

CHIRON CORP  
Form 10-Q  
November 07, 2001

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 10-Q**

(Mark one)

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

For the quarterly period ended September 30, 2001

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 0-12798

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**CHIRON CORPORATION**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**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)

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Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

**Title of Class**  
Common Stock, \$0.01 par value

**Outstanding at October 31, 2001**  
189,151,125

**CHIRON CORPORATION**

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**Item 1. Financial Statements**

**CHIRON CORPORATION**

**CONDENSED CONSOLIDATED BALANCE SHEETS**

**(Unaudited)**

**(In thousands, except share data)**

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	September 30, 2001	December 31, 2000
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 249,880	\$ 166,990
Short-term investments in marketable debt securities	381,568	534,621
Total cash and short-term investments	631,448	701,611
Accounts receivable, net	295,396	218,946
Current portion of notes receivable	5,088	6,179
Inventories	115,966	108,713
Current net deferred income tax asset	29,748	35,980
Derivative financial instruments	21,902	
Other current assets	44,818	31,129
Total current assets	1,144,366	1,102,558
Noncurrent investments in marketable debt securities	571,553	149,925
Property, plant, equipment and leasehold improvements, at cost:		
Land and buildings	140,903	138,981
Laboratory, production and office equipment	360,422	345,495
Leasehold improvements	87,289	87,899
Construction-in-progress	34,971	24,926
	623,585	597,301
Less accumulated depreciation and amortization	(314,546)	(284,098)
Property, plant, equipment and leasehold improvements, net	309,039	313,203
Purchased technologies, net	284,901	302,134
Goodwill, net	227,914	208,536
Other intangible assets, net	162,597	195,870
Investments in equity securities and affiliated companies	108,282	155,794
Noncurrent notes receivable	9,684	12,999
Other noncurrent assets	20,972	17,057
	\$ 2,839,308	\$ 2,458,076
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 43,225	\$ 48,492
Accrued compensation and related expenses	48,456	44,972
Short-term borrowings	1,383	1,171
Current portion of long-term debt		1,212
Current portion of unearned revenue	41,984	48,273
Income taxes payable	118,122	146,585
Derivative financial instruments	197	
Other current liabilities	110,250	123,151
Total current liabilities	363,617	413,856
Long-term debt	407,001	3,039
Noncurrent net deferred income tax liability	62,295	74,921
Noncurrent unearned revenue	77,637	41,677
Other noncurrent liabilities	43,224	40,476
Minority interest	3,666	3,025

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	September 30, 2001	December 31, 2000
Total liabilities	957,440	576,994
Commitments and contingencies (Note 10)		
Put options	42,954	
Stockholders' equity:		
Common stock	1,917	1,917
Additional paid-in capital	2,379,499	2,418,032
Deferred stock compensation	(19,177)	(22,986)
Accumulated deficit	(373,173)	(438,967)
Accumulated other comprehensive income (loss)	(14,592)	17,497
Treasury stock, at cost (2,875,000 shares at September 30, 2001 and 2,183,000 shares at December 31, 2000)	(135,560)	(94,411)
Total stockholders' equity	1,838,914	1,881,082
	\$ 2,839,308	\$ 2,458,076

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

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CHIRON CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2001	2000	2001	2000
Revenues:				
Product sales, net	\$ 214,039	\$ 143,580	\$ 556,545	\$ 462,207
Equity in earnings of unconsolidated joint businesses	21,260	23,430	59,141	61,552
Collaborative agreement revenues	11,449	5,107	32,480	19,202
Royalty and license fee revenues	44,672	37,588	147,817	105,539
Other revenues	10,538	11,276	26,767	30,081
Total revenues	301,958	220,981	822,750	678,581
Operating expenses:				
Cost of sales	79,494	58,007	198,053	157,537
Research and development	80,469	69,230	249,846	211,398

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	Three Months Ended September 30,		Nine Months Ended September 30,	
Selling, general and administrative	62,197	45,671	181,882	142,868
Amortization expense	11,498	1,985	34,383	6,158
Restructuring and reorganization charge reversals (Note 5)				(447)
Other operating expenses	4,076	2,138	12,352	8,963
<b>Total operating expenses</b>	<b>237,734</b>	<b>177,031</b>	<b>676,516</b>	<b>526,477</b>
Income from operations	64,224	43,950	146,234	152,104
Gain (loss) on sale of assets			2,426	(224)
Interest expense	(3,140)	(3,251)	(4,403)	(12,610)
Other income, net	14,052	26,971	46,279	70,051
Minority interest	(394)	(224)	(936)	(625)
<b>Income from continuing operations before income taxes</b>	<b>74,742</b>	<b>67,446</b>	<b>189,600</b>	<b>208,696</b>
Provision for income taxes	23,364	24,441	59,535	68,195
<b>Income from continuing operations</b>	<b>51,378</b>	<b>43,005</b>	<b>130,065</b>	<b>140,501</b>
Gain on disposal of discontinued operations (Note 3)	1,515	74	5,168	2,416
<b>Net income</b>	<b>\$ 52,893</b>	<b>\$ 43,079</b>	<b>\$ 135,233</b>	<b>\$ 142,917</b>
Basic earnings per share (Note 2):				
Income from continuing operations	\$ 0.27	\$ 0.24	\$ 0.69	\$ 0.78
Net income	\$ 0.28	\$ 0.24	\$ 0.71	\$ 0.79
Diluted earnings per share (Note 2):				
Income from continuing operations	\$ 0.26	\$ 0.23	\$ 0.67	\$ 0.74
Net income	\$ 0.27	\$ 0.23	\$ 0.69	\$ 0.75

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

**CHIRON CORPORATION**  
**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME**

(Unaudited)

(In thousands)

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	Three Months Ended September 30,		Nine Months Ended September 30,	
	2001	2000	2001	2000
Net income	\$ 52,893	\$ 43,079	\$ 135,233	\$ 142,917
Other comprehensive income (loss):				
Change in foreign currency translation adjustment during the period, net of tax provision (benefit) of \$1,808 and \$(1,579) for the three months ended September 30, 2001 and 2000, respectively, and \$1,263 and \$(2,213) for the nine months ended September 30, 2001 and 2000, respectively	32,720	(36,943)	(10,884)	(46,830)
Unrealized derivative gains (losses) from cash flow hedges:				
Net unrealized derivative gains (losses) from cash flow hedges arising during the period, net of tax benefit of \$516 and \$99 for the three and nine months ended September 30, 2001, respectively	(819)		76	
Reclassification adjustment for net (gains) losses included in net income, net of tax (provision) benefit of \$116 and \$(31) for the three and nine months ended September 30, 2001	184		(50)	
Net unrealized derivative gains (losses) from cash flow hedges	(635)		26	
Unrealized gains (losses) from investments:				
Net unrealized holding gains (losses) arising during the period, net of tax provision (benefit) of \$(8,006) and \$840 for the three months ended September 30, 2001 and 2000, respectively, and \$(11,407) and \$23,106 for the nine months ended September 30, 2001 and 2000, respectively	(12,740)	1,371	(17,633)	37,701
Reclassification adjustment for net losses (gains) included in net income, net of tax benefit (provision) of \$380 and \$374 for the three months ended September 30, 2001 and 2000, respectively, and \$(2,271) and \$314 for the nine months ended September 30, 2001 and 2000, respectively	603	610	(3,598)	512
Net unrealized gains (losses) from investments	(12,137)	1,981	(21,231)	38,213
Other comprehensive income (loss)	19,948	(34,962)	(32,089)	(8,617)
Comprehensive income	\$ 72,841	\$ 8,117	\$ 103,144	\$ 134,300

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

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(Unaudited)

(In thousands)

	Nine Months Ended September 30,	
	2001	2000
Net cash provided by operating activities	\$ 108,118	\$ 199,367
Cash flows from investing activities:		
Purchases of investments in marketable debt securities	(810,032)	(3,330,129)
Proceeds from sale and maturity of investments in marketable debt securities	535,913	3,907,677
Payments on notes receivable	6,599	3,233
Capital expenditures	(42,048)	(24,337)
Proceeds from sale of assets	8,191	1,000
Purchases of equity securities and interests in affiliated companies	(11,144)	(8,750)
Proceeds from sale of equity securities and interests in affiliated companies	11,355	4,788
Cash paid to purchase PathoGenesis Corporation	(6,922)	(677,065)
Other, net	(2,822)	(23,695)
Net cash used in investing activities	(310,910)	(147,278)
Cash flows from financing activities:		
Net proceeds from (repayment of) short-term borrowings	212	(16,325)
Repayment of debt and capital leases	(1,511)	(70,847)
Payments to acquire treasury stock	(163,187)	(213,105)
Proceeds from reissuance of treasury stock	52,186	63,751
Proceeds from issuance of common stock		1,045
Payment of issuance costs on Liquid Yield Option Notes	(9,892)	
Proceeds from issuance of Liquid Yield Option Notes	401,829	
Proceeds from put options	6,045	
Net cash provided by (used in) financing activities	285,682	(235,481)
Net increase (decrease) in cash and cash equivalents	82,890	(183,392)
Cash and cash equivalents at beginning of the period	166,990	363,865
Cash and cash equivalents at end of the period	\$ 249,880	\$ 180,473

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

CHIRON CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2001

(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, 2001, and for the three and nine months ended September 30, 2001 and 2000, is unaudited but includes all normal recurring adjustments, which the management of Chiron Corporation ("Chiron" or the "Company") believes to be necessary for fair presentation of the periods presented.

The Condensed Consolidated Balance Sheet amounts at December 31, 2000 have been derived from audited financial statements. Interim results are not necessarily indicative of results for a full year. This information should be read in conjunction with Chiron's audited Consolidated Financial Statements for the year ended December 31, 2000, which are included in the Annual Report on Form 10-K filed by the Company with the Securities and Exchange Commission.

*Principles of Consolidation*

The Condensed Consolidated Financial Statements include the accounts of the Company and its majority-owned subsidiaries. For consolidated majority-owned subsidiaries in which the Company owns less than 100%, the Company records "Minority interest" in the Condensed Consolidated Financial Statements to account for the ownership interest of the minority owner. Investments in joint ventures, partnerships and interests in which the Company has an equity interest of 50% or less are accounted for using either the equity or cost method. All significant intercompany accounts and transactions have been eliminated in consolidation.

On September 21, 2000, Chiron acquired PathoGenesis Corporation ("PathoGenesis"). The Company included PathoGenesis' operating results, including the seven business days from September 21 to 30, 2000, in its consolidated operating results beginning on October 1, 2000. PathoGenesis' operating results for the seven business days in September 2000 were not significant to the Company's consolidated operating results (see Note 4).

In 2001, the Company became a limited partner of Forward Venture IV, L.P. The Company will pay \$15.0 million over ten years, of which \$4.3 million was paid through September 30, 2001, for a 6.35% ownership percentage. In 2000, the Company became a limited partner of Burrill Biotechnology Capital Fund, L.P. The Company will pay \$25.0 million over five years, of which \$10.8 million was paid through September 30, 2001, for a 23.19% ownership percentage. The Company accounts for both investments under the equity method of accounting pursuant to EITF Topic No. D-46 "Accounting for Limited Partnership Investments."

*Use of Estimates and Reclassifications*

The preparation of financial statements in accordance with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the amounts reported in the Company's consolidated financial statements and accompanying notes. Actual results could differ materially from those estimates.

The Company, 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 the Company's earnings

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release and the filing of its 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.

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

Related to the acquisition of PathoGenesis on September 21, 2000, the Company allocated the purchase price based on the estimated fair values of the assets acquired and liabilities assumed. Through June 30, 2001, the Company recorded a purchase price adjustment resulting from (i) a final reconciliation of PathoGenesis registered shares of common stock, (ii) the true-up of severance, employee relocation, leasing and legal costs to amounts actually paid and (iii) the related deferred tax effects, the total of which resulted in a \$1.3 million increase to the purchase price and a \$0.1 million increase to goodwill. There was no purchase price adjustment in the third quarter of 2001. For the nine months ended September 30, 2001, this adjustment had no material impact on amortization expense or earnings per share.

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### *Inventories*

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

	September 30, 2001	December 31, 2000
Finished goods	\$ 24,297	\$ 25,590
Work-in-process	61,686	57,754
Raw materials	29,983	25,369
	\$ 115,966	\$ 108,713

### *Derivative Financial Instruments*

Effective January 1, 2001, the Company implemented Statement of Financial Accounting Standards ("SFAS") No. 133, "Accounting for Derivative Instruments and Hedging Activities" ("SFAS 133"), as amended by SFAS No. 138, which establishes accounting and reporting standards for derivatives and hedging activities. All derivatives are required to be recorded on the balance sheet at fair value. Changes in the fair value of derivatives are accounted for depending upon the exposure being hedged and whether the derivatives qualify and are designated for hedge accounting.

The Company uses various derivatives, such as foreign currency option contracts ("currency options") and forward foreign currency contracts ("currency forwards"), to reduce foreign exchange risks. The Company also uses forward sales contracts ("equity forwards") to reduce equity securities risk. Derivatives are not used for trading or speculative purposes. The Company's control environment includes policies and procedures for risk assessment and the approval, reporting and monitoring of foreign currency hedging activities. Counterparties to the Company's hedging agreements are major financial institutions. These hedging agreements are generally not collateralized. The Company

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manages the risk of counterparty default on its derivatives through the use of credit standards, counterparty diversification and monitoring of counterparty financial conditions. Chiron has not experienced any losses due to counterparty default.

### Foreign Currency Hedging

A significant portion of the Company's operations consists of manufacturing and sales activities in western European countries. As a result, the Company's financial results may be affected by changes in the foreign currency exchange rates of those related countries.

Chiron may selectively hedge anticipated currency exposures by purchasing currency options, which are designated as cash flow hedges under SFAS 133 and typically expire within twelve months. Changes in the fair value of currency options are recorded in "Other comprehensive income" and are recognized in earnings when the forecasted transaction occurs. When currency options expire, any amounts recorded in "Other comprehensive income" are reclassified to earnings.

The Company also uses currency forwards to hedge the gains and losses generated by the remeasurement of certain assets and liabilities denominated in nonfunctional currencies. These derivatives are not designated as hedges under SFAS 133. Changes in the fair value of currency forwards are recognized currently in earnings. Typically, changes in the fair value of currency forwards are offset largely by changes upon remeasurement of the underlying assets and liabilities. Typically, these contracts have maturities of three months or less.

### Equity Securities Hedging

The Company has exposure to equity price risk because of its investments in equity securities. Typically, the Company obtains these securities through its collaboration agreements with other pharmaceutical and biotechnology partners. Changes in share prices affect the value of Chiron's equity portfolio.

The Company selectively enters into equity forwards, which are designated as fair value hedges under SFAS 133 and typically expire within two to four years. At the inception of the hedge, the difference between the cost and the fair value of the equity investment remains in "Other comprehensive income." Subsequent changes in the fair value of the equity forwards and the underlying equity investment are recognized in

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earnings. When equity forwards mature and the underlying equity investment is sold, any amounts recorded in "Other comprehensive income" related to the underlying equity investment are reclassified to earnings.

For currency options and equity forwards, the Company assumes no ineffectiveness because the critical terms of the derivative instrument and of the underlying exposure are the same. The Company expects that changes in the fair value of the underlying exposure will be offset completely by changes in the fair value of the derivative instrument, both at inception and on an ongoing basis. The critical terms are reviewed quarterly. All time value changes are deemed ineffective and are recognized immediately in earnings.

### *Income Taxes*

The effective tax rate for 2001 is estimated to be approximately 31.4% of pretax income from continuing operations, which reflects the amortization of goodwill and acquired identifiable intangible assets related to the PathoGenesis acquisition. The effective tax rate may be affected in future periods by changes in management's estimates with respect to the Company's deferred tax assets and other items affecting the overall tax rate. Income tax expense for the three and nine months ended September 30, 2000 was based on an estimated annual effective tax rate on pretax income from continuing operations of approximately 32.7%.

The annual reported effective tax rate for 2000 was 84.4% of pretax income from continuing operations and reflected the write-off of purchased in-process technologies and amortization expense on goodwill and acquired identifiable intangible assets related to the PathoGenesis acquisition.

### *Put Options*

Proceeds from sales of put options, which allow for net-cash, net-share or physical settlement, are recorded in stockholders' equity and an amount equal to the redemption price of the common stock is reclassified from permanent equity to temporary equity. If a put option is reclassified from permanent or temporary equity to an asset or a liability, the change in fair value of the put option during the period it was classified as equity is recorded in stockholders' equity. The Company reassesses the classification of its put options on a quarterly basis. When a put option is physically settled, the amount reported in temporary equity is transferred and reported as an addition to permanent equity.

In January 2001, the Company initiated a put option program. Under this program, the Company enters into contracts with third parties to sell put options on Chiron stock, entitling the holders to sell to the Company a specified amount of shares at a specified price per share on a specified date. In connection with the sales, the Company collects premiums, which are recorded in "Additional paid-in capital" in the Condensed Consolidated Balance Sheets. For the nine months ended September 30, 2001, the Company collected premiums of \$6.0 million and, for contracts which expired, purchased 0.4 million shares in connection with the put option program. As of September 30, 2001, the Company has outstanding contracts with a third party to sell put options on Chiron stock, entitling the holder to sell to the Company 1.0 million shares. The options expire at various dates through December 2001 and have an average exercise price of \$42.95 per share. The amount of the Company's obligation to repurchase such shares upon exercise of the outstanding put options, totaling \$43.0 million, was reclassified from "Additional paid-in capital" to "Put options" in temporary equity in the Company's Condensed Consolidated Balance Sheets at September 30, 2001.

### *Comprehensive Income*

In the first and second quarters of 2001, the foreign currency translation component of comprehensive income included the tax effects of the non-permanently reinvested 2000 earnings in Chiron S.p.A. and 31 Corsa GmbH in accordance with the investment and tax policy adopted in 2000. During the first and second quarters of 2001, the undistributed 2001 earnings in Chiron S.p.A. and 31 Corsa GmbH were expected to be reinvested permanently and, as a result, no tax effect was

provided on the foreign currency translation component of comprehensive income. Beginning in the third quarter of 2001, tax effects of the decision not to permanently reinvest the 2001 earnings in Chiron S.p.A. and 31 Corsa GmbH were recorded. For all other foreign jurisdictions, the undistributed earnings of the Company's foreign investments are expected to be reinvested permanently.

### *Treasury Stock*

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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." The Company charged losses of \$28.6 million and \$69.4 million for the three and nine months ended September 30, 2001, respectively, and \$25.6 million and \$114.1 million for the three and nine months ended September 30, 2000, respectively, to "Accumulated deficit" in the Condensed Consolidated Balance Sheets.

### Note 2 Earnings Per Share

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2001	2000	2001	2000
<b>Income (Numerator):</b>				
Income from continuing operations available to common stockholders	\$ 51,378	\$ 43,005	\$ 130,065	\$ 140,501
Plus: Interest on 1.90% convertible debentures, net of taxes		1,607		5,264
Plus: Interest on 5.25% convertible debentures, net of taxes				440
Income from continuing operations available to common stockholders, plus assumed conversions	\$ 51,378	\$ 44,612	\$ 130,065	\$ 146,205
<b>Shares (Denominator):</b>				
Weighted-average common shares outstanding	189,626	182,782	189,643	181,418
Effect of dilutive securities:				
Stock options and equivalents	4,818	6,337	5,085	6,394
Warrants	107	439	318	427
Put options	31		18	
1.90% convertible debentures		8,637		8,731
5.25% convertible debentures				526
Weighted-average common shares outstanding, plus assumed conversions	194,582	198,195	195,064	197,496
Basic earnings per share	\$ 0.27	\$ 0.24	\$ 0.69	\$ 0.78
Diluted earnings per share	\$ 0.26	\$ 0.23	\$ 0.67	\$ 0.74

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2001	2000	2001	2000
<b>Income (Numerator):</b>				
Net income available to common stockholders	\$ 52,893	\$ 43,079	\$ 135,233	\$ 142,917
Plus: Interest on 1.90% convertible debentures, net of taxes		1,607		5,264
Plus: Interest on 5.25% convertible debentures, net of taxes				440
Net income available to common stockholders, plus assumed conversions	\$ 52,893	\$ 44,686	\$ 135,233	\$ 148,621
<b>Shares (Denominator):</b>				
Weighted-average common shares outstanding	189,626	182,782	189,643	181,418
Effect of dilutive securities:				
Stock options and equivalents	4,818	6,337	5,085	6,394
Warrants	107	439	318	427
Put options	31		18	
1.90% convertible debentures		8,637		8,731
5.25% convertible debentures				526
Weighted-average common shares outstanding, plus assumed conversions	194,582	198,195	195,064	197,496
Basic earnings per share	\$ 0.28	\$ 0.24	\$ 0.71	\$ 0.79
Diluted earnings per share	\$ 0.27	\$ 0.23	\$ 0.69	\$ 0.75

For the three months ended September 30, 2001 and 2000, stock options to purchase 9.0 million and 2.1 million shares, respectively, and for the nine months ended September 30, 2001 and 2000, stock options to purchase 6.7 million and 1.6 million shares, respectively, with exercise prices greater than the average market prices of common stock, were excluded from the respective computations of diluted earnings per share as their inclusion would be antidilutive.

Also excluded from the computations of diluted earnings per share were 5.2 million shares of common stock for each of the three and nine months ended September 30, 2001 issuable upon conversion of the Liquid Yield Option Notes, as discussed in Note 9, as their inclusion would be antidilutive.

As a result of the acquisition of Cetus on December 12, 1991, a warrant to purchase 0.6 million shares of Chiron common stock with an exercise price of \$13.125 per share was outstanding. On July 31, 2001, the holder elected a cashless exercise of the warrant, based upon the Company's closing

stock price on August 3, 2001, for which the Company issued approximately 0.4 million shares of its common stock.

As of December 31, 2000, substantially all of the 1.90% and 5.25% convertible debentures were converted into 12.0 million shares of common stock.

### Note 3 Discontinued Operations

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In a strategic effort to focus on its core businesses of Biopharmaceuticals, Vaccines and Blood Testing, the Company completed the sale of Chiron Diagnostics and Chiron Vision in 1998 and 1997, respectively. For the three and nine months ended September 30, 2001, basic and diluted earnings per share from discontinued operations were \$0.01 and \$0.02, respectively. Discontinued operations had no impact on basic or diluted earnings per share for the three months ended September 30, 2000. For the nine months ended September 30, 2000, basic and diluted earnings per share from discontinued operations were \$0.01.

The "Gain on disposal of discontinued operations" consisted of the following (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2001	2000	2001	2000
Reversal of reserves for severance obligations	\$ 1,600	\$	\$ 1,600	\$
Reversal of reserves for indemnity obligations			1,500	2,190
Gain on the sale of the real estate assets			1,644	
Other		119		364
Income tax benefit (provision)	(85)	(45)	424	(138)
	<u>\$ 1,515</u>	<u>\$ 74</u>	<u>\$ 5,168</u>	<u>\$ 2,416</u>

### *Chiron Diagnostics*

On November 30, 1998, Chiron completed the sale of its *in vitro* diagnostics business to Bayer Corporation ("Bayer") for \$1,013.8 million in cash, subject to certain post-closing adjustments. The sale was completed under the terms of a Stock Purchase Agreement (the "Bayer Agreement"), dated as of September 17, 1998, between Chiron and Bayer. Under the terms of the Bayer Agreement, the Company was responsible for severance payments to specific U.S. and international employees and, accordingly, reserved for such severance obligations. In the third quarter of 2001, the Company reversed approximately \$1.6 million reserved for severance obligations based upon a final reconciliation from Bayer. This amount was recorded as a component of "Gain on disposal of discontinued operations." Chiron has also provided other customary indemnities under the terms of the Bayer Agreement.

In connection with the sale of Chiron Diagnostics, Chiron granted to Chiron Diagnostics rights under certain Chiron patents, including non-exclusive rights to patents relating to human immunodeficiency virus ("HIV") and hepatitis C virus ("HCV") for use in nucleic acid testing

("NAT") diagnostic products (excluding blood screening). In exchange for these rights, Chiron Diagnostics paid to Chiron \$100.0 million, which is refundable in decreasing amounts through 2001. For the three months ended September 30, 2001 and 2000, Chiron recognized revenues of \$5.0 million and \$7.5 million, respectively, and for the nine months ended September 30, 2001 and 2000, Chiron recognized revenues of \$15.0 million and \$22.5 million, respectively, which represented the portions of the \$100.0 million payment that became nonrefundable during those periods. The revenues were recorded as a component of "Royalty and license fee revenues" in the Condensed Consolidated Statements of Operations. The Company anticipates recognizing the remaining revenue of \$3.3 million in the fourth quarter 2001.

### *Chiron Vision*

On December 29, 1997, Chiron completed the sale of all of the outstanding capital stock of Chiron Vision to Bausch & Lomb ("B&L") for approximately \$300.0 million in cash, subject to certain post-closing adjustments. The sale was completed under the terms of a Stock Purchase Agreement (the "B&L Agreement"), dated as of October 21, 1997, between Chiron and B&L. The Company retained Chiron Vision's cash and cash equivalents totaling \$2.7 million, certain Chiron Vision real estate assets (the "real estate assets") with a carrying value of \$25.1 million and Chiron Vision's future noncancelable operating lease costs totaling \$1.1 million upon the completion of the sale. Under the terms of the B&L Agreement, the Company provided customary indemnities and, accordingly, reserved for such contractual obligations to indemnify B&L against certain potential claims. In the second quarter of 2001, the Company reversed the remaining reserves of \$1.5 million upon the sale of the remaining real estate assets, as discussed below. In 2000, the Company reversed approximately \$2.2 million reserved for contractual obligations to indemnify B&L against certain potential claims as such obligations had expired unused. Both amounts were recorded as components of "Gain on disposal of discontinued operations."

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For a period of three years following the completion of the sale, Chiron Vision has the right to use a portion of the real estate assets, which were occupied at closing, on a rent-free basis. As of December 31, 2000, the real estate assets of \$1.9 million, which represented all of the remaining net assets of Chiron's discontinued operations, were recorded as "Other current assets" in the Condensed Consolidated Balance Sheets. In April 2001, the Company sold these remaining real estate assets and recognized a net gain on the sale of these assets of \$1.6 million. This gain was recorded as a component of "Gain on disposal of discontinued operations."

### *Income Taxes*

In connection with the sale of Chiron Diagnostics and Chiron Vision, the Company recorded cumulative net deferred tax assets of \$23.9 million and \$26.5 million as of September 30, 2001 and December 31, 2000, respectively, principally attributable to the timing of the deduction of certain expenses associated with these sales. The Company also recorded corresponding valuation allowances of \$23.9 million and \$26.5 million as of September 30, 2001 and December 31, 2000, respectively, to offset these deferred tax assets, as management does not believe that it is more likely than not that the deferred tax assets to which the valuation allowance relates will be realized. The future recognition of

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these deferred tax assets will be reported as a component of "Gain on disposal of discontinued operations" in the Condensed Consolidated Statements of Operations.

### **Note 4 Acquisition of PathoGenesis Corporation**

On September 21, 2000, Chiron acquired PathoGenesis, a company that developed and marketed drugs to treat infectious diseases, particularly serious lung infections. The acquisition was accounted for under the purchase method of accounting and included the purchase of substantially all of the outstanding shares of common stock of PathoGenesis at \$38.50 per share. As discussed in Note 1, through June 30, 2001, the Company recorded a purchase price adjustment resulting from (i) a final reconciliation of PathoGenesis registered shares of common stock, (ii) the true-up of severance, employee relocation, leasing and legal costs to amounts actually paid and (iii) the related deferred tax effects, the total of which resulted in a \$1.3 million increase to the purchase price and a \$0.1 million increase to goodwill. There was no purchase price adjustment in the third quarter of 2001. The revised components and allocation of the purchase price consisted of the following (in thousands):

<b>Consideration and acquisition costs:</b>	
Cash paid for common stock	\$ 643,026
Cash paid for options on common stock	66,216
Acquisition costs paid as of September 30, 2001	21,649
Acquisition costs not yet paid as of September 30, 2001	937
Fair value, less intrinsic value for unvested portion, of options exchanged	3,371
	<hr/>
<b>Total purchase price</b>	<b>\$ 735,199</b>
	<hr/>
<b>Allocation of purchase price:</b>	
Assets acquired	\$ 94,784
Write-off of purchased in-process technologies	171,600
Purchased technologies	300,600
Acquired intangible assets	53,900
Goodwill	212,174
Liabilities assumed	(23,609)
Income taxes payable	(2,800)
Net deferred tax liability	(71,450)
	<hr/>
<b>Total purchase price</b>	<b>\$ 735,199</b>
	<hr/>

Outstanding options on PathoGenesis' stock were either redeemed in cash or converted into options on Chiron's stock. The difference between the fair value of all options and the intrinsic value associated with the unvested portion of those options was included as part of the purchase

price.

Acquisition costs included contractual severance and involuntary termination costs, as well as other direct acquisition costs. Approximately \$13.9 million represented severance payments, assumed by the Company, to executives as dictated by their employment agreements.

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The Company allocated the 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 technologies and was written off entirely in the fourth quarter of 2000. The write-off of purchased in-process technologies represented the fair value at the acquisition date, calculated utilizing the income approach, of the portion of certain in-process research and development projects that were not reliant upon core technology. Core technology represents technology that has been utilized in approved or commercialized products. Certain research and development projects deemed too early in terms of completion metrics and any future yet-to-be-defined technologies were not included in the calculation of in-process technologies. The Company does not anticipate that there will be any alternative future use for the in-process technologies that were written off. In valuing the purchased in-process technologies, the Company used probability-of-success-adjusted cash flows and a 15% discount rate. Cash inflows from any one in-process product were assumed to commence between 2002 and 2008. Based on current information, management believes that the revenue projections underlying the purchase price allocation are substantially accurate. As with all biotechnology products, the probability of commercial success for any one research and development project is highly uncertain.

Purchased technologies represented the fair value of research and development projects, which will be developed further and supported after the acquisition date, and are being amortized on a straight-line basis over 15 years. Acquired intangible assets included the fair value of trademarks and trade names, patents, databases and the work force, which are being amortized on a straight-line basis over 5 to 16 years. Goodwill resulting from the PathoGenesis acquisition is being amortized on a straight-line basis over 15 years. Since the Company elected to treat the acquisition as taxable in California, the Company recorded current income taxes payable of \$2.8 million. The net deferred tax liability primarily related to the difference between the carrying amounts and tax bases of the purchased technology and acquired intangible assets, offset by future utilization of net operating loss and tax credit carryforwards. Upon acquisition, the Company acquired federal net operating loss carryforwards and federal business credits of approximately \$116.6 million and \$6.5 million, respectively, attributed to PathoGenesis.

The following unaudited pro forma information presents the results of continuing operations of Chiron and PathoGenesis for the three and nine months ended September 30, 2000 as if Chiron's acquisition of PathoGenesis had been consummated as of January 1, 2000. The pro forma information is presented in accordance with Accounting Principles Board Opinions No. 16, "Business Combinations," and 17, "Intangible Assets," and does not purport to be indicative of what would have occurred had the acquisition been made as of this date or of results that may occur in the future. The pro forma results exclude nonrecurring charges, such as the write-off of purchased in-process

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technologies, which resulted directly from the transaction. The unaudited pro forma information is as follows (in thousands, except per share data):

	Three Months Ended September 30, 2000	Nine Months Ended September 30, 2000
Total revenues	\$ 239,264	\$ 736,800
Income from continuing operations	\$ 16,348	\$ 93,542
Pro forma earnings per share from continuing operations:		
Basic	\$ 0.09	\$ 0.52
Diluted	\$ 0.09	\$ 0.50

On January 1, 2002, the Company will implement SFAS No. 142, "Goodwill and Other Intangible Assets" ("SFAS 142"). SFAS 142 will require that goodwill and intangible assets with indefinite useful lives no longer be amortized, but instead be tested for impairment at least annually in accordance with SFAS 142. The pro forma amounts above include amortization expense on the goodwill related to the PathoGenesis acquisition of \$3.5 million and \$10.6 million for the three and nine months ended September 30, 2000, respectively.

#### Note 5 Restructuring and Reorganization

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The Company 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 the Company'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 400 positions in manufacturing, research, development, sales, marketing and other administrative functions, and facility-related costs. Employee termination costs included wage continuation, advance notice pay and medical and other benefits. Facility-related costs included losses on disposal of property, plant and equipment, lease payments and other related costs.

During 1999, the Company decided to retain 18 of those 400 positions to support future contract manufacturing activities and, therefore, adjusted the number of positions for elimination to 382. Again during 2000, the Company decided to retain 11 of those 382 positions to support future contract manufacturing activities and, therefore, adjusted the number of positions for elimination to 371.

For the nine months ended September 30, 2001, the net restructuring and reorganization activity included a charge of \$0.2 million and a charge reversal of \$0.2 million. The charge of \$0.2 million primarily related to revised estimates of termination and other employee-related costs recorded in connection with the elimination of the 371 positions, of which 360 had terminated as of September 30, 2001. The charge reversal of \$0.2 million primarily related to revised estimates of facility-related costs.

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For the nine months ended September 30, 2000, the Company recorded net restructuring and reorganization charge reversals of \$0.4 million primarily related to revised estimates of termination and other employee-related costs recorded in connection with the retention of 11 of the 382 positions. As described above, the Company adjusted the number of positions for elimination to 371, of which 356 had terminated as of September 30, 2000.

Included in "Gain on disposal of discontinued operations" in the Condensed Consolidated Statements of Operations were net restructuring and reorganization charge reversals of \$0.1 million for the nine months ended September 30, 2000. This amount related to the restructuring of the Company's *in vitro* diagnostics business operations and primarily consisted of employee termination costs related to the termination of 331 employees, all of which were terminated as of December 31, 1998. The Company retained responsibility for \$4.5 million of restructuring accruals upon the completion of the sale of Chiron Diagnostics to Bayer. The restructuring accruals were fully utilized as of December 31, 2000.

The Company's restructuring and reorganization accruals are expected to be substantially settled within one to six years of accruing the related charges. As of September 30, 2001, \$0.4 million and \$0.4 million were included in "Other current liabilities" and "Other noncurrent liabilities," respectively, in the Condensed Consolidated Balance Sheets. As of December 31, 2000, \$1.7 million and \$1.0 million were included in "Other current liabilities" and "Other noncurrent liabilities," respectively, in the Condensed Consolidated Balance Sheets.

The activity in accrued restructuring and reorganization for the nine months ended September 30, 2001 and 2000 is summarized as follows (in thousands):

	Accrual at December 31, 2000	Amount of Total Restructuring Charge	Amount of Total Restructuring Charge Reversal	Amount Utilized Through September 30, 2001	Amount to Be Utilized In Future Periods
Employee-related costs	\$ 1,816	\$ 186	\$	\$ (1,679)	\$ 323
Other facility-related costs	839		(186)	(140)	513
	<u>\$ 2,655</u>	<u>\$ 186</u>	<u>\$ (186)</u>	<u>\$ (1,819)</u>	<u>\$ 836</u>
	Accrual at December 31, 1999	Amount of Total Restructuring Charge	Amount of Total Restructuring Charge Reversal	Amount Utilized Through September 30, 2000	Amount to Be Utilized In Future Periods
Employee-related costs	\$ 3,772	\$	\$ (607)	\$ (1,197)	\$ 1,968

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	Accrual at December 31, 1999	Amount of Total Restructuring Charge	Amount of Total Restructuring Charge Reversal	Amount Utilized Through September 30, 2000	Amount to Be Utilized In Future Periods
Other facility-related costs	1,631	160		(915)	876
	5,403	160	(607)	(2,112)	2,844
Discontinued operations	285		(109)		176
	\$ 5,688	\$ 160	\$ (716)	\$ (2,112)	\$ 3,020

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**Note 6 Sale of San Diego Facility**

In January 2001, the Company sold various assets, with a carrying value of approximately \$1.8 million, of its San Diego facility for \$4.9 million in cash. The Company incurred transaction costs of approximately \$0.7 million. The San Diego facility was part of the Company's biopharmaceuticals segment. The sale of the assets resulted in a net gain of \$2.4 million, which was included in "Gain (loss) on sale of assets" in the Condensed Consolidated Statements of Operations. For the three and nine months ended September 30, 2000, Chiron recognized operating expenses related to the San Diego facility of \$2.1 million and \$7.4 million, respectively.

**Note 7 Derivative Financial Instruments**

"Derivative financial instruments" in the Condensed Consolidated Balance Sheets consisted of the following (in thousands):

	September 30, 2001
<b>Assets:</b>	
Equity forward sales contracts	\$ 17,662
Forward foreign currency contracts	3,752
Foreign currency option contracts	488
	\$ 21,902
<b>Liabilities:</b>	
Embedded derivative instrument	\$ 197

Hedge ineffectiveness, determined in accordance with SFAS 133, had no impact on earnings for the three and nine months ended September 30, 2001. No cash flow or fair value hedges were derecognized or discontinued for the three and nine months ended September 30, 2001.

For cash flow hedges, derivative gains and losses included in "Other comprehensive income" are reclassified into earnings at the time the forecasted revenue is recognized. For the three and nine months ended September 30, 2001, approximately \$0.2 million and \$(0.05) million of net derivative (gains) losses were reclassified into earnings. Based on currency exchange rates as of September 30, 2001, the Company estimates that \$0.03 million of net derivative gains included in "Other comprehensive income" will be reclassified into earnings within the next twelve months. "Other income, net" in the Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2001 included net losses of \$0.2 million and \$0.9 million, respectively, for changes in the time value of cash flow hedges.

For fair value hedges, "Other income, net" in the Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2001 included net gains of \$0.5 million and \$2.0 million, respectively, for changes in the time value of fair value hedges.

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The contingent additional principal and contingent cash interest features of the LYONs are considered embedded derivatives pursuant to SFAS 133. The value of the embedded derivatives is

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reassessed at each balance sheet date, and any change from the prior balance sheet date is reflected currently in earnings. The change in the value of the embedded derivatives was not material for the three and nine months ended September 30, 2001.

Foreign currency transaction gains, net of the impact of hedging with forward foreign currency contracts, were \$1.0 million and \$1.5 million for the three and nine months ended September 30, 2001, respectively.

### Note 8 Segment Information

Chiron is organized based on the products and services that it offers. Under this organizational structure, the Company has the following 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 infection, as well as the development and acquisition of technologies related to recombinant proteins, small molecules and genomics. The vaccines segment consists principally of adult and pediatric vaccines for viral infections sold primarily in Germany, Italy, the United Kingdom, Canada and other international markets, as well as the development of novel vaccines and vaccination technology. The blood testing segment consists of Chiron's one-half interest in the pretax operating earnings of its joint business with Ortho-Clinical Diagnostics, Inc. ("Ortho"), a Johnson & Johnson ("J&J") company, and an alliance with Gen-Probe Incorporated ("Gen-Probe"). Chiron's joint business with Ortho sells a line of immunodiagnostic tests to detect hepatitis viruses and retroviruses and provides supplemental tests and microplate-based instrument systems to automate test performance and data collection. Chiron's alliance with Gen-Probe is focused on developing and selling NAT products using transcription-mediated amplification ("TMA") technology to screen transfused blood and plasma products for viral infection.

The Company's research and development unit earns revenues and incurs expenses that specifically benefit each of the reportable segments. As a result, such revenues and expenses have been included in the results of operations of the respective reportable segment.

Certain other revenues and expenses, particularly Novartis research and development funding, certain royalty and license fee revenues primarily related to Chiron's HIV and HCV patents, and unallocated corporate expenses, are not viewed by management as belonging to any one reportable segment. As a result, these items have been aggregated into an "Other" segment, as permitted by SFAS No. 131, "Disclosures about Segments of an Enterprise and Related Information."

The accounting policies of the Company's reportable segments are the same as those described in Note 1 The Company and Summary of Significant Accounting Policies. 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, which are shown as reconciling items in the table below.

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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,	
	2001	2000	2001	2000
<b>Revenues</b>				
Biopharmaceuticals	\$ 103,254	\$ 68,240	\$ 313,497	\$ 209,337
Vaccines	123,242	93,926	296,820	316,937
Blood testing, includes equity in earnings of unconsolidated joint businesses of \$21,260 and \$23,430 for the three months ended September 30, 2001 and 2000, respectively, and \$59,141 and \$61,552 for the nine months ended September 30, 2001 and 2000, respectively	53,165	41,217	130,907	102,665
Other	22,297	17,598	81,526	49,642

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	Three Months Ended September 30,		Nine Months Ended September 30,	
Total revenues	\$ 301,958	\$ 220,981	\$ 822,750	\$ 678,581
<i>Income from continuing operations</i>				
Biopharmaceuticals	\$ (6,126)	\$ (14,961)	\$ (15,408)	\$ (31,485)
Vaccines	43,256	27,252	88,051	121,562
Blood testing	27,426	24,833	63,793	57,200
Other	(332)	6,826	9,798	4,380
Segment income from operations	64,224	43,950	146,234	151,657
Operating income reconciling items:				
Restructuring and reorganization charge reversals				447
Income from operations	64,224	43,950	146,234	152,104
Gain (loss) on sale of assets			2,426	(224)
Interest expense	(3,140)	(3,251)	(4,403)	(12,610)
Other income, net	14,052	26,971	46,279	70,051
Minority interest	(394)	(224)	(936)	(625)
Income from continuing operations before income taxes	\$ 74,742	\$ 67,446	\$ 189,600	\$ 208,696

**Note 9 Debt Obligations**

In June 2001, Chiron issued zero coupon Liquid Yield Option Notes ("LYONs") with a face value of \$730.0 million and a yield to maturity of 2.0%. The LYONs are carried net of an original issue discount of \$328.2 million, which is being accreted to interest expense over the life of the LYONs using the effective interest method. The LYONs mature on June 12, 2031. The LYONs are uncollateralized and unsubordinated, and rank equal in right of payment to the Company's existing and future uncollateralized and unsubordinated indebtedness.

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Beginning on June 12, 2004 and continuing through June 12, 2006, the holder may receive contingent additional principal if the Company's stock price falls below the threshold specified in the indenture. The contingent additional principal will replace the original issue discount and bear an effective yield of 2.0-9.0% per year for the two-year period. After June 12, 2006, the original issue discount will continue to accrue at 2.0% per year.

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

At the option of the holder, the Company may be required to redeem all or a portion of the LYONs on the following dates at the following prices:

Date	Price
June 12, 2004	\$ 584.31
June 12, 2006	\$ 608.04
June 12, 2011	\$ 671.65
June 12, 2016	\$ 741.92
June 12, 2021	\$ 819.54

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Date	Price
June 12, 2026	\$ 905.29

The redemption prices would increase for any accrued contingent additional principal and accrued original issue discount thereon.

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

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

Bond issuance costs amounted to approximately \$9.9 million and are being amortized to interest expense on a straight-line basis, which approximated the effective interest method, over three years, which represents the period from the issue date to the earliest put date. Bond issuance costs are recorded in "Other intangible assets, net" in the Condensed Consolidated Balance Sheets.

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### Note 10 Commitments and Contingencies

In April 2001, Chiron, Rhein Biotech N.V. ("Rhein Biotech") and GreenCross Vaccine Corporation ("GCVC") 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, Rhein Biotech and GCVC. Based on current estimates, Chiron's commitment is approximately 24.4 million Euro (\$22.4 million at September 30, 2001), primarily for the expansion of the Company's Italian manufacturing facilities, which is scheduled to begin in the fourth quarter of 2001 and is expected to continue through 2008.

In February 2001, the Company's Board of Directors approved a \$235.0 million capital expansion project, which includes the construction of two buildings and a parking structure in Emeryville, California. As of September 30, 2001, the Company has committed to \$15.7 million in design and construction services, under which the Company has incurred costs of \$2.3 million. The Company currently is negotiating the remaining design and construction services and evaluating various financing alternatives for this capital expansion project.

The Company 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 the Company's consolidated financial position and annual results of operations and cash flows.

The Company is presently under audit in several domestic and international tax jurisdictions. While there is no assurance that the Company will prevail in all audits in the event the taxing authorities disagree with the Company's interpretations of the tax law, 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 the Company's consolidated financial position and annual results of operations and cash flows.

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

### Overview

*This Quarterly Report on Form 10-Q contains forward-looking statements. These include statements concerning plans, objectives, goals, strategies, future events or performance, and all other statements which are other than statements of historical fact, including, without limitation, statements containing words such as "believes," "anticipates," "expects," "estimates," "projects," "will," "may," "might," and words of a similar nature. The forward-looking statements contained in this Report reflect management's current beliefs and expectations on the date of this Report. Actual results, performance or outcomes may differ materially from those expressed in the forward-looking statements. Some of the important factors which, in the view of Chiron Corporation ("Chiron" or the "Company"), could cause actual results to differ are discussed*

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*under the caption "Factors That May Affect Future Results." The Company undertakes no obligation to publicly announce any revisions to these forward-looking statements to reflect facts or circumstances of which management becomes aware after the date thereof.*

*The discussion below should be read in conjunction with Part I, Item 1, "Financial Statements," of this Quarterly Report on Form 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 the Company's Annual Report on Form 10-K for the year ended December 31, 2000.*

Chiron is a biotechnology company that participates in three global healthcare markets: biopharmaceuticals, vaccines and blood testing. The biopharmaceuticals segment consists of therapeutic products and services, with an emphasis on the treatment of cancer and infection, as well as the development and acquisition of technologies related to recombinant proteins, small molecules and genomics. The biopharmaceuticals segment also includes collaborations with Berlex Laboratories, Inc. ("Berlex") and its parent company, Schering AG of Germany, related to Betaseron® (interferon beta-1b) and Ortho-McNeil Pharmaceutical, Inc. ("Ortho-McNeil"), a Johnson & Johnson ("J&J") company, related to PDGF (recombinant human platelet-derived growth factor-rhPDGF-BB). The vaccines segment consists principally of adult and pediatric vaccines for viral infections, including flu, rabies and tick-borne encephalitis, and bacterial infections, including meningococcus C and haemophilus influenzae type B, sold primarily in Germany, Italy, the United Kingdom, Canada and other international markets, as well as the development of novel vaccines and vaccination technology. The blood testing segment consists of Chiron's one-half interest in the pretax operating earnings of its joint business with Ortho-Clinical Diagnostics, Inc. ("Ortho"), a J&J company, and an alliance with Gen-Probe Incorporated ("Gen-Probe"). Chiron's joint business with Ortho sells a line of immunodiagnostic tests to detect hepatitis viruses and retroviruses and provides supplemental tests and microplate-based instrument systems to automate test performance and data collection. Chiron's alliance with Gen-Probe is focused on developing and selling nucleic acid testing ("NAT") products using transcription-mediated amplification ("TMA") technology to screen transfused blood and plasma products for viral infection. Certain other revenues and expenses are not viewed by management as belonging to any one segment. As a result, these items have been aggregated into an "Other" segment.

The accounting policies of the Company's 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. Specifically related to collaborative agreement revenues and royalty and license fee revenues, up-front refundable fees are deferred and recognized as revenues upon the later of when they become nonrefundable or when performance obligations are completed. Up-front nonrefundable fees where the Company has no continuing performance obligations are recognized as revenues when receivable. In situations where continuing performance obligations exist, up-front nonrefundable fees are deferred and amortized over the performance period.

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On September 21, 2000, Chiron acquired PathoGenesis Corporation ("PathoGenesis"), a company that developed and marketed drugs to treat infectious diseases, particularly serious lung infections. The Company accounted for the acquisition under the purchase method of accounting and included PathoGenesis' operating results, including the seven business days from September 21 to 30, 2000, in its consolidated operating results beginning on October 1, 2000. PathoGenesis' operating results for the seven business days in September 2000 were not significant to the Company's consolidated operating results. PathoGenesis is now part of the Company's biopharmaceuticals segment.

On December 29, 1997, Chiron completed the sale of its ophthalmics business ("Chiron Vision") to Bausch & Lomb ("B&L"), and on November 30, 1998, Chiron completed the sale of its *in vitro* diagnostics business ("Chiron Diagnostics") to Bayer Corporation ("Bayer"). The Company's Condensed Consolidated Statements of Operations reflect the after-tax results of amounts related to Chiron Vision and Chiron Diagnostics as discontinued operations.

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

### Results of Operations

#### Biopharmaceuticals

**Product sales** Biopharmaceutical product sales were \$76.8 million and \$49.6 million for the three months ended September 30, 2001 and 2000, respectively, and \$239.4 million and \$150.6 million for the nine months ended September 30, 2001 and 2000, respectively. Biopharmaceutical product sales in 2001 consisted principally of Betaseron®, TOBI® (tobramycin solution for inhalation), Proleukin® (aldesleukin) and PDGF. Biopharmaceutical product sales in 2000 consisted principally of Betaseron®, Proleukin® and PDGF.

**Betaseron®** Chiron manufactures Betaseron® for sale by Berlex and its parent company, Schering AG of Germany. Betaseron® is approved for relapsing/remitting multiple sclerosis in over 60 countries, including the U.S. and the European Union, and for secondary progressive

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multiple sclerosis in approximately 40 countries, including the European Union, Canada, Australia and New Zealand. Chiron earns a payment for Betaseron® upon shipment to Berlex and Schering AG, and a subsequent additional payment based on a contractual percentage of sales made by Berlex and Schering AG. The Company also earns royalties on Schering AG's European sales of Betaferon® (collectively, "Betaseron® revenues").

Betaseron® product sales were \$20.9 million and \$24.5 million for the three months ended September 30, 2001 and 2000, respectively, and \$67.7 million and \$59.2 million for the nine months ended September 30, 2001 and 2000, respectively. The decrease in Betaseron® product sales in the third quarter 2001 as compared with the third quarter 2000 primarily related to fluctuations in Berlex and Schering AG's inventory levels. Offsetting this decrease were increased underlying sales to end users in the U.S. driven by increased utilization of beta interferon therapy for multiple sclerosis. The increase in Betaseron® product sales year-to-date 2001 as compared with year-to-date 2000 was similarly influenced by increased sales to end users in the U.S. driven by increased utilization of beta interferon therapy. As discussed in "Royalties and license fee revenues" below, Betaferon® royalties also increased in year-to-date 2001 as compared with year-to-date 2000.

**TOBI®** Chiron obtained TOBI® as part of its acquisition of PathoGenesis on September 21, 2000. Chiron sells TOBI® directly in the U.S. and certain international markets. TOBI® was approved for cystic fibrosis lung infections by the FDA in December 1997 and was launched commercially in January 1998. In addition, TOBI® was approved in Canada in February 1999. TOBI® also cleared the mutual recognition process required for marketing in the European Union in August 2000 and was subsequently launched in several European countries. Chiron recorded TOBI® sales of \$33.6 million

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and \$89.5 million for the three and nine months ended September 30, 2001, respectively. For comparison purposes, sales of TOBI® for the three and nine months ended September 30, 2000 were \$20.9 million and \$60.5 million, respectively, including \$2.2 million from the last seven days in September 2000, which Chiron reported in its fourth quarter 2000 results. The fluctuation was due to (i) increased TOBI® use in the U.S. and Canada by patients with cystic fibrosis, (ii) increased TOBI® sales related to the launch in various European countries and (iii) fluctuations in wholesaler inventory levels. The Company continues to pursue the use of TOBI® to treat other serious lung infections. The Company also continues to seek approval in other countries. Future TOBI® sales may be influenced by wholesaler inventory management practices and foreign currency exchange rate fluctuations.

**Proleukin®** Proleukin® is Chiron's brand of recombinant human interleukin-2. Proleukin® is approved in over 50 countries for the treatment of metastatic (stage IV) renal cell carcinoma and in Canada and the U.S. for the treatment of metastatic (stage IV) melanoma, for which it became the first approved therapy in more than 20 years when it was approved by the Food and Drug Administration ("FDA") in 1998. Sales of Proleukin® were \$16.4 million and \$21.3 million for the three months ended September 30, 2001 and 2000, respectively, and \$63.8 million and \$76.6 million for the nine months ended September 30, 2001 and 2000, respectively. Proleukin® product sales in 2001 as compared with 2000 primarily were affected by (i) fluctuations in wholesaler inventory management practices, (ii) the increasing cost sensitivity from reimbursement authorities, particularly in Europe, and, to a lesser extent, (iii) a weaker exchange rate of the Euro as compared with the U.S. dollar. The Company expects these factors to continue into 2002.

**PDGF** Chiron manufactures PDGF for Ortho-McNeil, a J&J company. PDGF is the active ingredient in Regranex® (becaplermin) Gel, a treatment for diabetic foot ulcers. Regranex® Gel was approved by the FDA in December 1997 and was launched commercially in early 1998. Regranex® Gel was approved for use in the treatment of diabetic foot ulcers in Canada in December 1998 and Europe in March 1999. Net sales of PDGF were \$2.4 million and \$3.2 million for the three months ended September 30, 2001 and 2000, respectively, and \$8.4 million and \$10.8 million for the nine months ended September 30, 2001 and 2000, respectively. The decrease in net PDGF product sales year-to-date 2001 as compared with year-to-date 2000 was due to a \$2.9 million decrease in the product returns allowance in the second quarter 2000, based upon additional historical return information. Historically, Chiron's sales of PDGF have fluctuated based upon the inventory management practices of Ortho-McNeil.

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

The Company expects competitive pressures related to many of its biopharmaceutical products to continue into the foreseeable future, primarily as a result of the introduction of competing products into the market, as listed in Part I, Item 1., "Business Competition" of the Company's Annual Report on Form 10-K for the year ended December 31, 2000.

**Collaborative agreement revenues** Chiron recognizes collaborative agreement revenues for fees received as research services are performed and as specified milestones are achieved. The biopharmaceuticals segment recognized collaborative agreement revenues of \$6.0 million and \$2.8 million for the three months ended September 30, 2001 and 2000, respectively, and \$17.8 million and \$9.5 million for the nine months ended September 30, 2001 and 2000, respectively.

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*Novartis AG* Under the terms of a November 1995 agreement with Novartis, Chiron granted Novartis a license to utilize Chiron's combinatorial chemistry techniques. In exchange for this license, Novartis agreed to pay Chiron \$26.0 million over a five-year period, subject to certain adjustments. In addition, this agreement provides for research funding by Novartis, and certain up-front milestone and royalty payments, as well as product commercialization rights for both parties. This agreement expired

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in the fourth quarter 2000. In connection with this agreement, Chiron did not recognize collaborative agreement revenues for the three months ended September 30, 2000. For the nine months ended September 30, 2000, Chiron recognized collaborative agreement revenues of \$1.0 million.

In November 1996, Chiron and Novartis entered into a consent order with the Federal Trade Commission pursuant to which Chiron agreed to grant a royalty-bearing license to Rhone-Poulenc Rorer, Inc. under certain Chiron patents related to the Herpes Simplex Virus-thymidine kinase ("HSV-tk") gene in the field of gene therapy. Chiron and Novartis entered into a separate agreement which provided, among other things, for certain cross licenses between Chiron and Novartis, and under which Novartis agreed to pay Chiron up to \$60.0 million over five years. In connection with this agreement, Chiron recognized collaborative agreement revenues of \$2.5 million for each of the three months ended September 30, 2001 and 2000, and \$7.5 million for each of the nine months ended September 30, 2001 and 2000. This agreement expires in the fourth quarter 2001.

The Company's "Other" segment also earns collaborative agreement revenues under a third Novartis agreement. See "Other Collaborative agreement revenues" below.

*S\*Bio* In the second quarter 2000, the Company invested in a Singapore-based venture, S\*Bio Pte Ltd ("S\*Bio"), to research and develop therapeutic, diagnostic, vaccine and antibody products. The Company also granted to S\*Bio certain rights to the Company's gene expression and combinatorial chemistry technology. Under this arrangement, the Company will receive approximately \$22.0 million over two years for technology transfer. For the three and nine months ended September 30, 2001, the Company recognized collaborative agreement revenues of \$3.0 million and \$8.9 million, respectively, under this arrangement. The Company did not recognize any revenue under this arrangement for the three and nine months ended September 30, 2000.

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

Collaborative agreement revenues tend to fluctuate based on the amount of research services performed, the status of projects under collaboration and the achievement of milestones. Due to the nature of the Company's 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 the Company's technology. However, there can be no assurance that the collaborative partners will meet their development objectives or commercialize a product using the Company's technology. Also, the Company's ability to generate additional collaborative agreement revenues may depend, in part, on its ability to initiate and maintain relationships with potential and current collaborative partners. There can be no assurance that new relationships will be established or that current collaborative agreement revenues will not decline.

**Royalty and license fee revenues** The biopharmaceuticals segment earns royalties on third party sales of several products, including Betaferon®, recombinant insulin and glucagon products, as well as license fees for technologies, such as hepatitis C virus ("HCV") patents, used by third parties. The biopharmaceuticals segment recognized royalty and license fee revenues of \$13.7 million and \$12.8 million for the three months ended September 30, 2001 and 2000, respectively, and \$45.1 million and \$37.0 million for the nine months ended September 30, 2001 and 2000, respectively.

*Betaferon®* The Company earns royalties on Schering AG's European sales of Betaferon®. Chiron recognized \$8.8 million and \$10.2 million for the three months ended September 30, 2001 and 2000, respectively, and \$28.8 million and \$27.4 million for the nine months ended September 30, 2001 and 2000, respectively, under this arrangement. The decrease in the third quarter 2001 as compared with the third quarter 2000 related to various adjustments in the third quarters 2001 and 2000 and, to a lesser extent, a weaker exchange rate of the Euro as compared with the U.S. dollar. In every quarter,

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Chiron estimates royalties on Betaferon® product sales based on previous period actual sales. In the following quarter, Chiron records an adjustment equal to the difference between those estimated royalty revenues recorded in the previous quarter and the contractual percentage of

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actual Betaferon® product sales for that period. As discussed in "Product sales Betaferon®" above, the increase in Betaferon® revenues year-to-date 2001 as compared with year-to-date 2000 primarily related to increased utilization of beta interferon therapy, offset by a weaker exchange rate of the Euro as compared with the U.S. dollar. Betaferon® is the only product that is approved for the treatment of both relapsing/remitting and secondary progressive multiple sclerosis in Europe.

**Glaxo** In March 2000, Chiron granted to Glaxo Group Limited (now part of GlaxoSmithKline) rights under certain Chiron HCV patents, for which the Company recognized a license fee in the first quarter 2000. The Company did not recognize any revenue under this agreement in 2001.

**Japan Tobacco** In January 2001, Chiron granted to Japan Tobacco, Inc. ("Japan Tobacco") rights under certain Chiron HCV patents. The agreement provides for the payment of a license fee, which was received and recognized as revenue in the first quarter 2001. The Company did not recognize any revenue under this agreement for the three months ended September 30, 2001.

**Zarix** In January 2001, Chiron granted to Zarix Incorporated ("Zarix") rights under Chiron's recombinant protein technology, for which the Company recognized a license and technology transfer fee in the second quarter 2001. The Company did not recognize any revenue under this agreement for the three months ended September 30, 2001.

**Bristol-Myers Squibb** In July 2001, Chiron granted to Bristol-Myers Squibb Company ("BMS") rights under certain Chiron HCV patents, for which the Company recognized a license fee in the third quarter 2001.

**Other** Chiron estimates recombinant insulin and glucagon royalty revenues based on previous period actual recombinant insulin and glucagon product sales. Chiron recognized \$1.9 million and \$1.7 million for the three months ended September 30, 2001 and 2000, respectively, and \$5.2 million and \$4.7 million for the nine months ended September 30, 2001 and 2000, respectively, under this arrangement.

The balance of royalty and license fee revenues recognized by the biopharmaceuticals segment consisted of various other agreements, which individually were not material.

Royalty and license fee revenues may fluctuate based on the nature of the related agreements and the timing of receipt of license fees. In addition, Chiron estimates royalty revenues based on product sales estimates provided by the third party or previous period actual product sales. In the subsequent quarter, Chiron records 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. 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 the Company's technology. However, there can be no assurance that the licensees will meet their development objectives or commercialize a product using the Company's technology. In addition, the Company's ability to generate additional royalty and license fee revenues may depend, in part, on its ability to market and capitalize on its technologies. There can be no assurance that the Company will be able to do so or that future royalty and license fee revenues will not decline.

**Other revenues** The biopharmaceuticals segment recognized other revenues of \$6.7 million and \$3.0 million for the three months ended September 30, 2001 and 2000, respectively, and \$11.1 million and \$12.2 million for the nine months ended September 30, 2001 and 2000, respectively.

**Contract manufacturing revenues** The biopharmaceuticals segment recognized contract manufacturing revenues of \$5.9 million and \$3.1 million for the three months ended September 30, 2001 and 2000, respectively, and \$9.7 million and \$9.0 million for the nine months ended September 30, 2001 and 2000, respectively. The increase resulted from the timing of contract manufacturing activities.

The balance of other revenues recognized by the biopharmaceuticals segment consisted of various other arrangements, which individually were not material.

Biopharmaceuticals' other revenues may fluctuate due to the nature of the revenues recognized and the timing of events giving rise to these revenues. There can be no guarantee that the Company will be successful in obtaining additional revenues or that these revenues will not decline.

**Gross profit** For the three months ended September 30, 2001 and 2000, biopharmaceutical gross profit as a percentage of net product sales was 69% and 64%, respectively. The increase in biopharmaceutical gross profit margins in the third quarter 2001 as compared with the third quarter 2000 related to a favorable mix of biopharmaceutical product sales, including TOBI®. For the nine months ended September 30, 2001 and 2000, biopharmaceutical gross profit as a percentage of net product sales was 71% and 68%, respectively. The increase in biopharmaceutical gross profit margins year-to-date 2001 as compared with year-to-date 2000 primarily related to a more favorable mix of biopharmaceutical

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product sales, including TOBI®, offset by a decrease in gross profit margins caused by the timing of Betaseron® shipments.

Biopharmaceutical gross profit percentages may fluctuate significantly in future periods as the biopharmaceutical product and customer mixes change.

**Research and development** The biopharmaceuticals segment recognized research and development expenses of \$63.3 million and \$51.3 million for the three months ended September 30, 2001 and 2000, respectively, and \$193.4 million and \$156.4 million for the nine months ended September 30, 2001 and 2000, respectively. The increase in research and development spending in 2001 as compared with 2000 was due to the furtherance of the Company's clinical trials related to tifacogin (recombinant Tissue Factor Pathway Inhibitor or "TFPI") for severe sepsis, Proleukin® for HIV and progress in various other development platforms, including those obtained as part of the acquisition of PathoGenesis on September 21, 2000. The increases were offset by the conclusion of the second phase of clinical trials for Fibroblast Growth Factor ("FGF") for coronary and peripheral artery diseases and a reduction in gene therapy activities with the sale of the San Diego facility in January 2001 (see "Gain (loss) on sale of assets" below).

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

**Selling, general, and administrative** The biopharmaceuticals segment recognized selling, general and administrative ("SG&A") expenses of \$19.1 million and \$10.2 million for the three months ended September 30, 2001 and 2000, respectively, and \$59.0 million and \$30.0 million for the nine months ended September 30, 2001 and 2000, respectively. The increase primarily was due to the acquisition of PathoGenesis, as well as increased sales and marketing costs related to the relaunch of DepoCyt® in the first quarter 2001.

### *Vaccines*

**Product sales** Chiron sells pediatric and adult vaccines in Germany, Italy, the United Kingdom, Canada and other international markets. Certain of the Company's vaccine products, particularly its flu vaccine, are seasonal and typically have higher sales in the second half of the year. In addition, the Company expects Menjugate sales to continue to fluctuate as public health authorities potentially adopt broad vaccination programs. Vaccine product sales were \$115.3 million and \$78.6 million for the

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three months ended September 30, 2001 and 2000, respectively, and \$267.9 million and \$279.9 million for the nine months ended September 30, 2001 and 2000, respectively.

The fluctuations in product sales in 2001 as compared with 2000 primarily were due to sales of Menjugate, Chiron's conjugate vaccine against meningococcal meningitis caused by the bacterium *N. meningitidis* serogroup C, which amounted to \$23.1 million and \$6.6 million for the three months ended September 30, 2001 and 2000, respectively, and \$68.2 million and \$108.1 million for the nine months ended September 30, 2001 and 2000, respectively. Contributing to the third quarter 2001 increase in Menjugate sales as compared with the third quarter 2000 were shipments to Canada, which commenced in the second quarter 2001. Current year shipments to Canada offset the \$101.5 million of Menjugate shipped in 2000 to the National Health Service ("NHS") under a tender to begin a universal vaccination program in the United Kingdom. As of October 31, 2001, the Company has orders from various countries to ship approximately \$20.8 million of Menjugate through the second quarter 2002. The Company is exploring opportunities for additional Menjugate sales in other countries.

Sales of all other vaccine products were \$92.2 million and \$72.0 million for the three months ended September 30, 2001 and 2000, respectively, and \$199.7 million and \$171.8 million for the nine months ended September 30, 2001 and 2000, respectively. Contributing to the increase in 2001 other vaccine product sales as compared with 2000 was an increase in (i) tick-borne encephalitis vaccine sales, attributed to regulatory problems of certain of the Company's competitors, (ii) influenza vaccine sales, as the Company was the first to the German market this season and (iii) rabies vaccine sales, due to greater market penetration.

The Company expects competitive pressures related to many of its vaccine products to continue into the foreseeable 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 the Company's Annual Report on Form 10-K for the year ended December 31, 2000.

**Royalty and license fee revenues** The vaccines segment earns royalties on third party sales of and license fees on several products. The vaccines segment recognized royalty and license fee revenues of \$3.8 million and \$6.8 million for the three months ended September 30, 2001 and 2000, respectively, and \$13.5 million and \$18.7 million for the nine months ended September 30, 2001 and 2000, respectively.

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**SmithKline Beecham** An agreement with SmithKline Beecham (now part of GlaxoSmithKline) provides for royalties on sales of certain vaccine products. Under this agreement, Chiron recognized \$1.7 million and \$2.0 million of such royalties for the three months ended September 30, 2001 and 2000, respectively, and \$4.4 million and \$5.0 million of such royalties for the nine months ended September 30, 2001 and 2000, respectively. The decrease in 2001 as compared with 2000 primarily was due to a decrease in GlaxoSmithKline sales due to competitive vaccine products.

**Other** Chiron recognized \$2.1 million and \$4.8 million of royalty revenues on third party sales of hepatitis B virus ("HBV") vaccine products for the three months ended September 30, 2001 and 2000, respectively, and \$9.1 million and \$13.7 million for the nine months ended September 30, 2001 and 2000, respectively. The decrease in 2001 as compared with 2000 primarily was due to a decrease in sales of the HBV vaccine products due to competitive multivalent HBV vaccine products. In addition, certain terms of one of the HBV arrangements expired in the third quarter 2001.

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, the Company's ability to generate additional royalty and license fee revenues may depend, in part, on its ability to market and capitalize on its technologies.

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There can be no assurance that the Company will be able to do so or that future royalty and license fee revenues will not decline.

**Other revenues** The vaccines segment recognized other revenues of \$4.1 million and \$8.5 million for the three months ended September 30, 2001 and 2000, respectively, and \$15.4 million and \$18.3 million for the nine months ended September 30, 2001 and 2000, respectively.

**Commission revenues** The Company earns commission revenues on sales of HBV vaccine products. Previously, the Company also earned commission revenues on sales of immunoglobulin products. Commission revenues were \$0.5 million and \$1.7 million for the three months ended September 30, 2001 and 2000, respectively, and \$2.2 million and \$5.6 million for the nine months ended September 30, 2001 and 2000, respectively. The decrease in commission revenues in 2001 as compared with 2000 primarily related to a decrease in sales of the HBV vaccine products due to competitive multivalent HBV vaccine products and the expiration of the immunoglobulin arrangement on December 31, 2000.

**National Institutes of Health** In the second quarter 2000, the Company entered into an agreement with the U.S. National Institutes of Health ("NIH") to advance its HIV vaccine program into human clinical trials. Under this arrangement, the Company could receive \$23.2 million over five years. Under a supplemental arrangement with NIH, the Company may perform other work related to NIH's HIV vaccine program on a contract-by-contract basis. Under these arrangements, the Company recognized \$2.1 million and \$1.0 million for the three months ended September 30, 2001 and 2000, respectively, and \$7.8 million and \$1.0 million for the nine months ended September 30, 2001 and 2000, respectively.

The balance of other revenues recognized by the vaccines segment consisted of various other agreements, which individually were not material.

Vaccines' other revenues may fluctuate due to the nature of the revenues recognized and the timing of events giving rise to these revenues. There can be no guarantee that the Company 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 63% and 61% for the three months ended September 30, 2001 and 2000, respectively. The increase in vaccines' gross profit margins in the third quarter 2001 as compared with the third quarter 2000 primarily was due to a favorable customer mix in Menjugate sales and increased tick-borne encephalitis vaccine sales during the off-season, attributed to regulatory problems of certain of the Company's competitors. Vaccines' gross profit as a percentage of net product sales was 64% and 69% for the nine months ended September 30, 2001 and 2000, respectively. The decrease in vaccine gross profit margins year-to-date 2001 as compared with year-to-date 2000 primarily related to comparatively lower sales of Menjugate in the current period, offset by a favorable mix of other vaccine product sales. The Company recorded a significantly higher gross profit on 2000 Menjugate sales, because a significant portion of Menjugate production occurred in 1999. As the Company had not received approval to market Menjugate as of the end of fiscal year 1999, the Company expensed manufacturing costs to research and development.

Vaccines' gross profit percentages may fluctuate significantly in future periods as vaccines' product and customer mixes change.

**Research and development** The vaccines segment recognized research and development expenses of \$13.5 million and \$15.0 million for the three months ended September 30, 2001 and 2000, respectively, and \$44.3 million for each of the nine months ended September 30, 2001 and 2000.

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In April 2001, Chiron, Rhein Biotech N.V. ("Rhein Biotech") and GreenCross Vaccine Corporation ("GCVC") entered into a collaboration to research and develop certain pediatric combination vaccine products for sale outside of Europe and North America. Under the collaboration

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agreement, the Company shares the research and development expenses, which actually began in the first quarter 2001, with Rhein Biotech and GCVC. The collaboration agreement also requires capital commitments from Chiron, Rhein Biotech and GCVC (see "Liquidity and Capital Resources Sources and uses of cash" below).

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

**Selling, general, and administrative** The vaccines segment recognized SG&A expenses of \$21.1 million and \$20.0 million for the three months ended September 30, 2001 and 2000, respectively, and \$58.9 million and \$55.5 million for the nine months ended September 30, 2001 and 2000, respectively. The increase in SG&A expenses in 2001 as compared with 2000 primarily was due to commissions recognized under a co-marketing and co-promotion agreement with Aventis Pasteur MSD related to Menjugate and Fludax ("AP MSD agreement"), offset by a weaker exchange rate of the Euro as compared with the U.S. Dollar. Under the AP MSD agreement, Aventis Pasteur MSD distributes, markets and sells (co-markets) Menjugate under its own label in Europe, excluding the United Kingdom and Ireland, and assists the Company in marketing and sales efforts (co-promotion) related to Menjugate in the United Kingdom and Ireland. Aventis Pasteur MSD similarly co-markets and co-promotes Fludax in Europe. For the three and nine months ended September 30, 2001, co-promotion commissions to Aventis Pasteur MSD amounted to \$2.7 million and \$6.0 million, respectively. Co-promotion commissions to Aventis Pasteur MSD were not material in 2000.

**Amortization expense** The vaccines segment recognized amortization expense of \$1.9 million and \$2.0 million for the three months ended September 30, 2001 and 2000, respectively, and \$5.6 million and \$6.1 million for the nine months ended September 30, 2001 and 2000, respectively. In the second quarter 1998, Chiron acquired the remaining 51% interest in Chiron Behring from Hoechst AG and accounted for the acquisition under the purchase method of accounting (for additional information, see Note 5, "Acquisition of Chiron Behring," of the Company's Annual Report on Form 10-K for the year ended December 31, 2000). A portion of the purchase price was allocated to acquired intangible assets and goodwill, which are being amortized on a straight-line basis over the estimated useful life of each intangible asset. Acquired intangible assets included the fair value of trademarks, patents and customer lists, which are being amortized on a straight-line basis over 6 to 20 years. Goodwill is being amortized on a straight-line basis over 20 years. As circumstances dictate, Chiron evaluates the useful life and value of each intangible asset, which may result in future adjustments to the amortization periods or book values.

As discussed in "New Accounting Standards" below, the Company will implement Statement of Financial Accounting Standards ("SFAS") No. 142, "Goodwill and Other Intangible Assets" ("SFAS 142"), on January 1, 2002. SFAS 142 will require that goodwill and intangible assets with indefinite useful lives no longer be amortized, but instead be tested for impairment at least annually in accordance with SFAS 142.

### **Blood testing**

**Product sales** The blood testing segment recognized product sales of \$22.4 million and \$15.4 million for the three months ended September 30, 2001 and 2000, respectively, and \$49.7 million and \$31.4 million for the nine months ended September 30, 2001 and 2000, respectively.

**Ortho** Under the Ortho arrangement, the Company manufactures bulk reagents and antigens for immunodiagnostic products. The Company recognized product sales under this agreement of \$7.9 million and \$6.6 million for the three months ended September 30, 2001 and 2000, respectively, and \$16.7 million and \$17.0 million for the nine months ended September 30, 2001 and 2000,

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respectively. The fluctuation between 2001 and 2000 primarily was due to the timing of manufacturing services.

**NAT** Under the collaboration agreement with Gen-Probe, Chiron and Gen-Probe are jointly participating in new assay and instrument research and development. Currently, Gen-Probe is the only manufacturer of NAT products using TMA technology. Worldwide product sales related to tests and instruments were \$14.5 million and \$8.8 million for the three months ended September 30, 2001 and 2000, respectively, and \$33.0 million and \$14.4 million for the nine months ended September 30, 2001 and 2000, respectively.

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The Company has contracts with various agencies and distributors worldwide. In addition, evaluation studies are being conducted to consider the adoption of NAT for blood screening in different countries. Product revenues are recognized based on the details of each contract.

In the U.S., the Company recognized revenues from sales of nucleic acid tests under an IND application. In the third quarter 2000, the Company assumed primary account responsibility for a key U.S. customer, which resulted in increased product sales. In the third quarter 2001, all of the Company's U.S. customers renewed their agreements, most with moderate price increases, for NAT products. In January 2001, Gen-Probe completed submission of data to the FDA for the Procleix HIV-1/HCV assay. In July 2001, Gen-Probe received a Complete Review Letter from the FDA for the Procleix HIV-1/HCV assay, to which a response was submitted in late August. There can be no assurance as to the receipt of FDA approval or the timing of any such approval.

Outside the U.S., the French government adopted NAT for blood screening effective July 2001 and, as a result, the Company began recognizing revenues from the commercial sales of assays and instruments and the provision of services.

The Company expects competitive pressures related to its blood testing products to continue into the foreseeable future, primarily as a result of the introduction of competing products into the market, as listed in Part I, Item 1., "Business Competition" of the Company's Annual Report on Form 10-K for the year ended December 31, 2000.

**Equity in earnings of unconsolidated joint businesses** Chiron's share of earnings of its joint business with Ortho were \$21.3 million and \$23.4 million for the three months ended September 30, 2001 and 2000, respectively, and \$59.2 million and \$61.5 million for the nine months ended September 30, 2001 and 2000, respectively. The decrease in 2001 as compared with 2000 was due to the timing of Ortho's shipments to third parties.

**Collaborative agreement revenues** Chiron recognizes collaborative agreement revenues for fees received as research services are performed and as specified milestones are achieved. Under the Ortho arrangement, the Company conducts research and development services related to the Ortho arrangement. The blood testing segment recognized collaborative agreement revenues related to immunodiagnostic products of \$2.4 million and \$2.3 million for the three months ended September 30, 2001 and 2000, respectively, and \$8.6 million and \$8.3 million for the nine months ended September 30, 2001 and 2000, respectively. Total collaborative agreement revenues for the nine months ended September 30, 2001 and 2000 were \$8.6 million and \$9.7 million, respectively.

The collaborative agreement revenues recognized by the blood testing segment in 2000, not related to the Ortho arrangement, consisted of various other agreements, which individually were not material.

Collaborative agreement revenues tend to fluctuate based on the amount of research services performed, the status of projects under collaboration and the achievement of milestones. Due to the nature of the Company's collaborative agreement revenues, results in any one period are not necessarily indicative of results to be achieved in the future. The Company's ability to generate additional collaborative agreement revenues may depend, in part, on its ability to initiate and maintain

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relationships with potential and current collaborative partners. There can be no assurance that new relationships will be established or that current collaborative agreement revenues will not decline.

**Royalty and license fee revenues** The blood testing segment earns royalties on third party utilization of Chiron's HCV and HIV patents, as well as third party sales of HCV and HIV immunodiagnostic products. The blood testing segment recognized royalty and license fee revenues of \$7.2 million and \$13.2 million for the three and nine months ended September 30, 2001, respectively.

**Roche Settlement** In October 2000, the Company entered into three license agreements with F. Hoffmann La-Roche AG and several of its affiliated companies (collectively, "Roche") related to the settlement of certain litigation in the U.S. and certain other countries for the use of Chiron's HCV 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 HCV and HIV. Revenues under these agreements were \$5.9 million and \$11.9 million for the three and nine months ended September 30, 2001, respectively. The blood testing segment did not recognize any royalty and license fee revenues during 2000 under these agreements. Royalties will continue under these new agreements through the lives of the HCV and HIV patents covering Roche's NAT products. Currently, the applicable issued HCV patents expire in 2015 for the U.S. and in 2008 for Europe. Currently, the applicable issued HIV patent in Europe expires in 2005. If and when a patent is issued under pending U.S. applications, the HIV patent life in the U.S. will be seventeen years from the date of issuance.

**Bayer** In June 2001, Chiron and Ortho entered into an agreement with Bayer, under which Bayer will manufacture and sell certain of Ortho's HCV and HIV immunodiagnostic products for use on Bayer instrument platforms. Bayer paid Chiron a license fee of \$45.3 million, which the

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Company deferred and began recognizing as revenue in the third quarter 2001. Chiron 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, the Company's ability to generate additional royalty and license fee revenues may depend, in part, on its ability to market and capitalize on its technologies. There can be no assurance that the Company will be able to do so or that future royalty and license fee revenues will not decline.

**Gross profit** For the three months ended September 30, 2001 and 2000, blood testing gross profit as a percentage of net product sales was 34% and 40%, respectively. The decrease in blood testing gross profit margins in the third quarter 2001 as compared with the third quarter 2000 was driven by the mix of assay and instrument sales in certain countries and the timing of manufacturing services under the Ortho arrangement. For the nine months ended September 30, 2001 and 2000, blood testing gross profit as a percentage of net product sales was 30% and 28%, respectively. The increase in blood testing gross profit margins in year-to-date 2001 as compared with year-to-date 2000 primarily related to proportionately higher sales of NAT products. In July 2000, Chiron began recognizing NAT product sales for one of its key U.S. customers, which previously were recorded as collaborative agreement revenues, and all of the Company's U.S. customers renewed their agreements during the third quarter 2001, most with moderate price increases, for NAT products.

Blood testing gross profit percentages may fluctuate significantly in future periods as the blood testing product and customer mixes change.

**Research and development** The blood testing segment recognized research and development expenses of \$3.6 million and \$2.9 million for the three months ended September 30, 2001 and 2000, respectively, and \$12.0 million and \$10.7 million for the nine months ended September 30, 2001 and 2000, respectively. The increase in research and development spending in 2001 as compared with 2000

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was due to a slight increase in development costs related to the NAT business, as Chiron and Gen-Probe completed submission of data to the FDA for the Procleix instruments and assays in January 2001 (see "Product sales" above).

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

**Selling, general, and administrative** The blood testing segment recognized SG&A expenses of \$7.3 million and \$4.2 million for the three months ended September 30, 2001 and 2000, respectively, and \$20.0 million and \$12.2 million for the nine months ended September 30, 2001 and 2000, respectively. The increase in SG&A expenses in 2001 as compared with 2000 primarily was due to sales and marketing activities associated with the NAT business. The Company expects continued growth in SG&A expenses related to the NAT business as the Company expands its sales opportunities for additional NAT adoptions in other countries.

### **Other**

**Collaborative agreement revenues** Chiron recognizes collaborative agreement revenues for fees received as research services are performed and as specified milestones are achieved. For the three and nine months ended September 30, 2001, the other segment recognized collaborative agreement revenues of \$3.0 million and \$6.0 million, respectively. For the three and nine months ended September 30, 2000, the other segment did not recognize any collaborative agreement revenues.

**Novartis AG** In December 1995, Chiron and Novartis entered into an agreement under which Novartis agreed to provide, at Chiron's request, research funding for certain projects. The funded projects currently consist of certain adult and pediatric vaccines, Insulin-Like Growth Factor-I ("IGF-I"), Factor VIII and HSV-tk. Based upon a December 2000 amendment, Novartis has agreed to fund through December 31, 2001, at Chiron's request and subject to certain annual and aggregate limits, up to 100% of the development costs incurred between January 1, 1995 and December 31, 2000 on these projects. In December 1999, Chiron and Novartis amended this agreement to increase the maximum amount of funding provided by Novartis from \$250.0 million to \$265.0 million. Under this agreement, Chiron recognized collaborative agreement revenues of \$3.0 million and \$6.0 million for the three and nine months ended September 30, 2001, respectively. Chiron did not recognize any collaborative agreement revenues for the three and nine months ended September 30, 2000. This agreement expires on December 31, 2001. The amount of remaining funding available to be provided by Novartis is limited to \$3.1 million.

Collaborative agreement revenues tend to fluctuate based on the amount of research services performed, the status of projects under collaboration and the achievement of milestones. Due to the nature of the Company's collaborative agreement revenues, results in any one period are not necessarily indicative of results to be achieved in the future. The Company's ability to generate additional collaborative agreement revenues may depend, in part, on its ability to initiate and maintain relationships with potential and current collaborative partners. There can be

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no assurance that new relationships will be established or that current collaborative agreement revenues will not decline.

**Royalty and license fee revenues** The other segment earns royalties on third party sales of and license fees on several products. The other segment recognized royalty and license fee revenues of \$20.0 million and \$17.9 million for the three months ended September 30, 2001 and 2000, respectively, and \$76.1 million and \$49.8 million for the nine months ended September 30, 2001 and 2000, respectively.

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*HCV and HIV* The other segment earns royalties and license fees related to the use of Chiron's HCV and HIV patents by various third parties. The other segment's HCV and HIV royalty and license fee revenues consisted of the following (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2001	2000	2001	2000
Royalty revenues	\$ 15,029	\$ 968	\$ 38,438	\$ 2,647
License fee revenues	5,000	7,500	35,000	32,500
	<u>\$ 20,029</u>	<u>\$ 8,468</u>	<u>\$ 73,438</u>	<u>\$ 35,147</u>

**Roche Settlement** In October 2000, the Company entered into three license agreements with Roche related to the settlement of litigation in the U.S. and certain other countries for use of Chiron's HCV and HIV intellectual property.

Under the HCV agreement, Chiron was paid \$85.0 million, of which \$40.0 million was recognized in the fourth quarter 2000. The remaining \$45.0 million, which was deferred and becomes nonrefundable over time, was recognized as revenue commencing in the first quarter 2001 and will continue through 2005 as royalties on future sales related to Roche's use of Chiron's HCV patents in its *in vitro* diagnostic products. The agreement also provides for royalties on future sales related to Roche's use of Chiron's HCV patent in its *in vitro* diagnostic products, which commenced in the first quarter 2001.

Under the HIV agreement, Chiron received \$10.0 million in the fourth quarter 2000, which was deferred, and received \$10.0 million in the first quarter 2001. These amounts included a refundable license fee and royalties for past sales related to Roche's use of Chiron's HIV patent in its *in vitro* diagnostic products in Europe. These amounts became nonrefundable in January 2001 when the European Patent Office Board of Technical Appeals upheld the Company's HIV patent, and the Company recognized the entire \$20.0 million as revenue in the first quarter 2001. The agreement also provides for royalties on future sales related to Roche's use of Chiron's HIV patent in its *in vitro* diagnostic products, which commenced in the first quarter 2001 when the European Patent Office Board of Technical Appeals upheld the Company's HIV patent. Also, the Company will recognize additional revenue of \$10.0 million under this arrangement when and if patents on HIV are issued to it in the U.S.

Such royalties will continue through the lives of the HCV and HIV patents covering Roche's NAT products. Currently, the applicable issued HCV patents expire in 2015 for the U.S. and in 2008 for Europe. Currently, the applicable issued HIV patent in Europe expires in 2005. If and when a patent is issued under pending U.S. applications, the HIV patent life in the U.S. will be seventeen years from the date of issuance.

See "Blood testing Royalties and license fee revenues" above for a discussion of the third agreement entered into with Roche in October 2000 and two additional agreements entered into with Roche in May 2001, which superseded the October 2000 agreement.

**Bayer Cross-License Agreement** In connection with the sale of Chiron Diagnostics to Bayer, Chiron granted to Bayer rights under patents relating to HIV and HCV for use in NAT diagnostic tests (excluding blood screening). In exchange for these rights, Bayer paid to Chiron a license fee of \$100.0 million, which becomes nonrefundable in decreasing amounts over a period of three years. Chiron recognized license fee revenues in 2001 and 2000, which represented the portions of the \$100.0 million payment that became nonrefundable during those periods. The Company anticipates recognizing the remaining revenue of \$3.3 million in the fourth quarter 2001. In addition, the cross-

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license agreement provides for royalties to Chiron on HIV and HCV products sold by Bayer, for which Chiron recognized increased royalty revenues in 2001 as compared with 2000.

**Organon** In January 2001, Chiron granted to Organon Teknika BV ("Organon") rights under certain Chiron HIV patents. The agreement provides for royalties on future sales by Organon of assays for the detection of nucleic acid sequences for use in *in vitro* diagnostic (excluding blood screening) products, which commenced in the first quarter 2001.

**Abbott Laboratories** In 1999, Chiron entered into a cross-license agreement with Abbott, under which Chiron granted to Abbott rights under Chiron's HCV patents for use in NAT diagnostic tests (excluding blood screening). In exchange for these rights, Abbott paid Chiron a license fee, which became nonrefundable and was recognized as revenue in the second quarter 2000. In addition, the cross-license agreement provides for royalties to Chiron on HCV products sold by Abbott.

**Roche PCR Agreement** In accordance with a July 1991 agreement with Roche, the Company received royalties on sales of polymerase chain reaction ("PCR") products sold by Roche. The Company did not recognize any revenue under this agreement for the three months ended September 30, 2001. For the three months ended September 30, 2000, the Company recognized \$9.5 million under this agreement. For the nine months ended September 30, 2001 and 2000, the Company recognized \$2.6 million and \$14.7 million, respectively, under this agreement. Roche's royalty obligations, with certain limited exceptions for future products, expired in the fourth quarter 2000. However, Chiron estimated royalties on PCR product sales based on previous period actual sales. In the following quarter, Chiron recorded an adjustment equal to the difference between those estimated royalty revenues recorded in the previous quarter and the contractual percentage of actual PCR product sales for that period. As a result, Chiron recorded the adjustment for the final fourth quarter 2000 royalties in the first quarter 2001.

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, the Company's ability to generate additional royalty and license fee revenues may depend, in part, on its ability to market and capitalize on its technologies. There can be no assurance that the Company will be able to do so or that future royalty and license fee revenues will not decline.

**Selling, general, and administrative** The other segment recognized SG&A expenses of \$14.7 million and \$11.3 million for the three months ended September 30, 2001 and 2000, respectively, and \$44.0 million and \$45.2 million for the nine months ended September 30, 2001 and 2000, respectively. The increase in SG&A expenses in the third quarter 2001 as compared with the third quarter 2000 primarily was due to various tax consulting and professional services. The decrease in SG&A expenses in year-to-date 2001 as compared with year-to-date 2000 primarily was due to lower patent litigation costs upon substantial conclusion of the Roche litigation in October 2000 and lower payroll taxes related to stock option exercises during a period of lower average Company stock prices. In March 2000, the Company posted an all-time high in its stock price.

**Amortization expense** The Company's other segment recognized amortization expense of \$9.6 million and \$28.7 million for the three and nine months ended September 30, 2001, respectively. As discussed above, Chiron acquired PathoGenesis on September 21, 2000 and accounted for the acquisition under the purchase method of accounting. A portion of the purchase price was allocated to purchased technologies, acquired intangible assets and goodwill, which are being amortized on a straight-line basis over the estimated useful life of each intangible asset. Purchased technologies represent the fair value of research and development projects, which will be developed further and supported after the acquisition date, and are being amortized on a straight-line basis over 15 years. Acquired intangible assets include the fair value of trademarks and trade names, patents, databases and

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the work force, and are being amortized on a straight-line basis over 5 to 16 years. Goodwill is being amortized on a straight-line basis over 15 years. As circumstances dictate, Chiron evaluates the useful life and value of each intangible asset, which may result in future adjustments to the amortization periods or book values.

As discussed in "New Accounting Standards" below, the Company will implement SFAS 142, "Goodwill and Other Intangible Assets," on January 1, 2002. SFAS 142 will require that goodwill and intangible assets with indefinite useful lives no longer be amortized, but instead be tested for impairment at least annually in accordance with SFAS 142.

**Restructuring and reorganization** The Company previously 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 the Company'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 400 positions in manufacturing, research, development, sales, marketing and other administrative functions, and facility-related costs. Employee termination costs included wage

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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.

During 1999, the Company decided to retain 18 of those 400 positions to support future contract manufacturing activities and, therefore, adjusted the number of positions for elimination to 382. Again during 2000, the Company decided to retain 11 of those 382 positions to support future contract manufacturing activities and, therefore, adjusted the number of positions for elimination to 371.

For the nine months ended September 30, 2001, the net restructuring and reorganization activity included a charge of \$0.2 million and a charge reversal of \$0.2 million. The charge of \$0.2 million primarily related to revised estimates of termination and other employee-related costs recorded in connection with the elimination of the 371 positions, of which 360 had terminated as of September 30, 2001. The charge reversal of \$0.2 million primarily related to revised estimates of facility-related costs.

For the nine months ended September 30, 2000, the Company recorded net restructuring and reorganization charge reversals of \$0.4 million primarily related to revised estimates of termination and other employee-related costs recorded in connection with the retention of 11 of the 382 positions. As described above, the Company adjusted the number of positions for elimination to 371, of which 356 had terminated as of September 30, 2000.

The restructuring and reorganization accruals are expected to be substantially settled within one to six years of accruing the related charges. Management expects employee and facility-related cost savings due to these restructuring activities in cost of sales, research and development expense and SG&A expense through 2008. The Company believes that it has begun to achieve these cost savings.

**Gain (loss) on sale of assets** In January 2001, the Company sold various assets of its San Diego facility, resulting in a net gain of \$2.4 million. In February 2000, the Company sold substantially all assets of an Australian subsidiary, resulting in a net loss of \$0.2 million.

**Interest expense** Chiron recognized interest expense of \$3.1 million and \$3.3 million for the three months ended September 30, 2001 and 2000, respectively, and \$4.4 million and \$12.6 million for the nine months ended September 30, 2001 and 2000, respectively. The decrease in interest expense in 2001 as compared with 2000 primarily was due to the conversions of \$253.8 million of the 1.90% convertible debentures to common stock in October 2000 and \$98.4 million of the 5.25% convertible debentures to

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common stock in May 2000, offset by interest expense recognized on the Liquid Yield Option Notes ("LYONS") that were issued in June 2001.

**Other income, net** Other income, net, primarily consisted of interest income on the Company's cash and investment balances and other non-operating gains and losses. Chiron recognized interest income of \$14.1 million and \$26.3 million for the three months ended September 30, 2001 and 2000, respectively, and \$40.0 million and \$70.0 million for the nine months ended September 30, 2001 and 2000, respectively. The decrease in interest income in 2001 as compared with 2000 primarily was due to lower average cash and investment balances following the \$720.7 million cash payment to purchase PathoGenesis in September 2000, offset by the \$401.8 million received upon issuance of the LYONS in June 2001, and lower interest rates. Due to the declining interest rates, the Company does not expect interest income in the following periods to be commensurate with 2000.

The Company invests in a diversified portfolio of financial investments, including debt and equity securities. The price of these securities is subject to significant volatility. The Company performs periodic reviews for temporary or other than temporary impairment of its securities and records adjustments to the carrying values of those securities accordingly. For the nine months ended September 30, 2001 and 2000, Chiron recognized losses attributable to the other-than-temporary impairment of certain of these debt and equity securities of \$5.5 million and \$5.0 million, respectively. For the nine months ended September 30, 2001 and 2000, Chiron recognized gains of \$6.1 million and \$0.8 million, respectively, related to the sale of certain equity securities.

On December 31, 1998, Chiron completed the sale of its 30% interest in General Injectibles & Vaccines, Inc. ("GIV"), a distribution business, to Henry Schein, Inc. and received payment in full of certain advances made by the Company to GIV. The agreement also provided for Chiron to receive additional payments, calculated as a pre-determined percentage of Henry Schein, Inc.'s gross profit, through 2003. For the nine months ended September 30, 2001 and 2000, the Company received \$2.5 million and \$2.9 million, respectively.

In January 2000, the Company hedged a portion of its exposure to the British pound related to Menjugate sales. The Company settled this hedging contract upon substantial conclusion of Menjugate sales in the United Kingdom in the second quarter 2000. This settlement resulted in a gain of approximately \$5.4 million.

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**Income taxes** The effective tax rate for 2001 is estimated to be approximately 31.4% of pretax income from continuing operations, which reflects the amortization of goodwill and acquired identifiable intangible assets related to the PathoGenesis acquisition. The effective tax rate may be affected in future periods by changes in management's estimates with respect to the Company's deferred tax assets and other items affecting the overall tax rate. Income tax expense for the three and nine months ended September 30, 2000 was based on an estimated annual effective tax rate on pretax income from continuing operations of approximately 32.7%.

The annual reported effective tax rate for 2000 was 84.4% of pretax income from continuing operations and reflected the write-off of purchased in-process technologies and amortization expense on goodwill and acquired identifiable intangible assets related to the PathoGenesis acquisition.

**Discontinued operations** In a strategic effort to focus on its core businesses of Biopharmaceuticals, Vaccines and Blood Testing, the Company completed the sale of Chiron Diagnostics and Chiron Vision in 1998 and 1997, respectively.

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The "Gain on disposal of discontinued operations" consisted of the following (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2001	2000	2001	2000
Reversal of reserves for severance obligations	\$ 1,600	\$	\$ 1,600	\$
Reversal of reserves for indemnity obligations			1,500	2,190
Gain on the sale of the real estate assets			1,644	
Other		119		364
Income tax benefit (provision)	(85)	(45)	424	(138)
	\$ 1,515	\$ 74	\$ 5,168	\$ 2,416

Under the terms of the Bayer Agreement, the Company was responsible for severance payments to specific U.S. and international employees and, accordingly, reserved for such severance obligations. In the third quarter 2001, the Company reversed approximately \$1.6 million reserved for severance obligations based upon a final reconciliation from Bayer. This amount was recorded as a component of "Gain on disposal of discontinued operations."

Under the terms of the B&L Agreement related to the sale of Chiron Vision, the Company provided customary indemnities and, accordingly, reserved for such contractual obligations to indemnify B&L against certain potential claims. In the second quarter 2001, the Company reversed the remaining reserves of \$1.5 million upon the sale of the remaining real estate assets, as discussed below. In the second quarter 2000, the Company reversed approximately \$2.2 million reserved for contractual obligations to indemnify B&L against certain potential claims as such obligations had expired unused. Both amounts were recorded as a component of "Gain on disposal of discontinued operations."

The Company retained certain Chiron Vision assets, including certain Chiron Vision real estate assets (the "real estate assets") with a carrying value of \$25.1 million, upon the completion of the sale. As of December 31, 2000, the remaining real estate assets amounted to \$1.9 million. In April 2001, the Company sold these remaining real estate assets and recognized a net gain on the sale of these assets of \$1.6 million. This gain was recorded as a component of "Gain on disposal of discontinued operations."

### New Accounting Standards

In August 2001, the FASB issued SFAS 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." SFAS 144 supercedes SFAS 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed Of," in that it removes goodwill from its impairment scope and allows for different approaches in cash flow estimation. However, SFAS 144 retains the fundamental provisions of SFAS 121 for (a) recognition and measurement of the impairment of long-lived assets to be held and used and (b) measurement of long-lived assets to be disposed of. SFAS 144 also supercedes the business segment concept in APB Opinion No. 30, "Reporting the Results of Operations Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions," in that it permits presentation of a component of an entity, whether classified as held for sale or disposed of, as a discontinued operation. However, SFAS 144 retains the requirement of APB Opinion No. 30 to report discontinued operations separately from continuing operations. The Company is required to adopt the provisions of SFAS 144 effective January 1, 2002, with earlier application encouraged. The Company believes that the implementation of this standard will not have a material effect on the Company's results of operations and financial position.

In June 2001, the FASB issued SFAS 143, "Accounting for Asset Retirement Obligations." SFAS 143 requires liability recognition for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. The Company is required to adopt the provisions of SFAS 143 effective January 1, 2003, with earlier application encouraged. The Company is currently analyzing the effect, if any, the adoption of this standard will have on its financial statements.

In July 2001, the FASB issued SFAS 141, "Business Combinations," and SFAS 142, "Goodwill and Other Intangible Assets." SFAS 141 requires that the purchase method of accounting be used for all business combinations initiated or completed after June 30, 2001. SFAS 141 also specifies criteria that intangible assets acquired in a purchase business combination must meet to be recognized and reported apart from goodwill, noting that any purchase price allocable to an assembled workforce may not be accounted for separately. SFAS 142 will require that goodwill and intangible assets with indefinite useful lives no longer be amortized, but instead be tested for impairment at least annually in accordance with SFAS 142. SFAS 142 will also require that intangible assets with definite useful lives be amortized over their respective useful lives to their estimated residual values, and reviewed for impairment in accordance with SFAS 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of," which is superceded by SFAS 144 as discussed above.

The Company is required to adopt the provisions of SFAS 141 immediately, and SFAS 142 effective January 1, 2002. Furthermore, any goodwill and intangible asset determined to have an indefinite useful life that is acquired in a purchase business combination completed after June 30, 2001 will not be amortized, but will continue to be evaluated for impairment in accordance with SFAS 121 (as superceded by SFAS 144) or Accounting Principles Board Opinion No. 17, "Intangible Assets," as appropriate. Goodwill and intangible assets acquired in business combinations completed before July 1, 2001 will continue to be amortized prior to the adoption of SFAS 142.

SFAS 141 requires, upon adoption of SFAS 142, the Company to evaluate its existing intangible assets and goodwill that were acquired in a purchase business combination prior to June 30, 2001, and to make any necessary reclassifications in order to conform with the new criteria in SFAS 141 for recognition apart from goodwill. Upon adoption of SFAS 142, the Company will be required to reassess the useful lives and residual values of all intangible assets acquired in purchase business combinations, and make any necessary amortization period adjustments by the end of the first interim period after adoption. In addition, if an intangible asset is identified as having an indefinite useful life, the Company will be required to test the intangible asset for impairment in accordance with SFAS 142 within the first interim period. Any impairment loss will be measured as of the date of adoption and recognized as the cumulative effect of a change in accounting principle in the first interim period.

In connection with the transitional goodwill impairment evaluation, SFAS 142 will require the Company to perform an assessment of whether there is an indication that goodwill is impaired as of the date of adoption. To accomplish this, the Company must identify its reporting units and determine the carrying value of each reporting unit by assigning the assets and liabilities, including the existing goodwill and intangible assets, to those reporting units as of the date of adoption. The Company will then have up to six months from the date of adoption to determine the fair value of each reporting unit and compare it to the reporting unit's carrying amount. To the extent a reporting unit's carrying amount exceeds its fair value, an indication exists that the reporting unit's goodwill may be impaired and the Company must perform the second step of the transitional impairment test. In the second step, the Company must compare the implied fair value of the reporting unit's goodwill, determined by allocating the reporting unit's fair value to all of its assets (recognized and unrecognized) and liabilities in a manner similar to a purchase price allocation in accordance with SFAS 141, to its carrying amount, both of which would be measured as of the date of adoption. This second step is required to be completed as soon as possible, but no later than the end of the year of adoption. Any transitional impairment loss will be recognized as the cumulative effect of a change in accounting principle.

As of the date of adoption, the Company expects to have unamortized goodwill in the amount of \$223.9 million and unamortized identifiable intangible assets in the amount of \$380.1 million, all of which will be subject to the transition provisions of SFAS 141 and 142. Amortization expense related to goodwill was \$4.0 million and \$12.1 million for the three and nine months ended September 30, 2001, respectively, and \$5.6 million for the year ended December 31, 2000. Because of the extensive effort needed to comply with adopting SFAS 141 and 142, it is not practicable to reasonably estimate the impact of adopting these Statements on the Company's financial statements at the date of this report, including whether any transitional impairment losses will be required to be recognized as the cumulative effect of a change in accounting principle.

### **Liquidity and Capital Resources**

Chiron's capital requirements have generally been funded from operations, cash and investments on hand, debt borrowings and issuance of common stock. Chiron's cash and investments in marketable debt securities, which totaled \$1.2 billion at September 30, 2001, are invested in a

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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 of high credit standing. By policy, the amount of credit exposure to any one institution is limited. Investments are generally not collateralized and primarily mature within three years.

**Sources and uses of cash** Chiron had cash and cash equivalents of \$249.9 million and \$180.5 million at September 30, 2001 and 2000, respectively.

*Operating activities* For the nine months ended September 30, 2001, net cash provided by operating activities was \$108.1 million as compared with \$199.4 million for the nine months ended September 30, 2000. The decrease in cash provided by operating activities largely was due to (i) an increase in accounts receivable, (ii) higher tax payments and (iii) \$13.9 million of cash received upon the settlement of a cross currency interest rate swap in 2000. The increase in accounts receivable was driven by the increase in product sales and the timing of royalty payments under the Roche settlement agreements. In addition, the Company paid approximately \$90.6 million in foreign and federal tax payments during the first nine months of 2001 as compared with approximately \$6.4 million during the same nine months in 2000. The decrease in cash provided by operating activities was offset partially by (i) higher income from operations before depreciation and amortization and other non-cash charges of \$244.0 million for the nine months ended September 30, 2001 as compared with \$202.4 million for the same nine months in 2000 and (ii) a \$45.3 million license fee payment received from Bayer in June 2001, as discussed in "Blood testing Royalty and license fee revenues".

Unutilized net operating loss carryforwards and federal business credits attributed to the acquisition of PathoGenesis amounted to approximately \$105.2 million and \$6.0 million, respectively, and are available to offset future domestic taxable income through 2007. The Company estimates that it will utilize approximately \$41.0 million, as restricted pursuant to section 382 of the Internal Revenue Code, of such net operating loss carryforwards and federal business credits on an aggregate basis over each year. As a result, the Company does not expect tax payments in following years to be commensurate with those in 2000.

The Company anticipates that research and development expenditures in 2002 will increase due to the research and development activities related to TFPI and Proleukin® for HIV, as well as research and development platforms acquired from PathoGenesis in September 2000. Net cash from operating activities will fund these research and development activities.

*Investing activities* For the nine months ended September 30, 2001, net cash used in investing activities consisted of purchases of investments in marketable debt securities of \$810.0 million, capital expenditures of \$42.0 million, purchases of equity securities and interests in affiliated companies of

\$11.1 million, cash paid for acquisition costs of PathoGenesis of \$6.9 million and other uses of cash of \$2.8 million. Cash used in investing activities was offset by proceeds from the sale and maturity of investments in marketable debt securities of \$535.9 million, proceeds from the sale of assets of \$8.2 million, proceeds from the sale of equity securities and interests in affiliated companies of \$11.4 million and payments on notes receivable of \$6.6 million.

The purchases of equity securities and interests in affiliated companies consisted of a \$4.3 million capital contribution under a 2001 limited partnership agreement, a \$3.9 million capital contribution under a 2000 limited partnership agreement and a \$3.0 million capital contribution under a joint venture agreement. Under the 2001 limited partnership agreement, the Company will pay \$15.0 million over ten years, of which \$4.3 million was paid through September 30, 2001, for a 6.35% ownership percentage. Under the 2000 limited partnership agreement, the Company will pay \$25.0 million over five years, of which \$10.8 million was paid through September 30, 2001, for a 23.19% ownership percentage. Both the 2001 and 2000 limited partnership investments are being accounted for under the equity method of accounting. Under the joint venture agreement, the Company invested in a Singapore-based joint venture, S\*BIO, to research and develop therapeutic, diagnostic and vaccine products. The Company has invested \$8.0 million, which the Company wrote off entirely due to the early stage of the joint venture's research and development activities, for a 19.9% ownership interest and is accounting for the investment on the cost method.

In February 2001, the Company's Board of Directors approved a \$235.0 million capital expansion project, which includes the construction of two buildings and a parking structure in Emeryville, California. As of September 30, 2001, the Company has committed to \$15.7 million in design and construction services, under which the Company has incurred costs of \$2.3 million. The Company currently is negotiating the remaining design and construction services and evaluating various financing alternatives for this capital expansion project.

Based on current estimates provided in the April 2001 agreement with Rhein Biotech and GCVC (see "Results of Operations Vaccines Research and Development" above), Chiron committed approximately 24.4 million Euro (\$22.4 million at September 30, 2001), primarily for the expansion of the Company's Italian manufacturing facilities, which is scheduled to begin in the fourth quarter 2001 and is expected to continue through 2008. The Company currently is evaluating various financing alternatives to fund this expansion.

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In April 2001, the Company sold the remaining Chiron Vision real estate assets for \$3.3 million in cash. In January 2001, the Company sold various assets of its San Diego facility for \$4.9 million in cash.

The \$6.6 million in proceeds from notes receivable related to amounts collected under an April 1999 biopharmaceutical collaboration agreement and a February 2000 agreement to sell substantially all assets of the Company's Australian subsidiary to Mimotopes.

For the nine months ended September 30, 2000, net cash used in investing activities consisted of purchases of investments in marketable debt securities of \$3.3 billion, cash paid to purchase PathoGenesis of \$677.1 million, capital expenditures of \$24.3 million, purchases of equity securities and interests in affiliated companies of \$8.8 million and other uses of cash of \$23.7 million. Cash used in investing activities was offset by proceeds from the sale and maturity of investments in marketable debt securities of \$3.9 billion, proceeds from the sale of assets of \$1.0 million, proceeds from the sale of equity securities and interest in affiliated companies of \$4.8 million and payments on notes receivable of \$3.2 million. As of September 30, 2000, Chiron paid approximately \$677.1 million to purchase the outstanding shares of common stock of PathoGenesis. The purchases of equity securities and interests in affiliated companies consisted of a \$3.8 million capital contribution under the 2000 limited partnership agreement and a \$5.0 million capital contribution under the joint venture agreement.

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*Financing activities* For the nine months ended September 30, 2001, net cash provided by financing activities consisted of \$401.8 million in proceeds from the issuance of LYONs, \$52.2 million in proceeds from the reissuance of treasury stock, primarily related to stock option exercises and employee stock purchases, \$6.0 million in proceeds from put options and \$0.2 million in net proceeds from short-term borrowings. Cash provided by financing activities was offset by \$9.9 million for the payment of issuance costs on LYONs, \$163.2 million for the acquisition of treasury stock and \$1.5 million for the repayment of debt.

As discussed in Note 9, "Debt Obligations," in the Notes to Condensed Consolidated Financial Statements, Chiron issued zero coupon LYONs in June 2001 for proceeds of \$401.8 million. The LYONs mature on June 12, 2031.

The Company's Board of Directors authorized the repurchase of Chiron common stock on the open market to offset the dilution associated with the operation of the Company's stock option and employee stock purchase plans and the granting of share rights. In February 2001, the Board of Directors approved a 5.0 million share increase. The Board has authorized such repurchases through February 28, 2002. As of September 30, 2001, the Company may repurchase up to an additional 2.1 million shares of its common stock. In January 2001, the Company initiated a put option program to complement its ongoing stock repurchase program. Under this program, the Company enters into contracts with third parties to sell put options on Chiron stock, entitling the holders to sell to the Company a specified number of shares at a specified price per share on a specified date. For the nine months ended September 30, 2001, the Company collected premiums of \$6.0 million and, for contracts which expired, purchased 0.4 million shares in connection with the put option program. As of September 30, 2001, the Company has outstanding contracts with a third party to sell put options on Chiron stock, entitling the holder to sell to the Company 1.0 million shares. The options expire at various dates through December 2001 and have an average exercise price of \$42.95 per share.

For the nine months ended September 30, 2000, net cash used in financing activities consisted of \$213.1 million for the acquisition of treasury stock, \$70.8 million for the repayment of debt, including the note owed to Novartis, and \$16.3 million for the net repayment of short-term borrowings. Cash used in financing activities was offset by \$63.8 million and \$1.0 million in proceeds from the reissuance of treasury stock and the issuance of common stock, respectively, primarily related to stock option exercises and employee stock purchases.

The Company is currently evaluating a number of business development opportunities. To the extent that the Company is successful in reaching agreements with third parties, these transactions may involve the expenditure of a significant amount of the Company's current investment portfolio.

**Borrowing arrangements** Under a revolving, committed, uncollateralized credit agreement with a major financial institution, Chiron can borrow up to \$100.0 million in the U.S. This credit facility is guaranteed by Novartis under a November 1994 Investment Agreement, provides various interest rate options and matures in February 2003. There were no borrowings outstanding under this credit facility at September 30, 2001 and December 31, 2000. In December 1999, Chiron and Novartis amended the November 1994 Investment Agreement to reduce the maximum amount of Chiron obligations that Novartis would guarantee from \$725.0 million to \$702.5 million.

Chiron also has various uncommitted credit facilities available outside the U.S. One facility is maintained for all of Chiron's European subsidiaries and allows for total borrowings of \$50.0 million. There were no outstanding borrowings under this facility at September 30, 2001 and December 31, 2000. Chiron's Italian subsidiary also has various facilities, related to its receivables, which allow for total borrowings of 10.9 million Euro (\$10.0 million at September 30, 2001). There were no outstanding borrowings under this facility at September 30, 2001. At December 31, 2000, \$0.1 million were outstanding under this facility. A third facility is maintained for Chiron's 51%-owned Indian subsidiary and allows for total borrowings of 200 million Indian Rupee (\$4.2 million at September 30, 2001). At

September 30, 2001 and December 31, 2000, \$1.4 million and \$1.1 million, respectively, were outstanding under this facility.

### **Euro Conversion**

On January 1, 1999, eleven European Union member countries established fixed conversion rates between their existing currencies ("legacy currencies") and one common currency, the Euro. The legacy currencies will remain as legal tender in the member countries as denominations of the Euro between January 1, 1999 and January 1, 2002. The Euro is currently traded on currency exchanges and can be used in business transactions. The Company believes that its financial systems are Euro-ready in all material respects and has completed system upgrades to assist in its Euro-readiness effort. The cost of the upgrades was not material to the Company's results of operations and financial position. The Company believes that the Euro will not have a material effect on its product pricing and gross profit percentages.

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

As a biotechnology company, Chiron is engaged in a rapidly evolving and often unpredictable business. The forward-looking statements contained in this Report and in other periodic reports, press releases and other statements issued by the Company from time to time reflect management's 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 the Company's control, which could cause actual results to differ.

#### *Promising Technologies Ultimately May Not Prove Successful*

The Company focuses its research and development activities on areas in which it has 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 such 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 does not have 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. 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.

#### *Regulatory Approvals*

The Company is required to obtain and maintain regulatory approval in order to market most of its products. Generally, these approvals are on a product-by-product and country-by-country basis, and, in the case of therapeutic products, a separate approval is required for each therapeutic indication. See Part I, Item 1. "Business-Government Regulation" of the Company's Annual Report on Form 10-K for the year ended December 31, 2000. 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.

### *Manufacturing*

Most of the Company's 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. 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. Accordingly, 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.

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Specific to the Company's product, TOBI® (tobramycin solution for inhalation), the Company relies on others to supply raw materials and to manufacture TOBI® according to regulatory requirements. Although Chiron believes either one of its two suppliers of bulk powdered tobramycin will be able to supply sufficient quantities to meet its current needs, Chiron has not entered into long-term supply contracts with the suppliers. Rather, the Company has an agreement for the formulation and packaging of TOBI® for a minimum term of 10 years. There can be no assurance that Chiron will be able to obtain future supplies of bulk tobramycin on favorable terms, that contract manufacturers will be able to provide sufficient quantities of TOBI® or that the products supplied will meet specifications.

In addition, any prolonged interruption in the operations of Chiron's or its contractors' manufacturing facilities could result in cancellations of shipments. A number of factors could cause interruptions, including equipment malfunctions or failures, damage to a facility due to natural disasters or suspension of power supplied to these facilities arising out of regional power shortages. Difficulties or delays in Chiron's or its contractors' manufacturing of existing or new products could increase costs and cause loss of revenue or market share.

### *Patents Held By Third Parties May Delay or Prevent Commercialization*

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 the Company and its corporate partners. It is likely that third parties will obtain other such patents in the future. Certain of these patents may be sufficiently broad to prevent or delay Chiron and its corporate partners from manufacturing or marketing products important to the Company's current and future business. The scope, validity and enforceability of such patents, if granted, the extent to which Chiron may wish or need to obtain licenses to such patents, and the cost and availability of such licenses cannot be accurately predicted. If Chiron does not obtain such licenses, products may be withdrawn from the market or delays could be encountered in market introduction while an attempt is made to design around such patents. Alternatively, Chiron could find that the development, manufacture or sale of such products is foreclosed. Chiron could also incur substantial costs in licensing or challenging the validity and scope of such patents.

### *Product Acceptance*

The Company may experience difficulties in launching new products, many of which are novel products based on technologies that are unfamiliar to the healthcare community. There can be 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 the Company's products directly (for example, by recommending a decreased dosage of the Company's product in conjunction with a concomitant therapy) or indirectly (for example, by recommending a competitive product over the Company's product).

### *Competition*

Chiron operates in a highly competitive environment, and the competition is expected to increase. Competitors include large pharmaceutical, chemical and blood testing companies, as well as biotechnology companies. Some of these competitors, particularly large pharmaceutical and blood testing companies, have greater resources than the Company. Accordingly, even if the Company is successful in launching a product, it 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 marketing capabilities; or the competitive product may have therapeutic or other advantages. The technologies applied by the Company and its competitors are rapidly evolving, and new developments frequently result in price competition and product obsolescence.

### *Chiron's Patents May Not Prevent Competition or Generate Revenues*

Chiron seeks to obtain patents on its inventions. Without the protection of patents, competitors may be able to use the Company's inventions to manufacture and market competing products without being required to undertake the lengthy and expensive development efforts made by Chiron and without having to pay royalties or otherwise compensate Chiron for the use of the invention.

There can be no assurance that patents and patent applications owned or licensed to Chiron 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. It is not known how many of the Company's 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. The Company has engaged in significant litigation to determine the scope and validity of certain of its patents

and expects to continue to do so in the future.

Even if the Company is 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 the 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) and 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.

*Availability of Reimbursement; Government and Other Pressures on Pricing*

In the U.S. and other significant markets, sales of the Company's 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

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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. 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.

*Costs Associated with Expanding the Business*

Management expects to grow the business in areas in which the Company can be most competitive, either through in-licensing, collaborations or acquisitions of products or companies. In connection with these efforts, the Company may incur significant charges, costs and expenses which could impact the Company's profitability, including impairment losses, restructuring charges, the write-off of purchased in-process technologies, transaction-related expenses, costs associated with integrating new businesses and the cost of amortizing goodwill and other intangibles. Further, success in clinical trials will likely lead to increased investment, adversely affecting short-term profitability, to bring such products to market.

*Other New Products and Sources of Revenue*

Many products in the Company's current pipeline are in relatively early stages of research or development. The Company's ability to grow earnings in the near- to medium-term may depend, in part, on its ability to initiate and maintain other revenue generating relationships with third parties, such as licenses to certain of the Company's technologies, and on its ability to identify and successfully acquire rights to later-stage products from third parties. There can be no assurance that such other sources of revenue will be established.

*Interest Rate and Foreign Currency Exchange Rate Fluctuations*

The Company has significant cash balances and investments. The Company's financial results, therefore, are sensitive to interest rate fluctuations in the U.S. In addition, the Company sells products in many countries throughout the world, and its financial results could be significantly affected by fluctuations in foreign currency exchange rates or by weak economic conditions in foreign markets.

*Corporate Partners*

An important part of the Company's business strategy depends upon collaborations with third parties, including research collaborations and joint efforts to develop and commercialize new products. As circumstances change, the Company and its corporate partners may develop conflicting priorities or other conflicts of interest. The Company 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, the parties may differ in their views 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 biotechnology industry may affect the Company's corporate partners, causing them to reprioritize their efforts related to the research collaborations and other joint efforts with the Company. 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 the Company's profitability.

*Stock Price Volatility*

The price of the Company's stock, like that of other biotechnology companies, is subject to significant volatility. Any number of events, both internal and external to the Company, may affect the

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stock price. These include, without limitation, results of clinical trials conducted by the Company or by its competitors; announcements by the Company or its competitors regarding product development efforts, including the status of regulatory approval applications; the outcome of legal proceedings, including claims filed by the Company against third parties to enforce its patents and claims filed by third parties against the Company relating to patents held by the third parties; the launch of competing products; the resolution of (or failure to resolve) disputes with collaboration partners; corporate restructuring by the Company; licensing activities by the Company; and the acquisition or sale by the Company of products, products in development or businesses.

In connection with its research and development collaborations, from time to time the Company invests in equity securities of its 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 the Company's stock. Changes in the market price of these securities may impact the Company's profitability.

*Income Taxes*

The Company is taxable principally in the U.S., Germany, Italy, The Netherlands and 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 the Company's tax provision in the future. The Company has 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 the Company believes that all material tax liabilities are reflected properly in its balance sheet, the Company is presently under audit in several jurisdictions, and there can be no assurance that the Company will prevail in all cases in the event the taxing authorities disagree with the Company's interpretations of the tax law. In addition, the Company has assumed liabilities for all income taxes incurred prior to the sales of its former subsidiaries, Chiron Vision (subject to certain limitations) and Chiron Diagnostics. Future levels of research and development spending, capital investment and export sales will impact the Company's entitlement to related tax credits and benefits which have the effect of lowering its effective tax rate.

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

**Market risk management** The Company's cash flow and earnings are subject to fluctuations due to changes in foreign currency exchange rates, interest rates, the fair value of equity securities held and the Company's stock price. The Company attempts to limit its exposure to some or all of these market risks through the use of various financial instruments. There were no significant changes in the Company's market risk exposures during the third quarter 2001. For further discussions of the Company's market risk exposures, refer to Part II, Item 7A., "Quantitative and Qualitative Disclosures About Market Risk" of the Company's Annual Report on Form 10-K for the year ended December 31, 2000 and Part I, Item 3., "Quantitative and Qualitative Disclosures About Market Risk" of the Company's Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2001 and June 30, 2001.

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**PART II**

**Item 1. Legal Proceedings**

The Company is party to certain lawsuits and legal proceedings, which are described in Part I, Item 3., "Legal Proceedings" of the Company's Annual Report on Form 10-K for the year ended December 31, 2000 and in Part II, Item 1., "Legal Proceedings" of the Company's Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2001 and June 30, 2001. 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 and the first and second quarter reports on Form 10-Q.

***Dade Behring Marburg GmbH and Dade Behring S.p.A.***

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In January 2001, Dade Behring Marburg GmbH and Dade Behring S.p.A. (collectively, "Dade Behring") filed suit in the Court of Milan against Chiron seeking a pan European declaration that its Enzygnost® HIV 1/2 plus immunoassay kit does not infringe Chiron's European Patent No. 0 181 150 (the "'150 patent") relating to HIV technology, and to nullify the Italian portion of the '150 patent. In April 2001, Chiron filed a counterclaim seeking a declaration of infringement of the Italian portion of the '150 patent by the Enzygnost® HIV 1/2 plus kit and related damages.

In May 2001, Chiron filed a petition for a preliminary injunction in the German Federal Court ("Landgericht") in Dusseldorf, asserting that the manufacture and sale of Dade's Enzygnost® HIV 1/2 plus immunoassay kit infringes the '150 patent. In October 2001, the Court ruled that, due to a procedural insufficiency irrelevant to the merits of the patent, Chiron's petition would not be granted. This result is subject to appeal.

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

### ***F. Hoffman La-Roche A.G.***

Chiron was involved in certain previously reported litigation in the U.S. and several other countries with F. Hoffman-LaRoche AG and related foreign entities (collectively "Roche") concerning infringement and/or validity of certain patents related to HCV and HIV technology. In October 2000, Chiron and Roche resolved all litigation regarding HCV and HIV nucleic acid technology. Among the settlement provisions, Chiron granted Roche licenses to manufacture and sell HCV and HIV nucleic acid clinical diagnostic tests. In May 2001, Chiron further granted Roche licenses to manufacture and sell HCV and HIV nucleic acid tests for blood screening.

These licensing agreements, however, did not resolve disputes regarding HCV immunoassay technology. In connection therewith, 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 HCV immunoassay products infringe Chiron's German Patent Nos. DD 298 527 (the "527 patent"), DD 298 524 (the "524 patent"), DD 287 104 (the "104 patent"), DD 297 446 (the "446 patent") (collectively, the "German patents") and Chiron's European Patent No. EP 0 450 931 (the "931 patent"). The Landgericht subsequently separated the matter into five individual actions, and recently postponed oral hearings on the German patents, pending results of the nullity proceedings described below. An oral hearing on the '931 patent is scheduled for October 30, 2001.

In July 2000, Chiron initiated an action against Roche Diagnostics GmbH and related foreign entities in the German Administrative Court ("Verwaltungsgericht") in Karlsruhe, asserting that Roche's manufacture and sale of HCV immunoassay products in various European countries infringe the '931 patent. Over Roche's objections, the action was referred to the District Court of Mannheim in March 2001. An oral hearing is currently scheduled for January 18, 2002.

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In December 2000, Roche initiated two nullity actions against Chiron's German HCV national patents (the '104, '524 and '527 patents), and the '931 patent in the German Federal Patent Court ("Bundespatentgericht"). In January 2001, the Bundespatentgericht divided the German nullity suit into three individual actions. The Bundespatentgericht has indicated that oral hearings on the nullity actions will not occur before June 2002.

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

The October 2000 settlement also did not resolve disputes between Chiron and Dr. Daniel Bradley ("Dr. Bradley"). In January 1998, Chiron initiated an action against Roche and Dr. Bradley in the United States District Court for the Northern District of California. With respect to Dr. Bradley, the action asserted that Dr. Bradley breached a 1990 settlement agreement with Chiron, that Roche wrongfully induced this breach, and that Dr. Bradley committed slander of title with respect to Chiron's HCV technology. The action sought damages, injunctive relief and a declaratory judgment that Chiron is the sole and exclusive owner of its HCV technology. The Court found that foreign and domestic rights were assigned by Dr. Bradley to Chiron under the 1990 settlement, that Dr. Bradley's earlier litigation against Chiron was Res Judicata as to foreign rights, and that Dr. Bradley's assignment of such rights to Roche breached his settlement agreement with Chiron.

In October 2001, Dr. Bradley and Chiron entered into a consent judgment declaring 1) that Dr. Bradley was not an inventor of the disputed patents or of patents related thereto; 2) that Dr. Bradley was properly not named as an inventor of Chiron's HCV patents; and 3) that Dr. Bradley has no ownership interest in said patents. Chiron and Dr. Bradley entered a confidential settlement agreement on October 25, 2001, which fully resolves Chiron's action against Dr. Bradley.

### ***Gen-Probe Incorporated***

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In February 2001, Gen-Probe Incorporated ("Gen-Probe") filed a demand for arbitration alleging Chiron breached certain of the terms of their June 1998 collaboration agreement regarding nucleic acid tests used for blood screening. Gen-Probe seeks various declarations of the parties' rights under the agreement and compensatory damages. Chiron denies Gen-Probe's claims and asserts certain cross claims against Gen-Probe. On August 3, 2001, the arbitrator entered summary judgment in Chiron's favor on several of the issues in dispute. On October 24, 2001, the arbitrator denied Gen-Probe's motion for summary judgment. The remaining disputed issues will proceed through a full evidentiary hearing, which is expected to take place in December 2001. It is not known when nor on what basis this matter will be resolved.

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

In October 2001, the German Red Cross Donation Service and Working Society of Physicians brought a complaint against Chiron and Roche before the Commission of the European Communities (the "Commission"). The parties allege that Chiron and Roche violate Articles 81 and 82 of the European competition law in connection with marketing of nucleic acid test for blood screening. It is not known when nor on what basis this matter will be resolved.

### *Lipton Et. Al.*

On February 18, 2000, the United States District Court for the Western District of Washington dismissed with prejudice all eight consolidated putative class action lawsuits that had been filed in March and April 1999 against PathoGenesis Corporation ("PathoGenesis"), its chief executive officer and its chief financial officer. The eight consolidated lawsuits alleged claims on behalf of all purchasers of PathoGenesis common stock during the period January 15, 1999 to March 22, 1999. Plaintiffs claimed that PathoGenesis and its officers violated certain provisions of the federal securities laws by making statements in early 1999 regarding PathoGenesis' 1998 financial results. The court's order

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dismissed the consolidated cases and bars plaintiffs from filing another lawsuit on the matter. In October 2001, the United States Court of Appeals for the Ninth Circuit heard oral argument based on plaintiffs appeal of the dismissal order. It is not known when nor on what basis this matter will be resolved.

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

None.

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

(a) Exhibits

Exhibit Number	Exhibit
3.01	Restated Certificate of Incorporation of the Registrant, as filed with the Office of the Secretary of State of Delaware on August 17, 1987, incorporated by reference to Exhibit 3.01 of the Registrant's report on Form 10-K for fiscal year 1996.
3.02	Certificate of Amendment of Restated Certificate of Incorporation of the Registrant, as filed with the Office of the Secretary of State of Delaware on December 12, 1991, incorporated by reference to Exhibit 3.02 of the Registrant's report on Form 10-K for fiscal year 1996.
3.03	Certificate of Amendment of Restated Certificate of Incorporation of the Registrant, as filed with the Office of the Secretary of State of Delaware on May 22, 1996, incorporated by reference to Exhibit 3.04 of the Registrant's report on Form 10-Q for the period ended June 30, 1996.
3.04	Bylaws of the Registrant, as amended, incorporated by reference to Exhibit 3.04 to the Registrant's report on Form 10-K for fiscal year 2000.
4.01	Indenture between the Registrant and State Street Bank and Trust Company, dated as of June 12,

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Exhibit Number	Exhibit
	2001, incorporated by reference to Exhibit 4.01 of the Registrant's report on Form 10-Q for the period ended June 30, 2001.
4.02	Registration Rights Agreement between the Registrant and Merrill Lynch & Co., Inc., and Merrill Lynch, Pierce, Fenner & Smith, Incorporated, incorporated by reference to Exhibit 4.02 of the Registrant's report on Form 10-Q for the period ended June 30, 2001.
4.03	Form of Liquid Yield Option Note due 2031 (Zero Coupon Senior) (included as exhibits A-1 and A-2 to the Indenture filed as Exhibit 4.01 hereto), incorporated by reference to Exhibit 4.03 of the Registrant's report on Form 10-Q for the period ended June 30, 2001.
4.04	Reserved.
10.210	Contract Manufacturing Agreement dated as of July 26, 2001, between Chiron S.p.A. and SynCo Bio Partners B.V. (Certain information has been omitted from the Agreement and filed separately with the Securities and Exchange Commission pursuant to a request by Registrant for confidential treatment pursuant to Rule 24b-2. The omitted confidential information has been identified by the following statement "Confidential Treatment Requested".)

(b)

Reports on Form 8-K

None.

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## CHIRON CORPORATION

September 30, 2001

## SIGNATURES

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

CHIRON CORPORATION

DATE: November 7, 2001

BY: /s/ SEÁN P. LANCE

Seán P. Lance  
Chief Executive Officer and President;  
Chairman of the Board

DATE: November 7, 2001

BY: /s/ JAMES R. SULAT

James R. Sulat  
Vice President; Chief Financial Officer

DATE: November 7, 2001

BY: /s/ DAVID V. SMITH

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David V. Smith

*Vice President; Principal Accounting Officer*

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PART II

CHIRON CORPORATION

September 30, 2001

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