 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 40% for the each of the three months ended September 30, 2003 and 2002, and 42% and 39% for the nine months ended September 30, 2003 and 2002, respectively. The increase in blood testing gross profit margin year-to-date 2003 as compared with year-to-date 2002 related to (i) increased profitability of the nucleic acid testing business due to a lower level of fixed costs over an increased volume of sales and (ii) the timing of manufacturing services under the Ortho-Clinical



Diagnostics contract.

In November 2003, Chiron and Gen-Probe Incorporated agreed to amend their world-wide blood screening collaboration agreement in order to adopt permanent, fixed revenue shares for each party. Effective January 1, 2004, Gen-Probe's share will be set at 45.75% of net revenues for assays which include a test for the hepatitis C virus. For commercial assays which do not test for the hepatitis C virus such as the prospective West Nile test, the agreement remains unchanged with each party retaining 50% of the net revenues after deduction of appropriate expenses.

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

50

---

**Research and development** Our blood testing segment recognized research and development expenses of \$5.9 million and \$3.8 million for the three months ended September 30, 2003 and 2002, respectively, and \$16.7 million and \$13.2 million for the nine months ended September 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 \$9.7 million and \$6.2 million for the three months ended September 30, 2003 and 2002, respectively, and \$27.1 million and \$21.4 million for the nine months ended September 30, 2003 and 2002, respectively. The increased selling, general and administrative expenses in the third quarter 2003 as compared with the third 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 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 our sales opportunities expand in new markets through anticipated additional nucleic acid testing adoption.

#### **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 \$19.1 million and \$17.6 million for the three months ended September 30, 2003 and 2002, respectively, and \$55.5 million and \$46.0 million for the nine months ended September 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 recognized under this agreement year-to-date 2003 were consistent with year-to-date 2002.

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 September 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 \$22.9 million and \$13.7 million for the three months ended September, 2003 and 2002, respectively, and \$56.9 million and \$48.7 million for the nine months ended September, 2003 and 2002, respectively. The increase in selling, general and administrative expenses in the third quarter 2003 as compared with the third quarter 2002 primarily resulted from integration costs of \$1.7 million associated with our third quarter acquisition of PowderJect Pharmaceuticals, an impairment charge associated with long-lived assets, employee-related expenses and additional consulting costs. In addition, the increase year-to-date 2003 as compared with year-to-date 2002 was impacted by additional severance costs and was partially offset by lower litigation costs in the first and second quarters of 2003 related to our investment in and defense of our patents and technology.

**Write-off of purchased in-process research and development** The write-off of purchased in-process research and development was \$122.7 million and \$54.8 million for the nine months ended September 30, 2003 and 2002, respectively.

On July 8, 2003, we acquired PowderJect Pharmaceuticals and accounted for the acquisition using the purchase method of accounting. 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 \$122.7 million in the third quarter 2003. We do not anticipate that there will be any alternative future use for the in-process research and development. In valuing the purchased in-process research and development, we used probability-of-success-adjusted cash flows and a 14% discount rate. Cash flows from projects including those relating to (i) viral infectious disease, (ii) certain travel vaccines and (iii) vaccines for allergies were assumed to commence between 2004 and 2012.

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. 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.

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

**Restructuring and reorganization** For the three and nine months ended September 30, 2003, we recorded restructuring and reorganization charges of \$1.1 million and \$1.8 million, respectively. The charges consisted of termination and other employee-related costs recognized in connection with the elimination of 15 positions in our Amsterdam manufacturing facility.

**Interest expense** We recognized interest expense of \$6.2 million and \$3.2 million for the three months ended September 30, 2003 and 2002, respectively, and \$12.5 million and \$9.5 million for the nine months ended September 30, 2003 and 2002, respectively. The increase in the third quarter 2003 as compared with the third quarter 2002 primarily related to interest expense recognized on the \$500.0 million convertible debentures that were issued on July 30, 2003, additional expense resulting from debt assumed following our third quarter acquisition of PowderJect Pharmaceuticals.

**Interest and other income, net** Interest and other income, net, primarily consisted of interest income on our cash and investment balances and other non-operating gains and losses. We recognized interest income of \$5.4 million and \$8.8 million for the three months ended September 30, 2003 and 2002, respectively, and \$18.7 million and \$27.9 million for the nine months ended September 30, 2003 and 2002, respectively. The decrease in interest income in 2003 as compared with 2002 primarily was due to lower average cash and investment balances following the acquisition of PowderJect Pharmaceuticals and lower average interest rates.

We recognized gains of \$9.4 million and \$14.3 million for the nine months ended September 30, 2003 and 2002, respectively, related to the sale of certain equity securities. There were no gains related to the sale of equity securities during the three months ended September 30, 2003 and 2002.

There were no losses attributable to the other-than-temporary impairment of equity securities for the three months ended September 30, 2003 and 2002, and the nine months ended September 30, 2003. For the nine months ended September 30, 2002, we recognized losses attributable to the other-than-temporary impairment of certain equity securities of \$4.8 million.

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 \$1.5 million in "Interest and other income, net," for the nine months ended September 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 nine months ended September 30, 2003 and 2002, respectively.

**Income taxes** The reported effective tax rate for 2003 is 25% of pretax income from continuing operations, excluding the write-off of purchased in-process research and development related to the

53

---

PowderJect Pharmaceuticals acquisition. The reported effective tax rate for the nine months ended September 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 2003 and 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.

Management believes the acquisition of PowderJect Pharmaceuticals may cause an increase in the future effective tax rate and is in the process of evaluating certain options that may mitigate any potential increase. Specifically, most of PowderJect Pharmaceutical's profits are earned in the United Kingdom, subject to a 30% marginal tax rate. Management is currently negotiating debt-to-equity levels with United Kingdom Inland Revenue that it expects will, more likely than not, maintain the reported effective tax rate of 25% through 2004. There is no assurance that such debt-to-equity levels being negotiated with United Kingdom Inland Revenue will be accepted and accordingly, the reported effective tax rate of 25% for 2004 may change.

**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 and third quarters 2003, we reversed approximately \$1.7 million related to unutilized reserves for Chiron Diagnostics and Chiron Vision, which was recorded as a "Gain from discontinued operations" for the nine months ended September 30, 2003.

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

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 from discontinued operations" for the nine months ended September 30, 2003.

In the third quarter 2002, we recognized a charge of \$0.4 million related to a settlement with a former employee arising out of the sale of Chiron Diagnostics. This amount was recorded as a "Loss from discontinued operations" for the three and nine months ended September 30, 2002.

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 September 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 September 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) from discontinued operations."

### New Accounting Standards

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 us at the end of the first

54

---

reporting period ending after December 15, 2003. The adoption of FIN No. 46 is not expected to have a material impact on the 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 \$1,038.0 million at September 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 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.

**Sources and uses of cash** We had cash and cash equivalents of \$499.9 million and \$316.9 million at September 30, 2003 and 2002, respectively.

*Operating activities* For the nine months ended September 30, 2003, net cash provided by operating activities was \$260.6 million as compared with \$191.8 million for the nine months ended September 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 primarily 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 payable and accrued liabilities at September 30, 2003 as compared to September 30, 2002. Partially offsetting these increases were (i) 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 (ii) larger increases in inventory and accounts receivable at September 30, 2003 as compared to September 30, 2002.

At September 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

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

offset future taxable income without limitation.

At September 30, 2003, we had unutilized federal net operating loss carryforwards attributable to the acquisition of Matrix Pharmaceutical of approximately \$51.9 million, which are available to offset future domestic taxable income ratably through 2021.

At September 30, 2003, we had \$45.9 million of state net operating loss carryforwards, which expire between 2003 and 2021, and state net operating loss carryforwards attributable to the acquisition of Matrix Pharmaceutical, Inc. of approximately \$27.3 million, which are available to offset taxable income ratably through 2012.

At September 30, 2003, we had \$2.2 million of federal business tax credit carryforwards attributed to the acquisition of PathoGenesis Corporation, which expire in 2012.

55

---

At September 30, 2003, we had \$45.5 million of federal alternative minimum tax foreign tax credit carryovers, which expire in 2007, and state business tax credit carryovers of \$23.2 million, which are available to offset future state tax liabilities without limitation.

We anticipate that research and development expenditures in the fourth quarter 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, (vi) research activities focused on identifying several novel vaccines and therapeutics for clinical development in the areas of oncology and infectious disease and (vii) those activities related to development with tifacogin in severe community-acquired pneumonia. In addition, we are required to make capital improvements to our existing manufacturing facilities to support the supply of Betaferon® to Schering. In connection with this project, we are continuing to incur expenses relating to the development of new processes and the performance of test runs related to installed equipment. Net cash from operating activities are expected to fund these research and development activities.

*Investing activities* For the nine months ended September 30, 2003, net cash used in investing activities consisted of cash paid for acquisitions, net of cash acquired of \$804.7 million, purchases of investments in marketable debt securities of \$622.6 million, capital expenditures of \$81.4 million, purchases of equity securities and interests in affiliated companies of \$4.3 million, and other uses of cash of \$13.0 million. For the nine months ended September 30, 2003, cash paid for acquisitions, net of cash acquired, consisted of cash paid to acquire PowderJect Pharmaceuticals, net of cash acquired, of \$803.5 million and cash paid for acquisition costs related to the acquisitions of PathoGenesis Corporation and Matrix Pharmaceutical of \$1.0 million and \$0.2 million, respectively. Cash used in investing activities was offset by proceeds from sales and maturities of investments in marketable debt securities of \$1,112.8 million, proceeds from the sale of equity securities and interests in affiliates companies of \$12.5 million and proceeds from notes receivable of \$0.8 million.

On July 8, 2003, we acquired PowderJect Pharmaceuticals, a company based in Oxford, United Kingdom that develops and commercializes vaccines. We acquired all of the outstanding shares of common stock of PowderJect Pharmaceuticals for 550 pence per ordinary share, which, including estimated acquisition costs, resulted in a total preliminary purchase price of approximately \$945.6 million. As part of the acquisition of PowderJect, we assumed the debt of PowderJect including convertible notes with a face value of 35.0 million British Pounds (fair value of \$57.0 million at July 8, 2003). We paid the convertible notes during the third quarter 2003 and the payment is included in "Net repayment of debt and capital lease" in the Condensed Consolidated Statement of Cash Flows for the nine months ended September 30, 2003.

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 (\$30.6 million at September 30, 2003) for the expansion of our Italian manufacturing facilities, of which we paid 7.9 million Euro (\$8.9 million), as of September 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.

56

---

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

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 \$28.5 million, as of September 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 equity contributions under several venture capital funds including a \$1.3 million capital contribution under two 2003 limited partnership agreements, a \$0.1 million capital contribution under a 2002 limited partnership agreement, a \$1.4 million capital contribution under a 2001 limited partnership agreement and a \$1.5 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 \$29.8 million was paid through September 30, 2003.

For the nine months ended September 30, 2002, net cash used in investing activities consisted of purchases of investments in marketable debt securities of \$581.2 million, capital expenditures of \$74.1 million, net cash paid to acquire Matrix Pharmaceutical, Inc. of \$55.4 million, purchases of equity securities and interests in affiliated companies of \$5.5 million, cash paid to acquire Pulmopharm of \$2.4 million, cash paid for acquisition costs related to the acquisition of PathoGenesis of \$0.4 million and other uses of cash of \$4.0 million. Cash used in investing activities was offset by proceeds from the sale and maturity of investments in marketable debt securities of \$568.5 million, proceeds from the sale of equity securities and interests in affiliated companies of \$18.9 million, proceeds from equity forward contracts of \$6.0 million, proceeds from notes receivable of \$5.2 million and proceeds from sales of assets of \$0.4 million.

*Financing activities* For the nine months ended September 30, 2003, net cash provided by financing activities consisted of \$500.0 million of proceeds from the issuance of convertible debentures (discussed below), \$86.0 million of proceeds from the reissuance of treasury stock (related to stock option exercises), \$2.1 million of proceeds from put options and \$0.5 million of proceeds from the issuance of debt. Cash provided by financing activities was offset by \$132.7 million for the acquisition of treasury stock, \$62.3 million for the repayment of debt and capital lease and \$2.3 million for the net repayment of short-term borrowings.

As discussed in "Note 9 Debt Obligations," on July 30, 2003, we issued \$500.0 million aggregate principal amount of convertible debentures, which mature on August 1, 2033. The convertible debentures accrue interest at a rate of 1.625% per year and interest is payable on February 1 and August 1, commencing February 1, 2004.

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 September 30, 2003, we may repurchase up to an additional 2.1 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. For the third quarter 2003, we had no outstanding put option contracts.

57

---

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 nine months ended September 30, 2002, net cash used in financing activities consisted of \$96.7 million for the acquisition of treasury stock and \$0.6 million for the repayment of short-term borrowings. Cash used in financing activities was offset by \$22.0 million in proceeds from the reissuance of treasury stock (related to stock option exercises) and \$3.7 million in 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 September 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 September 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 (\$4.4 million at September 30, 2003). There were no outstanding borrowings under this facility at September 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 (\$12.6 million at September 30, 2003). There were no outstanding borrowings under these facilities at September 30, 2003 and December 31, 2002.

**Capital Lease** As discussed in "Note 10 Commitments and Contingencies," in July 2003, we entered into a new six-year lease to rent a research and development facility in Emeryville, California following the expiration of the existing operating lease. Effective July 1, 2003, we accounted for this new lease as a capital lease and, as a result, recorded the leased facility and the corresponding liability on our balance sheet. The amount recorded on the balance sheet for the leased facility is \$157.5 million. The amount of the leased facility less the expected value of the facility at the end of the lease term is being amortized on a straight-line basis over the lease term. We expect the value of the facility at the end of the lease term to be approximately \$151.6 million. At the inception of the lease, the future minimum lease payments, exclusive of a residual value guarantee, are approximately \$15.7 million over the lease term. The interest payments represent variable-rate interest payments indexed to a three-month London interbank offered rate plus 40 basis points. The lease provides a \$156.0 million residual value guarantee from Chiron 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 the research collaborations and other joint efforts with us. Decisions by corporate partners on key clinical, regulatory, marketing (including pricing), inventory management and other issues may prevent successful commercialization of the product or otherwise impact our profitability.

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

We must obtain and maintain regulatory approval in order to market most of our products. Generally, these approvals are on a product-by-product and country-by-country basis. In the case of therapeutic products, a separate approval is required for each therapeutic indication. Product candidates that appear promising based on early, and even large-scale, clinical trials may not receive regulatory approval. The results of clinical trials often are susceptible to varying interpretations that may delay, limit or prevent approval or result in the need for post-marketing studies. In addition,

59

---

regulations may be amended from time to time. Revised regulations may require us to reformulate products on a country or regional basis, obtain additional regulatory approvals, or accept additional risks that our products will not maintain market acceptance or be eligible for third party insurance coverage. Increased regulatory scrutiny and restrictions regarding marketing practices for products that are subject to government reimbursement may impact the sales of such products. There is no guarantee that we will be able to satisfy these new regulatory requirements and may suffer a loss of revenue as a result.

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

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

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

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

In connection with our research and manufacturing activities, we utilize some hazardous materials. 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.

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.

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

In connection with the production of our flu vaccine products, we must purchase large quantities of chicken eggs. Currently, we purchase those eggs and incubation services from a single supplier and, pursuant to the contract with that supplier, we are 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 our supplier were to fail to supply eggs in sufficient quantities or quality, including as a result of any health or other issues related to the chickens, our business would be materially adversely affected.

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

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

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

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

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

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

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

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

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

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

the competitive product may have therapeutic or other advantages; or

new competitors may enter into markets where we currently have significant competitive advantage.

---

The technologies applied by our competitors and us are rapidly evolving, and new developments frequently result in price competition and product obsolescence. In addition, we may be impacted by competition from generic forms of our products or substitute products. 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. Subsequently, the application was withdrawn and under terms of a settlement agreement reached in October 2003, approval will not be sought to market this generic product until the 2014 expiration of our patent in the U.S. covering the formulation of TOBI®.

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

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

We seek to obtain patents on many of our inventions. Without the protection of patents, competitors may be able to use our inventions to manufacture and market competing products without being required to undertake the lengthy and expensive development efforts made by us and without having to pay royalties or otherwise compensate us for the use of the invention. We have no assurance that patents and patent applications owned or licensed to us will provide substantial protection. Important legal questions remain to be resolved as to the extent and scope of available patent protection for biotechnology products and processes in the U.S. and other important markets. We do not know how many of our pending patent applications will be granted, or the effective coverage of those that are granted. In the U.S. and other important markets, the issuance of a patent is neither conclusive as to its validity nor the enforceable scope of its claims. We have engaged in significant litigation to determine the scope and validity of certain of our patents and expect to continue to do so. An adverse outcome of litigation could result in the reduction or loss of royalty revenues. Engaging in patent litigation against one party may place significant royalty revenues received or to be received from other parties at risk. Even if we are successful in obtaining and defending patents, there can be no assurance that these patents will provide substantial protection. The length of time necessary to resolve patent litigation successfully may allow infringers to gain significant market advantage. Third parties may be able to design around the patents and develop competitive products that do not use the inventions covered by our patents. Many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties (for example, the third party's product is needed to meet a threat to public health or safety in that country, or the patent owner has failed to "work" the invention in that country, or the third party has patented improvements). In addition, most countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may be limited to monetary relief and may be unable to enjoin infringement, which could materially diminish the value of the patent. In addition, royalty revenues 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. If the United States Congress enacts legislative proposals addressing parallel importation currently being deliberated, revenues from certain products may be affected by this change in U.S. policy. The growth of managed care in the U.S. also has placed pressure on the pricing of healthcare products. These pressures can be expected to continue.

63

---

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

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

use of cash resources;

potentially dilutive issuances of equity securities;

the incurrence of debt and contingent liabilities, impairment losses or restructuring charges;

large write-offs and difficulties in assessment of the relative percentages of in-process research and development expense that can be immediately written off as compared to the amount which must be amortized over the appropriate life of the asset; and

amortization expenses related to other intangible assets.

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

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

challenges associated with managing an increasingly diversified business;

difficulties in assimilating the operations, products, technology, information systems or personnel of the acquired company;

diversion of management's attention from other business concerns;

inability to maintain uniform standards, controls, procedures and policies;

the assumption of known and unknown liabilities of the acquired company, including intellectual property claims; and

subsequent loss of key personnel 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, foreign currency exchange rates and levels of indebtedness could harm our business.*

We have significant cash balances and investments. Our financial results, therefore, are sensitive to interest rate fluctuations. In addition, we sell products in many countries throughout the world, and our

financial results could be significantly affected by fluctuations in foreign currency exchange rates or by weak economic conditions in foreign markets.

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

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

We have an alliance with Novartis AG, a life sciences company headquartered in Basel, Switzerland. Under a series of agreements between Chiron and Novartis, and as a result of subsequent stock issuances by Chiron, Novartis' ownership interest in Chiron was approximately 42% as of September 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

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

registration statements under the Securities Act in order to permit Novartis to offer and sell shares of our common stock. Sales of a substantial number of shares of our common stock by Novartis in the public market could adversely affect the market price of our common stock.

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

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

fluctuations in earnings from period to period;

results of clinical trials conducted by us or by our competitors;

announcements by us or our competitors regarding product development efforts, including the status of regulatory approval applications;

the outcome of legal proceedings, including claims filed by us against third parties to enforce our patents and claims filed by third parties against us relating to patents held by the third parties;

the launch of competing products;

the resolution of (or failure to resolve) disputes with 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, The Netherlands and, with the acquisition of PowderJect, the United Kingdom. All of these jurisdictions have in the past and may in the future make changes to their corporate tax rates and other tax laws, which could increase our future tax provision. We have negotiated a number of rulings regarding income and other taxes that are subject to periodic review and renewal. If such rulings are not renewed or are substantially modified, income taxes payable in particular jurisdictions could increase. While we believe that all material tax liabilities are reflected properly in our balance sheet, we are presently under audit in several jurisdictions and may be subject to further audits in the future, and we have no assurance that we will prevail in all cases in the event the taxing authorities disagree with our interpretations of the tax law. In addition, we have assumed liabilities for all income taxes incurred prior to the sales of our former subsidiaries,

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

Chiron Vision (subject to certain limitations) and Chiron Diagnostics. Future levels of research and development spending, capital investment and export sales will impact our entitlement to related tax credits and benefits which have the effect of lowering our effective tax rate.

*Volatility of earnings could negatively impact our business.*

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

inventory management practices, including wholesale ordering patterns;

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

seasonality of certain vaccine products;

the tender driven nature of certain vaccine products;

the nature of our collaborative, royalty and license arrangements and other revenue sources;

foreign currency exchange rate fluctuations; and

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

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

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

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

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

**Market risk management** Our cash flow and earnings are subject to fluctuations due to changes in foreign currency exchange rates, changes in interest rates and changes in the fair value of equity securities held for sale. We attempt to limit our exposure to some or all of these market risks through the use of various financial instruments and derivative securities. During the third quarter of 2003, our exposure to market risks changed as our cash balances decreased and our exposure to changes in foreign currency exchange rates increased with the acquisition of Powderject Pharmaceuticals and our debt balances increased with the issuance of \$500.0 million of convertible debt. We seek to manage our exposures to market risks as discussed in further detail in Part II, Item 7A, "Quantitative and Qualitative Disclosures About Market Risk" in our annual Report on Form 10-K for the year ended December 31, 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) 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.

67

---

## 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.

#### *Active Biotech AB*

In June 2003, PowderJect Pharmaceuticals Plc ("PowderJect") filed a Request for Arbitration before the Arbitral Tribunal of the Arbitration Institute of the Stockholm Chamber of Commerce in Sweden against Active Biotech AB ("Active Biotech"). PowderJect claims that Active Biotech breached certain warranties and representations made in the July 2, 2001 Agreement by which PowderJect acquired SBL Vaccin AB ("SBL") from Active Biotech (the "Agreement"). PowderJect seeks compensatory damages and legal fees.

In July 2003, the Committee for Proprietary Medicinal Products granted a positive opinion to Chiron's oral travel vaccine Dukoral for the prevention of cholera. Based on this opinion, Active Biotech sent Chiron a letter in September 2003 stating that pursuant to the Royalty Agreement between Active Biotech and SBL, Chiron would be obligated to pay Active Biotech certain milestone payments and royalties on future sales upon final approval. Chiron disputes these obligations on a variety of grounds. If the parties are unable to resolve this dispute, the dispute may become subject to arbitration.

It is not known when nor on what basis this matter 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 the October 10, 2000 HIV Probe License Agreement and the January 1, 2001 HIV Blood Screening Agreement (the "License Agreements") 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 License Agreements. In April 2003, the parties initiated alternative dispute resolution procedures (the "ADR procedures") mandated by the License Agreements to address these and potentially other disputes. The parties have been unable to resolve the matter, and in November 2003, Chiron invoked the arbitration provisions provided under the ADR procedures, thereby initiating formal arbitration pursuant to 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

68

---

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. In August 2003, Chiron enforced the injunction on Roche. 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 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. In October 2003, the Court of Appeals ruled that Roche's HCV immunoassay kits containing a certain antigen infringe all three German patents. Accordingly, the Court of Appeals 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 1994 and to destroy any such kits in its possession in Germany. This judgment is subject to appeal. 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.

*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. Chiron has appealed this judgment to the United States Court of Appeals for the Federal Circuit. Meanwhile, the Delaware Court has scheduled the trial for May 16, 2005.

In August 2003, Chiron filed a complaint in the United States District Court for the Northern District of California against Laboratory Corporation of America Holdings, Laboratory Corporation of America and National Genetics Institute (collectively, the "Defendants"), seeking damages and an injunction against Defendants manufacture, use and sale of certain HIV assays for infringing Chiron's U.S. Patent No. 6,531,276 (the "'276 patent").

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

69

---



*Medicare, Medi-Cal Investigation*

In September 2000, the Office of the Attorney General of the State of California Department of Justice (the "California Attorney General") served a subpoena on Chiron. Chiron believes that the subpoena was issued in connection with a pending, but as yet unserved, qui tam lawsuit against Chiron and a number of other pharmaceutical companies. With respect to Chiron, the subpoena seeks information related to pricing to the Medi-Cal program of certain generic oncology drugs sold by Cetus-Ben Venue Therapeutics, a joint venture between Chiron and Ben Venue Laboratories. Chiron sold its interest in that joint venture in 1996. In November 2003, the California Attorney General served Chiron with a second subpoena, which Chiron believes is also connected to a qui tam action.

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

*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 sought 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. In October 2003, pursuant to a settlement agreement, the lawsuit was dismissed. Under the terms of the settlement agreement, Roxane, which had previously withdrawn its U.S. Food and Drug Administration application for approval of a generic equivalent of TOBI®, agreed it would not seek U.S. Food and Drug Administration approval to market the product until the expiration of the '269 patent in 2014. Chiron and Children's Hospital agreed to dismiss their infringement relief claims against Roxane, and Roxane dropped its challenge to the '269 patent. No party received monetary compensation as part of the settlement. This matter is now concluded.

*Sorin Biomedica/Snia*

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

70

---

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.

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

None.

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

Edgar Filing: CHIRON CORP - Form 10-Q

(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, dated as of June 12, 2003, between Chiron and Merrill Lynch & Co., Inc., and Merrill Lynch, Pierce, Fenner & Smith, Incorporated, incorporated by reference to Exhibit 4.02 of Chiron's report on Form 10-Q for the period ended June 30, 2001.
4.03	Form of Liquid Yield Option Note™ due 2031 (Zero Coupon Senior) (included as exhibits A-1 and A-2 to the Indenture filed as Exhibit 4.01 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	Indenture between Chiron and U.S. Bank National Association, as trustee, dated as of July 30, 2003, incorporated by reference to Exhibit 4.1 of Chiron's registration statement on Form-3 filed with the Commission on September 23, 2003.
4.05	Registration Rights Agreement dated as of July 30, 2003, between Chiron and Morgan Stanley & Co., Goldman, Sachs & Co., Banc of America Securities LLC and BNP Paribas Securities Corp., incorporated by reference to Exhibit 4.3 of Chiron's registration statement on Form-3 filed with the Commission on September 23, 2003.
4.06	Form of Convertible Debentures (included in Exhibit 4.04), incorporated by reference to Exhibit 4.2 of Chiron's registration statement on Form-3 filed with the Commission on September 23, 2003.
4.07	Reserved.

71

10.102	Amended and Restated Revolving Credit Agreement, dated as of August 13, 2002, by and between Chiron and Bank of America, N.A., and exhibits thereto, incorporated by reference to Exhibit 10.102 of Chiron's report on Form 10-Q for September 30, 2002.
10.325	Agreement, dated as of July 1, 2003, between The American National Red Cross and Chiron. (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".)
10.326	WNV Association Agreement, dated as of July 1, 2003, between America's Blood Centers and Chiron, and Form of Member Supplement. (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".)
10.519	Corporate Governance Guidelines.
10.624	Letter Agreement dated August 12, 2003, between Chiron and Craig A. Wheeler.*
31.1	Certification of the Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
31.2	Certification of the Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
32.1	Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

\*

Management contract, compensatory plan or arrangement.

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

On July 8, 2003, Chiron filed a Current Report on Form 8-K, furnishing under Item 5, announcement that the recommended cash offer being made by UBS Investment Bank on behalf of Chiron's indirect wholly-owned subsidiary, Chiron UK-1 Limited, to acquire all of the issued and to be issued share capital of PowderJect Pharmaceuticals plc, as set out in the offer document dated May 19, 2003, had been declared unconditional and would remain open for acceptance until further notice.

On July 23, 2003, Chiron filed a Current Report on Form 8-K, furnishing under Item 2, announcement that its indirect wholly-owned subsidiary, Chiron UK-1 Limited, had acquired or agreed to acquire or had received valid acceptances of 83,069,482 shares, representing 90.07% of the issued and to be issued share capital of PowderJect Pharmaceuticals plc for 550 pence per PowderJect ordinary share (the "Offer"), and that as of July 21, 2003, Chiron had paid \$804.7 million to purchase 88.5 million PowderJect shares, representing 93.9% of the existing issued share capital of PowderJect as of that date.

On July 23, 2003, Chiron filed a Current Report on Form 8-K, furnishing under Item 9, Chiron's preliminary results for its second quarter ended June 30, 2003, via a press release.

On July 28, 2003, Chiron filed a Current Report on Form 8-K, furnishing under Item 5, announcement that it intended to raise approximately \$450 million through an offering of convertible debentures, and may raise up to an additional \$50 million upon exercise of an option to purchase additional convertible debentures granted by Chiron in connection with the offering. The convertible

72

debentures will be 1.625% interest coupons convertible into shares of Chiron common stock. Chiron intends to use the net proceeds from the offering for general corporate purposes.

On September 15, 2003, Chiron filed a Current Report on Form 8-K, furnishing under Item 5, announcement that its chairman, Seán P. Lance intends to retire from active service with Chiron and its board of directors as of the annual meeting of stockholders in May 2004. The board has determined that it would elect Chiron president and chief executive officer Howard H. Pien as chairman at that same meeting.

On September 22, 2003, Chiron filed an Amendment No. 1 to its Current Report on Form 8-K/A, relating to the acquisition of PowderJect Pharmaceuticals plc, and furnishing under Item 7 the audited consolidated financial statements of PowderJect Pharmaceuticals plc and subsidiaries as of and for the year ended March 31, 2003, giving effect to Chiron's acquisition of PowderJect for approximately \$919.3 million.

On September 23, 2003, Chiron filed a Current Report on Form 8-K, furnishing under Item 5, announcement that it has filed a registration statement on Form S-3 with the Commission relating to the resale of \$500 million principal amount of its 1.625% convertible debentures due 2033 and the shares of its common stock issuable upon conversion of the debentures. Chiron will not receive any proceeds from any resale by the selling security holders of the debentures or the shares of common stock issuable upon conversion of the debentures.

73

**CHIRON CORPORATION**

**September 30, 2003**

**SIGNATURES**

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

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

### CHIRON CORPORATION

DATE: November 12, 2003

BY: /s/ HOWARD H. PIEN

---

Howard H. Pien  
*President and Chief Executive Officer*

DATE: November 12, 2003

BY: /s/ DAVID V. SMITH

---

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

74

---

### 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 BALANCE SHEETS (Continued) (Unaudited) (In thousands, except share data)

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

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

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

CHIRON CORPORATION NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS September 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

#### SIGNATURES