

CHIRON CORP  
Form 10-Q  
November 03, 2005

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

---

## FORM 10-Q

(Mark one)

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

For the quarterly period ended September 30, 2005

OR

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

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

Commission File Number: 0-12798

---

## CHIRON CORPORATION

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**4560 Horton Street, Emeryville, California**  
(Address of principal executive offices)

**94-2754624**

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

**94608**  
(Zip code)

**(510) 655-8730**

(Registrant's telephone number, including area code)

**Not Applicable**

(Former name, former address and former fiscal year, if changed since last report)

---

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

Yes  No

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

Edgar Filing: CHIRON CORP - Form 10-Q

Yes  No

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

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

Title of Class	Outstanding at October 31, 2005
Common Stock, \$0.01 par value	188,575,753

---

**CHIRON CORPORATION**  
**TABLE OF CONTENTS**

	<b>Page No.</b>
<b>PART I. FINANCIAL INFORMATION</b>	
<b><u>ITEM 1. Financial Statements (Unaudited)</u></b>	
<u>Condensed Consolidated Balance Sheets at September 30, 2005 and December 31, 2004</u>	3
<u>Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2005 and 2004</u>	5
<u>Condensed Consolidated Statements of Comprehensive Income (loss) for the three and nine months ended September 30, 2005 and 2004</u>	6
<u>Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2005 and 2004</u>	7
<u>Notes to Condensed Consolidated Financial Statements</u>	8
<b><u>ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u></b>	23
<b><u>ITEM 3. Quantitative and Qualitative Disclosures About Market Risk</u></b>	60
<b><u>ITEM 4. Controls and Procedures</u></b>	61
<b><u>PART II. OTHER INFORMATION</u></b>	
<b><u>ITEM 1. Legal Proceedings</u></b>	63
<b><u>ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds</u></b>	65
<b><u>ITEM 3. Defaults Upon Senior Securities</u></b>	65
<b><u>ITEM 4. Submission of Matters to a Vote of Security Holders</u></b>	65
<b><u>ITEM 5. Other Information</u></b>	65
<b><u>ITEM 6. Exhibits</u></b>	66
<b><u>SIGNATURES</u></b>	68

## Item 1. Financial Statements

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

	September 30, 2005	December 31, 2004
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 204,368	\$ 209,509
Short-term investments in marketable debt securities	375,738	394,112
Total cash, cash equivalents and short-term investments	580,106	603,621
Accounts receivable, net of allowances	383,925	402,094
Inventories, net of reserves	268,566	221,154
Assets held for sale	1,221	
Current net deferred income tax asset	61,398	71,287
Derivative financial instruments	5,418	4,969
Other current assets	141,488	90,898
Total current assets	1,442,122	1,394,023
Non-current investments in marketable debt securities	437,650	409,421
Property, plant, equipment and leasehold improvements, at cost:		
Land and buildings	379,799	379,861
Laboratory, production and office equipment	674,094	637,394
Leasehold improvements	137,099	125,858
Construction-in-progress	247,349	225,482
	1,438,341	1,368,595
Less accumulated depreciation and amortization	(614,244 )	(569,180 )
Property, plant, equipment and leasehold improvements, net	824,097	799,415
Purchased technologies, net	200,830	216,037
Goodwill	805,948	861,394
Other intangible assets, net	375,994	457,707
Investments in equity securities and affiliated companies	64,812	100,951
Non-current notes receivable	12,467	7,500
Other non-current assets	52,886	59,055
	\$ 4,216,806	\$ 4,305,503

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

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

	September 30, 2005	December 31, 2004
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 124,612	\$ 129,942
Accrued compensation and related expenses	80,634	79,113
Derivative financial instruments		10,395
Current portion of long-term debt and capital lease	1,569	2,687
Current portion of unearned revenue	54,454	35,651
Income taxes payable	18,051	16,363
Other current liabilities	180,202	160,293
Total current liabilities	459,522	434,444
Long-term debt	938,449	936,652
Long-term portion of capital lease	156,723	156,952
Non-current derivative financial instruments		156
Non-current net deferred income tax liability	37,063	60,427
Non-current unearned revenue	25,146	26,175
Other non-current liabilities	68,549	79,643
Minority interest	10,679	9,350
Total liabilities	1,696,131	1,703,799
Commitments and contingencies		
Stockholders' equity:		
Common stock	1,917	1,917
Additional paid-in capital	2,539,628	2,527,709
Deferred stock compensation	(15,988 )	(13,825 )
Accumulated deficit	(14,920 )	(11,843 )
Accumulated other comprehensive income	158,809	330,491
Treasury stock, at cost (3,156,000 shares at September 30, 2005 and 4,804,000 shares at December 31, 2004)	(148,771 )	(232,745 )
Total stockholders' equity	2,520,675	2,601,704
	\$ 4,216,806	\$ 4,305,503

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

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

	Three Months Ended September 30, 2005		Nine Months Ended September 30, 2005	
		2004 Restated		2004 Restated
<b>Revenues:</b>				
Product sales, net	\$ 367,175	\$ 375,549	\$ 947,913	\$ 937,836
Revenues from joint business arrangement	36,093	34,017	103,154	92,910
Collaborative agreement revenues	3,149	4,124	11,129	14,467
Royalty and license fee revenues	70,726	111,396	227,309	221,384
Other revenues	2,470	4,450	16,221	22,363
<b>Total revenues</b>	<b>479,613</b>	<b>529,536</b>	<b>1,305,726</b>	<b>1,288,960</b>
<b>Operating expenses:</b>				
Cost of sales (excludes amortization expense related to acquired developed products)	168,726	241,044	511,005	498,808
Research and development	107,309	103,000	324,620	301,736
Selling, general and administrative	117,152	112,013	375,802	321,775
Amortization expense of intangible assets acquired in business combinations and asset purchases	12,361	20,566	54,237	63,077
Purchased in-process research and development		9,629		9,629
Impairment loss on acquired intangible assets	14,522		14,522	
Other operating expenses	3,621	1,280	12,823	8,040
<b>Total operating expenses</b>	<b>423,691</b>	<b>487,532</b>	<b>1,293,009</b>	<b>1,203,065</b>
<b>Income from operations</b>	<b>55,922</b>	<b>42,004</b>	<b>12,717</b>	<b>85,895</b>
Interest expense	(7,759 )	(7,063 )	(22,932 )	(19,440 )
Interest and other income, net	18,514	5,369	66,259	41,252
Minority interest	(531 )	(504 )	(1,723 )	(1,583 )
<b>Income from continuing operations before income taxes</b>	<b>66,146</b>	<b>39,806</b>	<b>54,321</b>	<b>106,124</b>
Provision for income taxes	14,835	12,359	11,903	28,938
<b>Income from continuing operations</b>	<b>51,311</b>	<b>27,447</b>	<b>42,418</b>	<b>77,186</b>
Gain (loss) from discontinued operations, net of taxes		(450 )		24,854
<b>Net income</b>	<b>\$ 51,311</b>	<b>\$ 26,997</b>	<b>\$ 42,418</b>	<b>\$ 102,040</b>
<b>Basic earnings per share:</b>				
Income from continuing operations	\$ 0.27	\$ 0.15	\$ 0.23	\$ 0.41
Net income	\$ 0.27	\$ 0.14	\$ 0.23	\$ 0.54
<b>Diluted earnings per share:</b>				
Income from continuing operations	\$ 0.27	\$ 0.14	\$ 0.22	\$ 0.40
Net income	\$ 0.27	\$ 0.14	\$ 0.22	\$ 0.53

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

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

	Three Months Ended September 30, 2005		Nine Months Ended September 30, 2005	
		2004 Restated		2004 Restated
Net income	\$ 51,311	\$ 26,997	\$ 42,418	\$ 102,040
Other comprehensive loss:				
Change in foreign currency translation adjustment during the period	(27,980 )	2,960	(152,119 )	(34,452 )
Unrealized gains (losses) from investments:				
Net unrealized holding gains (losses) arising during the period, net of tax (provision) benefit of (\$3,098) and (\$5,977) for the three months ended September 30, 2005 and 2004, respectively, and (\$1,419) and (\$3,865) for the nine months ended September 30, 2005 and 2004, respectively	5,013	(2,680 )	2,564	4,864
Reclassification adjustment for net gains included in net income, net of tax (provision) of (\$2,773) and (\$400) for the three months ended September 30, 2005 and 2004, respectively, and (\$13,682) and (\$9,753) for the nine months ended September 30, 2005 and 2004, respectively	(4,472 )	(625 )	(22,127 )	(15,254 )
Net unrealized gains (losses) from investments	541	(3,305 )	(19,563 )	(10,390 )
Other comprehensive loss	(27,439 )	(345 )	(171,682 )	(44,842 )
Comprehensive income (loss)	\$ 23,872	\$ 26,652	\$ (129,264 )	\$ 57,198

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

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

	Nine Months Ended September 30, 2005	2004 Restated
Net cash provided by operating activities	\$ 117,561	\$ 132,633
Cash flows from investing activities:		
Purchases of investments in marketable debt securities	(714,151 )	(724,616 )
Proceeds from sales of investments in marketable debt securities	194,500	415,100
Proceeds from maturities of investments in marketable debt securities	499,119	225,959
Capital expenditures	(140,952 )	(134,079 )
Purchases of equity securities and interests in affiliated companies	(4,291 )	(6,216 )
Proceeds from sale of equity securities and interests in affiliated companies	30,036	31,421
Cash paid for acquisitions, net of cash acquired	(3,294 )	(32,289 )
Proceeds from (issuance of) notes receivable	(4,967 )	1,479
Other, net	(10,420 )	(5,167 )
Net cash used in investing activities	(154,420 )	(228,408 )
Cash flows from financing activities:		
Repayment of debt and capital leases	(599 )	(380,159 )
Payments to acquire treasury stock		(129,665 )
Proceeds from re-issuance of treasury stock	38,619	64,178
Proceeds from issuance of debt	1,002	4,996
Payment of bond issuance costs		(8,285 )
Proceeds from issuance of convertible debentures		385,000
Net cash provided by (used in) financing activities	39,022	(63,935 )
Effect of exchange rate changes on cash and cash equivalents	(7,304 )	(3,577 )
Net decrease in cash and cash equivalents	(5,141 )	(163,287 )
Cash and cash equivalents at beginning of the period	209,509	364,270
Cash and cash equivalents at end of the period	\$ 204,368	\$ 200,983

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



**CHIRON CORPORATION**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**September 30, 2005**  
**(Unaudited)**

**Note 1 Basis of Presentation**

The information presented in the Condensed Consolidated Financial Statements at September 30, 2005, and for the three and nine months ended September 30, 2005 and 2004, is unaudited but includes all adjustments, consisting only of normal recurring adjustments, which Chiron Corporation believes to be necessary for fair presentation of the periods presented.

The Condensed Consolidated Balance Sheet amounts at December 31, 2004, have been derived from audited financial statements. Historically, Chiron's operating results have varied considerably from period to period due to the nature of Chiron's collaborative, royalty and license arrangements and the seasonality of certain vaccine products. In addition, the mix of products sold and the introduction of new products will affect comparability from quarter to quarter. As a consequence, Chiron's interim results in any one quarter are not necessarily indicative of results to be expected for a full year. This information should be read in conjunction with Chiron's audited Consolidated Financial Statements as of and for the year ended December 31, 2004, which are included in the Annual Report on Form 10-K filed by Chiron with the Securities and Exchange Commission, or SEC.

*Principles of Consolidation*

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

*Restated Second-Quarter and Third-Quarter 2004 Financial Statements*

During our 2004 year-end financial statement review, we determined that certain sales of the travel vaccine recorded as revenues in the second quarter of 2004 should not have been recorded as revenue at that time, and that portions of those sales should have been recorded as revenues in the third and fourth quarters of 2004 and possibly in later quarters. As a result, we restated the financial statements included in our Quarterly Reports on Form 10-Q for such quarters and filed amended Form 10-Qs for such quarters on April 6, 2005.

*Use of Estimates and Reclassifications*

The preparation of financial statements requires management to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures of contingent assets and liabilities. On an on-going basis, management evaluates its estimates, including those related to investments; inventories; derivatives; capital leases; intangible assets; goodwill; purchased in-process research and development; product discounts, rebates and returns; bad debts; collaborative, royalty and license arrangements; restructuring; pension and other post-retirement benefits; income taxes; and litigation and other contingencies. Chiron bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of

**CHIRON CORPORATION**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**September 30, 2005**  
**(Unaudited)**

**Note 1 Basis of Presentation (Continued)**

which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from those estimates under different assumptions or conditions.

Chiron, prior to filing its financial statements on Form 10-Q, publicly releases an unaudited condensed consolidated balance sheet and statement of operations. Between the date of Chiron's earnings release and the filing of Form 10-Q, reclassifications may be required. These reclassifications, when made, have no effect on income from continuing operations, net income or earnings per share. There has been no such reclassification in the third quarter of 2005.

Chiron currently owns certain manufacturing and inspection equipment which is no longer useful and became available for sale in 2005. Chiron has committed to a plan to sell these assets and is actively marketing these assets. These assets are classified as "Assets held for sale" in the Condensed Consolidated Balance Sheet at September 30, 2005.

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

*Stock-Based Compensation*

Chiron measures compensation expense for its stock-based employee compensation using the intrinsic value method. Compensation expense is based on the difference, if any, between the fair value of Chiron's common stock and the exercise price of the option or share right on the measurement date, which is typically the date of grant. This amount is recorded as "Deferred stock compensation" in the Condensed Consolidated Balance Sheets and amortized as a charge to operations over the vesting period of the applicable options or share rights.

**CHIRON CORPORATION**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**September 30, 2005**  
**(Unaudited)**

**Note 1 Basis of Presentation (Continued)**

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

		Three Months Ended September 30, 2005		Nine Months Ended September 30, 2005	
		2004	2004	2005	2004
		Restated			Restated
(in thousands, except per share data)					
Net income (loss):					
As reported		\$ 51,311	\$ 26,997	\$ 42,418	\$ 102,040
Add:	Stock-based employee compensation expense included in reported net income, net of related tax effects	1,189	1,118	3,264	3,807
Less:	Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	17,450	23,778	53,186	68,055
Pro forma		\$ 35,050	\$ 4,337	\$ (7,504 )	\$ 37,792
Basic net income (loss) per share:					
As reported		\$ 0.27	\$ 0.14	\$ 0.23	\$ 0.54
Pro forma		\$ 0.19	\$ 0.02	\$ (0.04 )	\$ 0.20
Diluted net income (loss) per share:					
As reported		\$ 0.27	\$ 0.14	\$ 0.22	\$ 0.53
Pro forma		\$ 0.19	\$ 0.02	\$ (0.04 )	\$ 0.20

**Note 2 New Accounting Standards**

In December 2004, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment* (SFAS 123(R)), which requires the cost resulting from all share-based payment transactions to be recognized in the consolidated financial statements. That cost will be measured based on the fair value of the equity instruments issued or on the fair value of liabilities incurred. Under SFAS 123(R), the fair-value-based method for recognition or disclosure of compensation expense will be applied using the modified prospective application transition method or the modified retrospective application transition method. Chiron currently measures compensation expense for its stock-based employee compensation under the intrinsic method. Chiron is currently evaluating transition methods, option valuation methodologies and assumptions in light of SFAS 123(R) and, therefore, cannot estimate the impact of its adoption at this time, although Chiron expects that its adoption will have a material impact on Chiron's consolidated financial statements. Current option values determined using the Black-Scholes-Merton formula, used for purposes of proforma disclosure, may not be indicative of results from the valuation methodologies Chiron finally adopts. The effective date of SFAS 123(R) is the first reporting period beginning after June 15, 2005. However, on April 14, 2005, the Securities and Exchange Commission (SEC) announced the adoption of a new rule that delays the effective date of SFAS 123(R) for registrants, such as Chiron, that are not small business issuers. The

**CHIRON CORPORATION**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**September 30, 2005**  
**(Unaudited)**

**Note 2 New Accounting Standards (Continued)**

SEC's new rule allows calendar year non-small business issuers to implement SFAS 123(R) at the beginning of 2006, which makes SFAS 123(R) effective for Chiron in the first quarter of 2006.

On October 22, 2004, the American Jobs Creation Act of 2004 (the Act) was signed into law. The Act includes a temporary incentive for U.S. multinationals to repatriate accumulated income earned outside the U.S. at an effective tax rate of 5.25%. On December 21, 2004, the FASB issued Staff Position 109-2, *Accounting and Disclosure Guidance for the Foreign Earnings Repatriation Provisions within the American Jobs Creation Act of 2004* (FSP 109-2). FSP 109-2 allows companies additional time to evaluate the effect of the law on whether unrepatriated foreign earnings continue to qualify for SFAS No. 109's exception to recognizing deferred tax liabilities and would require explanatory disclosures from those who need the additional time. Through September 30, 2005, Chiron has not provided deferred taxes on foreign earnings because such earnings were intended to be indefinitely reinvested outside the U.S. Presently Chiron does not have any plan to repatriate earnings under the Act. Accordingly, Chiron has made no change in its current intention to indefinitely reinvest accumulated earnings of its foreign subsidiaries. If Chiron repatriates these earnings, a tax charge to its consolidated results of operations could occur. Chiron will continue to evaluate the impact of this provision.

**Note 3 Inventories**

Inventories, net of reserves, are stated at the lower of cost or market using the moving weighted-average cost method. Chiron maintains inventory reserves primarily for product failures, expiration and obsolescence. Inventory that is obsolete (inventory that will no longer be used in the manufacturing process), expired, or in excess of forecasted usage is written down to its market value, if lower than cost.

Inventories, net of reserves, consisted of the following:

	<b>September 30, 2005</b>	<b>December 31, 2004</b>
	<b>(in thousands)</b>	
Finished goods	\$ 84,675	\$ 59,206
Work-in-process	138,211	116,660
Raw materials	45,680	45,288
	<b>\$ 268,566</b>	<b>\$ 221,154</b>

**Note 4 Income Taxes**

The effective tax rate was 21.9% and 27.3% of pretax income from continuing operations for the nine months ended September 30, 2005 and 2004, respectively. The tax rate decreased primarily due to lower expected taxable incomes, year to year, in certain high tax jurisdictions, as well as increased benefits of U.S. research credits. Such items are not expected to recur in future years. The effective tax rate may be affected in future periods by changes in management's estimates with respect to our deferred tax assets and other items affecting the overall tax rate.

**CHIRON CORPORATION**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**September 30, 2005**  
**(Unaudited)**

**Note 5 Comprehensive Income (Loss)**

For the three and nine months ended September 30, 2005 and 2004, the foreign currency translation component of comprehensive income (loss) relates to permanent investments in non-U.S. subsidiaries and, accordingly, was not adjusted for income taxes.

**Note 6 Treasury Stock**

Treasury stock is stated at cost. Gains on reissuance of treasury stock are credited to Additional paid-in capital. Losses on reissuance of treasury stock are charged to Additional paid-in capital to the extent of available net gains on reissuance of treasury stock. Otherwise, losses are charged to Accumulated deficit. Chiron charged losses of \$21.4 million and \$45.6 million for the three and nine months ended September 30, 2005, respectively, and \$9.0 million and \$39.1 million for the three and nine months ended September 30, 2004, respectively, to Accumulated deficit in the Condensed Consolidated Balance Sheets.

**Note 7 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 and equivalents, which are included under the treasury-stock method; (ii) performance based share rights awards 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, if applicable. Due to rounding, quarterly amounts may not sum to full year amounts.

Contingently convertible debt instruments ( CoCos ) are included in diluted earnings per share, if dilutive. For the three months ended September 30, 2005, Chiron's \$500.0 million contingently convertible debentures due 2033 ( 2033 Debentures ) were included in the computation of diluted earnings per share. These debentures were not dilutive for the three months ended September 30, 2004. For the three months ended September 30, 2005 and 2004, Chiron's \$385.0 million contingently convertible debentures due 2034 ( 2034 Debentures ) were excluded from the computations of diluted earnings per share as the inclusion of these debentures would be antidilutive. For the nine months ended September 30, 2005 and 2004, the 2033 Debentures and the 2034 Debentures were excluded from the computation of diluted earnings per share as the inclusion of each of these CoCos would be antidilutive.

For the three months ended September 30, 2005, the Liquid Yield Option Notes (LYONs) were included in the computation of diluted earnings per share. For the nine months ended September 30, 2005, 0.6 million shares of common stock issuable upon conversion of the LYONs were excluded from the computations of diluted earnings per share as their inclusion would be antidilutive. For the three and nine months ended September 30, 2004, 0.6 million and 4.3 million shares of common stock that would be issued upon conversion of the LYONs were excluded from the computations of diluted earnings per share, as their inclusion would be antidilutive.

**CHIRON CORPORATION**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**September 30, 2005**  
**(Unaudited)**

**Note 7 Earnings Per Share (Continued)**

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):

	<b>Three Months Ended September 30, 2005</b>		<b>Nine Months Ended September 30, 2005</b>	
		<b>2004 Restated</b>		<b>2004 Restated</b>
<b>Income (Numerator):</b>				
Income from continuing operations	\$ 51,311	\$ 27,447	\$ 42,418	\$ 77,186
Plus: Interest on the 2033 Debentures, net of taxes	1,589			
Plus: Interest on Liquid Yield Option Notes, net of taxes	147			
Income from continuing operations, plus impact from assumed conversions	\$ 53,047	\$ 27,447	\$ 42,418	\$ 77,186
<b>Shares (Denominator):</b>				
Weighted-average common shares outstanding	188,039	187,368	187,564	187,751
<b>Effect of dilutive securities:</b>				
Stock options and equivalents	1,883	2,646	1,500	3,150
2033 Debentures	7,306			
Liquid Yield Option Notes	574			
Weighted-average common shares outstanding, plus impact from assumed conversions	197,802	190,014	189,064	190,901
Basic earnings per share from continuing operations	\$ 0.27	\$ 0.15	\$ 0.23	\$ 0.41
Diluted earnings per share from continuing operations	\$ 0.27	\$ 0.14	\$ 0.22	\$ 0.40

**CHIRON CORPORATION**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**September 30, 2005**  
**(Unaudited)**

**Note 7 Earnings Per Share (Continued)**

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, 2005		Nine Months Ended September 30, 2005	
		2004 Restated		2004 Restated
<b>Income (Numerator):</b>				
Net income	\$ 51,311	\$ 26,997	\$ 42,418	\$ 102,040
Plus: Interest on the 2033 Debentures, net of taxes	1,589			
Plus: Interest on Liquid Yield Option Notes, net of taxes	147			
Net income, plus impact from assumed conversions	\$ 53,047	\$ 26,997	\$ 42,418	\$ 102,040
<b>Shares (Denominator):</b>				
Weighted-average common shares outstanding	188,039	187,368	187,564	187,751
<b>Effect of dilutive securities:</b>				
Stock options and equivalents	1,883	2,646	1,500	3,150
2033 Debentures	7,306			
Liquid Yield Option Notes	574			
Weighted-average common shares outstanding, plus impact from assumed conversions	197,802	190,014	189,064	190,901
Basic earnings per share from net income	\$ 0.27	\$ 0.14	\$ 0.23	\$ 0.54
Diluted earnings per share from net income	\$ 0.27	\$ 0.14	\$ 0.22	\$ 0.53

Stock options to purchase 17.7 million shares and 11.7 million shares with exercise prices greater than the average market prices of common stock were outstanding during the three months ended September 30, 2005 and 2004, respectively, and 19.6 million shares and 10.1 million shares, respectively, for the nine months ended September 30, 2005 and 2004. These options were excluded from the respective computations of diluted earnings per share, as their inclusion would be antidilutive.

The dilutive effect of CoCos must be included in diluted earnings per share regardless of whether the triggering contingency has been satisfied, if dilutive. For the nine months ended September 30, 2005 and the three and nine months ended September 30, 2004, 7.3 million shares of common stock issuable upon conversion of the 2033 Debentures were excluded from the computations of diluted earnings per share as their inclusion would be antidilutive.

If the 2034 Debentures are tendered for conversion, the value ( Conversion Value ) of cash and shares of Chiron's common stock, if any, to be received by a holder converting \$1,000 principal amount of the debentures will be determined by multiplying the applicable conversion rate by a weighted average price. Chiron will deliver the Conversion Value to debenture holders as follows: (1) an amount in cash ( Principal Return ) equal to the lesser of (a) the aggregate Conversion Value of the debentures to be

**CHIRON CORPORATION**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**September 30, 2005**  
**(Unaudited)**

**Note 7 Earnings Per Share (Continued)**

converted and (b) the aggregate principal amount of the debentures to be converted and (2) if the aggregate Conversion Value of the debentures to be converted is greater than the Principal Return, an amount in shares ( Net Shares ) equal to the aggregate Conversion Value less the Principal Return ( Net Share Amount ). The number of Net Shares to be paid will be determined by dividing the Net Share Amount by a weighted average price. If dilutive, common shares to be added to the diluted shares outstanding would be determined by the net share settlement of the 2034 Debentures. For the three and nine months ended September 30, 2005 and 2004, the assumed conversion of the 2034 Debentures was not dilutive.

**Note 8 Discontinued Operations**

In a strategic effort to focus on Chiron's core businesses of blood-testing, vaccines and biopharmaceuticals, Chiron completed the sale of Chiron Diagnostics to Bayer Corporation, or Bayer, in 1998.

In the second quarter of 2004, Chiron and the IRS entered into a settlement agreement closing the open tax years 1996 to 1998. Pursuant to this settlement, Chiron recognized a tax benefit of approximately \$12.5 million for the nine months ended September 30, 2004.

Chiron and Bayer were involved in a dispute with respect to their respective rights to certain royalty refunds receivable for which a settlement was reached in 2004. Under this settlement agreement, Chiron made a settlement payment to Bayer in 2004. This settlement includes an agreement that all outstanding items with Bayer related to the sale of Chiron Diagnostics are resolved and no future indemnity obligations are required. Chiron released previously established reserves deemed to be in excess following this settlement. This settlement resulted in a net gain of \$12.8 million for the nine months ended September 30, 2004. This net gain primarily relates to a tax benefit as a result of the settlement payment to Bayer.



**CHIRON CORPORATION**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**September 30, 2005**  
**(Unaudited)**

**Note 9 Intangible Assets**

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

	September 30, 2005			December 31, 2004		
	Gross Carrying Value	Accumulated Amortization	Net Carrying Value	Gross Carrying Value	Accumulated Amortization	Net Carrying Value
Purchased technologies	\$ 332,283	\$ 131,453	\$ 200,830	\$ 333,085	\$ 117,048	\$ 216,037
Patents	\$ 141,114	\$ 78,061	\$ 63,053	\$ 132,385	\$ 71,616	\$ 60,769
Trademarks	60,330	25,840	34,490	65,609	25,450	40,159
Licenses and technology rights	48,760	37,692	11,068	47,745	34,079	13,666
Developed product technologies	327,381	98,595	228,786	374,025	77,253	296,772
Customer relationships	27,674	12,092	15,582	31,234	12,421	18,813
Know how(1)	12,568	7,366	5,202	14,185	7,548	6,637
Databases	7,100	2,367	4,733	7,100	2,012	5,088
Other	24,689	11,609	13,080	34,893	19,090	15,803
Total other intangible assets	\$ 649,616	\$ 273,622	\$ 375,994	\$ 707,176	\$ 249,469	\$ 457,707
Total intangible assets subject to amortization	\$ 981,899	\$ 405,075	\$ 576,824	\$ 1,040,261	\$ 366,517	\$ 673,744

(1) Upon acquisition of a 100% interest in Chiron Behring by the second quarter 1998, Chiron acquired a portfolio of products that were created by Behring and are currently being sold internationally. These products embody Chiron Behring's proprietary know-how consisting of unpatented technology and trade secrets. Since the unpatented technology and trade secrets meet the separability criterion, Chiron has recognized them collectively as a separate intangible asset apart from goodwill in accordance with SFAS No. 141, Business Combinations.

Aggregate future amortization expense is expected to be as follows (in thousands):

For the nine months ended September 30, 2005	\$ 64,009
For the remaining three months in the year ended December 31, 2005	\$ 15,557
For the year ended December 31, 2005	\$ 79,566
For the year ended December 31, 2006	\$ 68,618
For the year ended December 31, 2007	\$ 74,830
For the year ended December 31, 2008	\$ 75,239
For the year ended December 31, 2009	\$ 73,668
For the year ended December 31, 2010	\$ 72,766

**CHIRON CORPORATION**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**September 30, 2005**  
**(Unaudited)**

**Note 9 Intangible Assets (Continued)**

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

	Biopharmaceuticals	Vaccines	Total
Balance as of December 31, 2004	\$ 192,186	\$ 669,208	\$ 861,394
Effect of exchange rate changes		(55,446 )	(55,446 )
Balance as of September 30, 2005	\$ 192,186	\$ 613,762	\$ 805,948

Chiron performed its annual impairment test for goodwill in the third quarter 2005, as of July 1, 2005. Based on this analysis, Chiron has no indication of an impairment loss.

Certain developed product technologies from Chiron's acquisition of PowderJect are amortized under the estimated sales method, which considers forecasted FLUVIRIN® sales during each influenza season through the remaining period of the benefit. Related amortization was \$4.1 million and \$30.1 million as compared to \$12.3 million and \$34.9 million during the three and nine months ended September 30, 2005 and 2004, respectively, reflecting updated forecasted FLUVIRIN® sales.

In the third quarter of 2005, Chiron recognized an impairment loss of \$14.5 million on acquired intangible assets from Chiron's acquisition of PowderJect related to ARILVAX, a yellow fever vaccine. This impairment loss was due to a focus of resources towards the influenza market, resulting in a reduction of the expected activity for ARILVAX. ARILVAX remains in Chiron's portfolio of trademarks and Chiron may re-enter the yellow fever vaccine market in the future with this product. ARILVAX is included in the caption "Developed product technologies" in the table above.

**Note 10 Segment Information**

Chiron is organized based on the products and services that it offers. Under this organizational structure, there are three reportable segments: (i) blood-testing, (ii) vaccines and (iii) biopharmaceuticals. The blood-testing segment consists of an alliance with Gen-Probe and Chiron's one-half share in the pretax operating earnings generated by the joint business contractual arrangement with Ortho-Clinical Diagnostics. Chiron's alliance with Gen-Probe is focused on developing and commercializing nucleic acid testing products using Transcription-Mediated Amplification technology to screen donated blood, plasma products, organs and tissues for viral infection. Chiron's joint business arrangement with Ortho-Clinical Diagnostics is operated under a contractual arrangement and is not a separate and distinct legal entity. Through Chiron's joint business contractual arrangement with Ortho-Clinical Diagnostics, Chiron sells a line of immunodiagnostic tests to detect hepatitis viruses and retroviruses and provides supplemental tests and microplate and chemiluminescent instrument systems to automate test performance and data collection. The blood-testing segment also earns royalties from third parties based on their sales of immunodiagnostic and nucleic acid testing probe diagnostic products utilizing Chiron's hepatitis C virus and HIV-related patents, for use in blood screening and plasma fractionation markets. The vaccines segment consists principally of adult and pediatric vaccines for viral and bacterial infections. Chiron sells these vaccines primarily in the U.S., Germany, Italy, and the United Kingdom, as well as in other

**CHIRON CORPORATION**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**September 30, 2005**  
**(Unaudited)**

**Note 10 Segment Information (Continued)**

international markets. The vaccines segment is also involved in the development of novel vaccines and vaccination technology. The biopharmaceuticals segment consists of therapeutic products and services, with an emphasis on the treatment of cancer and infectious and pulmonary diseases, using the development and acquisition of technologies related to therapeutic proteins, antibodies and small molecules. The biopharmaceuticals segment earns royalties on third party sales of several products, including BETAFERON<sup>®</sup> interferon beta-1b, and earns license fees for technologies, such as hepatitis C virus-related patents, used by third parties to develop therapeutic products.

Revenues and expenses associated with Chiron's research and development activities specifically benefit each of the reportable segments and, as such, have been included in the results of operations of the respective reportable segment.

Chiron views certain other revenues and expenses, particularly certain royalty and license fee revenues primarily related to HIV and hepatitis C virus related patents, and unallocated corporate expenses, as not belonging to any one reportable segment. As a result, Chiron has aggregated these items into an Other segment.

The accounting policies of Chiron's reportable segments are the same as those described in Chiron's Annual Report on Form 10-K for the year ended December 31, 2004. Chiron evaluates the performance of its segments based on each segment's income (loss) from continuing operations, excluding certain special items such as purchased in-process research and development, which is shown as a reconciling item in the table below.

**CHIRON CORPORATION**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**September 30, 2005**  
**(Unaudited)**

**Note 10 Segment Information (Continued)**

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, 2005		Nine Months Ended September 30, 2005	
		2004 Restated		2004 Restated
<i>Revenues</i>				
Blood-testing:				
Product sales, net:				
PROCLEIX® products	\$ 70,677	\$ 63,629	\$ 201,212	\$ 186,104
Ortho-Clinical Diagnostics	7,023	7,098	21,473	19,940
Total product sales, net	77,700	70,727	222,685	206,044
Revenues from joint business arrangement	36,093	34,017	103,154	92,910
Collaborative agreement revenues	1,579	1,616	5,589	6,005
Royalty and license fee revenues	22,501	34,115	73,695	66,817
Other revenues	137	243	412	673
Total blood-testing revenues	138,010	140,718	405,535	372,449
Vaccines:				
Product sales, net:				
Influenza vaccines	60,321	93,486	63,400	109,398
Meningococcal vaccines	11,635	8,865	34,393	18,430
Travel vaccines	35,012	26,434	123,785	75,705
Pediatric and other vaccines	45,800	44,491	115,420	143,292
Total product sales, net	152,768	173,276	336,998	346,825
Collaborative agreement revenues	999	2,230	4,240	7,410
Royalty and license fee revenues	1,263	1,213	3,448	3,888
Other revenues	1,802	3,006	7,558	12,563
Total vaccines revenues	156,832	179,725	352,244	370,686
Biopharmaceuticals:				
Product sales, net				
BETASERON® interferon beta-1b	36,927	35,171	101,693	96,933
TOBI® tobramycin	57,890	55,734	167,425	159,600
PROLEUKIN® aldesleukin	31,028	31,739	92,290	98,664
Other	10,862	8,902	26,822	29,770
Total product sales, net	136,707	131,546	388,230	384,967
Collaborative agreement revenues	571	278	1,300	1,052
Royalty and license fee revenues	17,321	15,412	55,739	47,892
Other revenues	531	1,201	8,251	9,127
Total biopharmaceuticals revenues	155,130	148,437	453,520	443,038
Other:				
Royalty and license fee revenues	29,641	60,656	94,427	102,787
Total revenues	\$ 479,613	\$ 529,536	\$ 1,305,726	\$ 1,288,960
<i>Income (loss) from continuing operations:</i>				
Blood-testing	\$ 75,036	\$ 80,690	\$ 220,171	\$ 203,538
Vaccines	(28,295 )	(65,528 )	(195,428 )	(161,880 )
Biopharmaceuticals	8,660	1,683	5,149	29,709
Other	521	34,788	(17,175 )	24,157
Segment income from operations	55,922	51,633	12,717	95,524
Operating expense reconciling item:				
Purchased in-process research and development		(9,629 )		(9,629 )
Income from operations	55,922	42,004	12,717	85,895
Interest expense	(7,759 )	(7,063 )	(22,932 )	(19,440 )
Interest and other income, net	18,514	5,369	66,259	41,252
Minority interest	(531 )	(504 )	(1,723 )	(1,583 )
Income from continuing operations before income taxes	\$ 66,146	\$ 39,806	\$ 54,321	\$ 106,124



**CHIRON CORPORATION**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**September 30, 2005**  
**(Unaudited)**

**Note 11 Commitments and Contingencies**

In October 2004, the U.K. regulatory body, the Medicines and Healthcare products Regulatory Agency, or MHRA, suspended Chiron's license to manufacture FLUVIRIN® at our Liverpool, U.K. facility.

On March 2, 2005, the MHRA notified Chiron that it had lifted the license suspension, giving Chiron clearance to initiate full production of FLUVIRIN® vaccine, conditioned on the understanding that Chiron's commitment to its remediation plan will continue and will be subject to further inspections by the MHRA.

On October 17, 2005 Chiron initiated delivery and release of FLUVIRIN® vaccine to customers in the United States for the 2005-2006 influenza season. As of such time, Chiron had received all necessary approvals from the U.S. Food and Drug Administration (FDA) and MHRA to start supplying FLUVIRIN® vaccine to the U.S. market. Continued shipments of FLUVIRIN® vaccine will need to undergo corresponding internal release procedures and standard FDA influenza vaccine lot release procedures.

Chiron received a grand jury subpoena issued by the U.S. Attorney's Office for the Southern District of New York in October 2004 requesting production of certain documents relating to FLUVIRIN® vaccine and the suspension by the MHRA of Chiron's license. In February 2005, after having previously commenced an informal inquiry, the Securities and Exchange Commission, or SEC, notified Chiron that it would commence a formal investigation into whether Chiron or Chiron employees violated any federal securities laws in connection with these developments regarding FLUVIRIN® vaccine, and Chiron subsequently received subpoenas from the SEC requesting production of certain documents relating to our Liverpool facility and FLUVIRIN® vaccine. Chiron also received a voluntary request for information from the United States House of Representatives, Energy and Commerce Committee, Subcommittee on Oversight and Investigations requesting production of certain documents. Numerous documents have been collected and produced in response to these requests, and several witnesses have been interviewed by the U.S. Attorney's Office, the SEC staff and Congressional staff. Additional investigations regarding these matters may arise.

In addition, Chiron and certain of its officers and directors have also been named as defendants in several putative shareholder class action and derivative lawsuits alleging various claims arising out of or relating to these developments regarding FLUVIRIN® vaccine. Certain distributors and other parties with whom Chiron had contracted to supply FLUVIRIN® vaccine are considering or have communicated claims against Chiron as a result of our inability to supply FLUVIRIN® vaccine, and additional parties may do so in the future. On January 27, 2005, the U.S. Centers for Disease Control and Prevention, or CDC, terminated its contracts with Chiron for the supply of FLUVIRIN® vaccine for default on the basis of Chiron's failure to supply such vaccine to the U.S. government for the 2004-2005 influenza season. The CDC has reserved the right to hold Chiron liable for any excess costs it may have incurred in replacing any FLUVIRIN® vaccine that Chiron failed to deliver and further has reserved all other remedies provided under the contract. It is not possible to predict whether any of these claims will be pursued and, if so, whether those claims will be upheld. Investigations, litigation and disputes have caused us to incur substantial expense and have required significant time and attention from Chiron management and will

**CHIRON CORPORATION**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**September 30, 2005**  
**(Unaudited)**

**Note 11 Commitments and Contingencies (Continued)**

continue to do so in the future and could result in civil action and/or criminal proceedings against Chiron. The results of any such investigations, proceedings or disputes could have a material adverse effect on Chiron's consolidated financial position and results of operations and/or cash flow.

Although the MHRA has lifted its suspension of Chiron's license to manufacture FLUVIRIN® vaccine, Chiron expects to incur additional expenses in connection with ongoing FLUVIRIN® vaccine matters, which could be material, including in connection with (1) our continuing remediation efforts at our Liverpool facility; and (2) responding to the U.S. Attorney for the Southern District of New York, the SEC, the United States House of Representatives, Energy and Commerce Committee, Subcommittee on Oversight and Investigations and the private lawsuits and other claims and investigations that exist or may arise.

BEGRIVAC vaccine is manufactured at Chiron's facility in Marburg, Germany. In July 2005, Chiron reported that it would be unable to supply any BEGRIVAC vaccine doses for the 2005-2006 influenza season due to a product sterility issue and wrote off its existing product inventory resulting in charges of \$3.0 million and \$18.0 million to cost of sales for the three and nine months ended September 30, 2005, respectively. Investigation of the product sterility issue has been completed and implementation of remedial measures and facility modifications is underway. Chiron's inability to supply BEGRIVAC vaccine as planned to non-U.S. markets for the 2005-2006 season or, if remedial efforts are delayed or not successful, future seasons could have a material adverse effect on its business and results of operations. In addition, it is possible that distributors and other parties with whom Chiron had contracted to supply influenza vaccine may make claims against Chiron as a result of Chiron not supplying influenza vaccine. Any such claims may cause Chiron to incur substantial expense and require significant time and attention from Chiron management. The results of any such claims could have a material adverse effect on Chiron's consolidated financial position and results of operations and/or cash flow.

In addition to the investigations, inquiry and lawsuits related to the recent FLUVIRIN® vaccine developments, Chiron is party to various claims, investigations and legal proceedings arising in the ordinary course of business. These claims, investigations and legal proceedings relate to intellectual property rights, contractual rights and obligations, employment matters, claims of product liability and other issues. While it is possible that an adverse determination of any of such ordinary course matters could 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 ordinary course matters will have a material adverse effect upon Chiron's consolidated financial position and results of operations or cash flows.

Chiron's tax filings are presently under examination in several domestic and international tax jurisdictions. While there is no assurance that Chiron will prevail in all tax examinations in the event the taxing authorities disagree with Chiron's interpretation of the tax law, Chiron's management does not believe, based upon information known to it, that the final resolution of any of these audits will have a material adverse effect upon Chiron's consolidated financial position and results of operations or cash flows. Adequate provisions have been made for these tax examinations.

**CHIRON CORPORATION**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**September 30, 2005**  
**(Unaudited)**

**Note 12 Subsequent events**

On October 30, 2005, Chiron entered into a merger agreement with Novartis Corporation ( Novartis ), Novartis Biotech Partnership, Inc., a subsidiary of Novartis ( Merger Sub ), and Novartis AG. Pursuant to the terms of the merger agreement, Merger Sub will merge with and into Chiron, with Chiron as the surviving corporation. In the merger, each share of Chiron common stock, other than those held by Novartis and its affiliates, will be converted into the right to receive \$45.00 per share in cash. Completion of the merger is subject to approval of (1) the holders of a majority of the outstanding shares of Chiron common stock and (2) the holders of a majority of the outstanding shares of Chiron common stock, excluding shares owned by Novartis and its affiliates. The merger is also subject to the satisfaction of other customary conditions, including governmental and regulatory approvals. Chiron expects that the transaction will be completed in the first half of 2006.

Immediately prior to signing the merger agreement, Chiron gave notice to Novartis that Chiron was exercising its right under the Subscription Agreement, dated as of November 20, 1994, as amended, with Novartis (as successor to Ciba-Geigy) to require Novartis or its affiliate to purchase shares of Chiron common stock for an aggregate purchase price of \$300.0 million at a per share purchase price of \$43.50.



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

***Forward-Looking Statements***

This Form 10-Q contains forward-looking statements regarding our pending merger with Novartis, our expectations, hopes or intentions regarding the future, including statements relating to sales growth, product development initiatives, new product marketing, acquisitions, competition, and licensing activities that involve risks and uncertainties and are subject to change. The forward-looking statements contained in this Form 10-Q reflect our current expectations on the date of this Form 10-Q. Actual results, performance or outcomes may differ materially from current expectations. Our actual performance may differ from current expectations due to many factors, including additional adverse developments resulting from the suspension from October 5, 2004 through March 2, 2005 of our UK license to manufacture FLUVIRIN® influenza virus vaccine, the announcement of such suspension and the litigation and investigations relating to those matters, the outcome of clinical trials, regulatory review and approvals, manufacturing capabilities, intellectual property protections and defenses, litigation, stock price and interest rate volatility, marketing effectiveness and the severity of the 2005-2006 influenza season. In particular, there can be no assurance that we will increase sales of existing products, successfully develop and receive approval to market new products, or achieve market acceptance for such new products. No assurances can be given that additional issues with respect to BEGRIVAC or FLUVIRIN® vaccines or our manufacturing generally will not arise in the future, that we will be able to cover vaccine shortfalls, or that we will resume sale of BEGRIVAC vaccine for the 2006-2007 influenza season. In addition, we may face additional competition in the influenza market in the future and challenges in distribution arrangements as a result of recent BEGRIVAC and FLUVIRIN® vaccine developments. There can be no assurance that the merger with Novartis will be completed on a timely basis or completed at all. There can be no assurance that our out-licensing activity will generate significant revenue, or that our in-licensing activities will fully protect us from claims of infringement by third parties. In addition, we may engage in business opportunities, the successful completion of which is subject to certain risks, including approval by Novartis, stockholder and regulatory approvals and the integration of operations. We have discussed the important factors, which we believe could cause actual results to differ from what is expressed in the forward-looking statements, under the caption **Factors That May Affect Future Results** in this Form 10-Q. We do not undertake an obligation to update the forward-looking information contained in this Form 10-Q.

***Recent Developments***

On October 30, 2005, we entered into a merger agreement with Novartis Corporation ( **Novartis** ), Novartis Biotech Partnership, Inc., a subsidiary of Novartis ( **Merger Sub** ), and Novartis AG. Pursuant to the terms of the merger agreement, Merger Sub will merge with and into our company, with our company as the surviving corporation. In the merger, each share of our common stock, other than those held by Novartis and its affiliates, will be converted into the right to receive \$45.00 per share in cash. Completion of the merger is subject to approval of (1) the holders of a majority of the outstanding shares of our common stock and (2) the holders of a majority of the outstanding shares of our common stock, excluding shares owned by Novartis and its affiliates. The merger is also subject to the satisfaction of other customary conditions, including governmental and regulatory approvals. We expect that the transaction will be completed in the first half of 2006.

Immediately prior to signing the merger agreement, we gave notice to Novartis that we were exercising our right under the Subscription Agreement, dated as of November 20, 1994, as amended, with Novartis (as successor to Ciba-Geigy) to require Novartis or its affiliate to purchase shares of our common stock for an aggregate purchase price of \$300.0 million at a per share purchase price of \$43.50.

### **Introduction**

We are a global biopharmaceutical company that participates in three healthcare markets: blood-testing, vaccines, and biopharmaceuticals. Our research and development efforts are focused on developing products for cancer and infectious and pulmonary disease.

Our blood-testing segment is dedicated to preventing the spread of infectious diseases through the development and sale of novel blood-screening assays and equipment that protect the world's blood supply. We are the world leader in nucleic acid testing, or NAT, blood screening with a leading presence in the U.S, a strong presence in Europe, and sales in Asia. Our blood-testing segment consists of two separate collaborations: an alliance with Gen-Probe Incorporated for NAT products, and a joint business contractual arrangement with Ortho-Clinical Diagnostics, Inc., a Johnson & Johnson company for immunodiagnostic products. Our collaboration with Gen-Probe is focused on developing and commercializing NAT products to screen donated blood, plasma, organs and tissue for viral infection. We sell the collaboration's assays and instruments to blood banks under the PROCLEIX® brand name. Under a joint business contractual arrangement, Ortho-Clinical Diagnostics manufactures and sells immunodiagnostic tests to detect retroviruses and hepatitis viruses in blood. Our blood-testing segment also earns royalties and license fees from third parties based on their sales of immunodiagnostic and nucleic acid testing probe diagnostic products utilizing our hepatitis C virus and HIV-related patents, for use in blood screening and plasma fractionation markets.

Our vaccines segment is the fifth largest vaccines business in the world. We offer more than 20 pediatric and adult vaccines including influenza, meningococcal, travel and pediatric vaccines. These vaccines have protected millions of people globally from potentially fatal diseases such as polio, measles and meningococcal disease. We market our vaccines primarily in the United States, Germany, Italy and the United Kingdom. We acquired a number of vaccines including FLUVIRIN® vaccine as part of our July 8, 2003 acquisition of PowderJect. Our vaccines segment research and development is focused on developing next generation influenza manufacturing capability, developing new vaccines for pandemic preparedness, and broadening our meningococcal franchise.

Our biopharmaceuticals segment researches, develops, manufactures and markets a range of therapeutic products for cancer and infectious and pulmonary disease. Our marketed products include TOBI® tobramycin solution for inhalation for *Pseudomonas* lung infections in cystic fibrosis patients; PROLEUKIN®(aldesleukin) for injection for metastatic melanoma and renal cell carcinoma; and BETASERON® (interferon beta-1b) for subcutaneous injection for multiple sclerosis. In 2004, we filed for marketing approval in Europe for CUBICIN® (daptomycin for injection) for complicated skin and soft tissue infections. Research and development efforts include advancing clinical programs and product improvements in oncology and pulmonary and infectious disease, including the development of new formulations of TOBI® and the clinical advancement of tifacogin for treatment of severe community-acquired pneumonia, CHIR-258, a growth factor kinase inhibitor, and CHIR-12.12, a monoclonal antibody, and CHIR-265, a Raf kinase inhibitor.

We earn royalty and license fee revenue in all three segments by licensing some of our key intellectual property in areas such as hepatitis C and HIV. In addition, we generate royalties through agreements with development and marketing partners, including royalties from Schering AG's sales of BETAIFERON® (interferon beta-1b) for SC injection in Europe. Some royalties and license fees are not considered to be associated with any particular business segment and are recorded separately in the segment data as Other Royalty and License Fee Revenues.

We view certain other revenues and expenses as not belonging to any one segment. As a result, we have aggregated these items into an Other segment.

*Influenza Virus Vaccines Recent Events*

In October 2004, the U.K. regulatory body, the Medicines and Healthcare products Regulatory Agency, or MHRA, suspended our license to manufacture FLUVIRIN® at our Liverpool, U.K. facility. As a result of the suspension of our license, we did not release any FLUVIRIN® vaccine during the 2004-2005 influenza season. On March 2, 2005, the MHRA notified us that it had lifted the license suspension, giving Chiron clearance to initiate full production of FLUVIRIN® vaccine, conditioned on the understanding that Chiron's commitment to its remediation plan will continue and will be subject to further inspections by the MHRA.

On October 17, 2005 we initiated delivery and release of FLUVIRIN® vaccine to customers in the United States for the 2005-2006 influenza season. As of such time, we had received all necessary approvals from the U.S. Food and Drug Administration (FDA) and MHRA to start supplying FLUVIRIN® vaccine to the U.S. market. Continued shipments of FLUVIRIN® vaccine will need to undergo corresponding internal release procedures and standard FDA influenza vaccine lot release procedures.

We received a grand jury subpoena issued by the U.S. Attorney's Office for the Southern District of New York in October 2004 requesting production of certain documents relating to FLUVIRIN® vaccine and the suspension by the MHRA of our license. In February 2005, after having previously commenced an informal inquiry, the Securities and Exchange Commission, or SEC, notified us that it would commence a formal investigation into whether we or our employees violated any federal securities laws in connection with these developments regarding FLUVIRIN® vaccine, and Chiron subsequently received subpoenas from the SEC requesting production of certain documents relating to our Liverpool facility and FLUVIRIN® vaccine. We also received a voluntary request for information from the United States House of Representatives, Energy and Commerce Committee, Subcommittee on Oversight and Investigations requesting production of certain documents. Numerous documents have been collected and produced in response to these requests, and several witnesses have been interviewed by the U.S. Attorney's Office, the SEC staff and Congressional staff. Additional investigations regarding these matters may arise.

In addition, we and certain of our officers and directors have also been named as defendants in several putative shareholder class action and derivative lawsuits alleging various claims arising out of or relating to these developments regarding FLUVIRIN® vaccine which are described below in Part II, Item 1, Legal Proceedings. Certain distributors and other parties with whom we had contracted to supply FLUVIRIN® vaccine are considering or have communicated claims against us as a result of our inability to supply FLUVIRIN® vaccine, and additional parties may do so in the future. On January 27, 2005, the U.S. Centers for Disease Control and Prevention, or CDC, terminated its contracts with us for the supply of FLUVIRIN® vaccine for default on the basis of our failure to supply such vaccine to the U.S. government for the 2004-2005 influenza season. The CDC has reserved the right to hold us liable for any excess costs it may have incurred in replacing any FLUVIRIN® vaccine that we failed to deliver and further has reserved all other remedies provided under the contract. It is not possible to predict whether any of these claims will be pursued and, if so, whether those claims will be upheld. Investigations, litigation and disputes have caused us to incur substantial expense and have required significant time and attention from our management and will continue to do so in the future and could result in civil action and/or criminal proceedings against us. The results of any such investigations, proceedings or disputes could have a material adverse effect on our consolidated financial position and results of operations and/or cash flow.

Although the MHRA has lifted its suspension of our license to manufacture FLUVIRIN® vaccine, we expect to incur additional expenses in connection with ongoing FLUVIRIN® vaccine matters, which could be material, including in connection with (1) our continuing remediation efforts at our Liverpool facility; and (2) responding to the U.S. Attorney for the Southern District of New York, the SEC, the United



States House of Representatives, Energy and Commerce Committee, Subcommittee on Oversight and Investigations and the private lawsuits and other claims and investigations that exist or may arise.

BEGRIVAC vaccine is manufactured at our facility in Marburg, Germany. In July 2005, we reported that we would be unable to supply any BEGRIVAC vaccine doses for the 2005-2006 influenza season due to a product sterility issue and wrote off our existing product inventory resulting in charges of \$3.0 million and \$18.0 million to cost of sales for the three and nine months ended September 30, 2005, respectively. Investigation of the product sterility issue has been completed and implementation of remedial measures and facility modifications is underway. Our inability to supply BEGRIVAC vaccine as planned to non-U.S. markets for the 2005-2006 influenza season or, if remedial efforts are delayed or not successful, future seasons could have a material adverse affect on our business and results of operations. In addition, it is possible that distributors and other parties with whom we had contracted to supply influenza vaccine may make claims against us as a result of Chiron not supplying influenza vaccine. Any such claims may cause us to incur substantial expense and require significant time and attention from our management. The results of any such claims could have a material adverse effect on our consolidated financial position and results of operations and/or cash flow.

Our inability to supply influenza vaccine may also lead to loss of market share in future seasons. Following the announcement of our FLUVIRIN® license suspension, competitors announced plans to introduce influenza vaccine products in the United States and sought expedited regulatory approval to do so. Even though the license suspension has been lifted, some of our customers may choose to purchase influenza vaccine from other providers as their products become available in the United States. Loss of market share in the United States or foreign markets could have a material adverse effect on our business and results of operations. Delays in start-up procedures for ramping up to full production and normal manufacturing issues inherent in the complexity of influenza vaccine production, have adversely affected the amount of FLUVIRIN® vaccine that Chiron is able to produce for the 2005-2006 influenza season and may result in further loss of market share.

For additional information concerning the risks we face as a result of these influenza vaccine developments, see Factors That May Affect Future Results *Developments with respect to influenza vaccines over the past year will harm our business and results of operations.* For additional information on the U.S. Attorney's investigation, SEC investigation and private lawsuits and other claims, see Part II, Item 1. Legal Proceedings of this report on Form 10-Q.

#### ***Restated Second-Quarter and Third-Quarter 2004 Financial Statements***

During our 2004 year-end financial statement review, we determined that certain sales of the travel vaccine recorded as revenues in the second quarter of 2004 should not have been recorded as revenue at that time, and that portions of those sales should have been recorded as revenues in the third and fourth quarters of 2004 and possibly in later quarters. As a result, we restated the financial statements included in our Quarterly Reports on Form 10-Q for such quarters and filed amended Form 10-Qs for such quarters on April 6, 2005.

In light of the fact that we were already in contact with the SEC in relation to their investigation described above under *Influenza Virus Vaccines Recent Events*, we informed the SEC of these matters, and the adjustments we made after January 26, 2005 to the fourth quarter and full-year 2004 financial information we released on January 26, 2005, and have been providing the SEC information pursuant to its requests.

**Summary Consolidated Financial Data**

Following is an analysis and discussion of our operating results on a consolidated basis, which is followed by a description of our most critical accounting policies and use of estimates and more detailed analysis and discussion of our operating results by segment and our liquidity and capital resources.

	Three Months Ended September 30,		Nine Months Ended September 30,		\$ Change Three Months	Nine Months	% Change Three Months	Nine Months
	2005	2004 (Restated)	2005	2004 (Restated)				
	(\$ in 000 s, except per share data)							
Product sales, net	\$ 367,175	\$ 375,549	\$ 947,913	\$ 937,836	\$ (8,374 )	\$ 10,077	(2.2 )%	1.1 %
Revenue from joint business arrangement	36,093	34,017	103,154	92,910	2,076	10,244	6.1 %	11.0 %
Royalty and license fee revenues	70,726	111,396	227,309	221,384	(40,670 )	5,925	(36.5 )%	2.7 %
Total revenues	479,613	529,536	1,305,726	1,288,960	(49,923 )	16,766	(9.4 )%	1.3 %
Gross profit Margin	54 %	36 %	46 %	47 %				
Research and development expenses	107,309	103,000	324,620	301,736	4,309	22,884	4.2 %	7.6 %
Selling, general and administrative expenses	117,152	112,013	375,802	321,775	5,139	54,027	4.6 %	16.8 %
Purchased in-process research and development		9,629		9,629	(9,629 )	(9,629 )	(100 )%	(100 )%
Impairment loss on acquired intangible assets	14,522		14,522		14,522	14,522	100 %	100 %
Amortization expense of intangible assets acquired in business combinations and asset purchases	12,361	20,566	54,237	63,077	(8,205 )	(8,840 )	(39.9 )%	(14.0 )%
Income from continuing operations	51,311	27,447	42,418	77,186	23,864	(34,768 )	86.9 %	(45.0 )%
Diluted earnings per share: Income from continuing operations	\$ 0.27	\$ 0.14	\$ 0.22	\$ 0.40	\$ 0.13	\$ (0.18 )	92.9 %	(45.0 )%

Income from continuing operations was \$51.3 million or \$0.27 per diluted share and \$27.4 million or \$0.14 per diluted share for the three months ended September 30, 2005 and 2004, respectively. Income from continuing operations was \$42.4 million or \$0.22 per diluted share and \$77.2 million or \$0.40 per diluted share for the nine months ended September 30, 2005 and 2004, respectively. Income from continuing operations increased for the three months ended September 30, 2005 as compared with the three months ended September 30, 2004 primarily due to a \$91.3 million charge to cost of sales resulting from the write-off of our entire FLUVIRIN® vaccine inventory in the third quarter of 2004 and \$8.2 million lower amortization expense in the third quarter of 2005, resulting from a revision of estimated future sales. The amortization expense related to certain developed product technologies from our acquisition of PowderJect, which are amortized under the estimated sales method over ten years. These increases were partially offset by \$46.0 million of royalties and license fees recognized from the F. Hoffman-LaRoche settlement (the Roche settlement) in the third quarter of 2004 compared with \$8.0 million recognized in the third quarter of 2005 and the impairment loss of \$14.5 million on acquired intangible assets from our acquisition of PowderJect related to a yellow fever vaccine in the third quarter of 2005. In addition, there was a lost contribution from sales of BEGRIVAC influenza virus vaccine as there were no sales of BEGRIVAC vaccine in the third quarter of 2005, compared to \$41.0 million of sales for the three months ended September 30, 2004. Income from continuing operations decreased for the nine months ended September 30, 2005 as compared with the nine months ended September 30, 2004 primarily due to \$46.0 million of royalties and license fees recognized from the Roche settlement for the nine months ended September 30, 2004 compared with \$32.0 million of royalties and license fee revenues



recognized for the nine months ended September 30, 2005 and the impairment loss of \$14.5 million on acquired intangible assets from our acquisition of PowderJect related to a yellow fever vaccine in the third quarter of 2005. Lastly, there was a lost contribution from sales of BEGRIVAC influenza virus vaccine as there were no sales of BEGRIVAC vaccine for the nine months ended September 30, 2005, compared to \$41.0 million of sales for the nine months ended September 30, 2004. These decreases were partially offset by a \$91.3 million charge to cost of sales resulting from the write-off of our entire FLUVIRIN® vaccine inventory in the third quarter of 2004 and \$4.8 million lower amortization expense for the nine months ended September 30, 2005 related to certain developed product technologies from our acquisition of PowderJect, which are amortized under the estimated sales method over ten years, resulting from a revision of estimated future sales. For the three months ended September 30, 2005, we incurred \$3.0 million of FLUVIRIN® vaccine remediation costs and \$0.5 million of legal costs associated with the FLUVIRIN® vaccine-related developments. For the nine months ended September 30, 2005, we incurred \$27.0 million of FLUVIRIN® vaccine remediation costs and \$15.5 million of legal costs associated with the FLUVIRIN® vaccine-related developments. In addition, our Liverpool facility had limited influenza vaccine production during the first nine months of 2005. For the three months ended September 30, 2005 as compared with the three months ended September 30, 2004, idle facility costs from our Liverpool facility increased by \$9.0 million. For the nine months ended September 30, 2005 as compared with the nine months ended September 30, 2004, idle facility costs from our Liverpool facility increased by \$36.0 million. In addition, BEGRIVAC product inventory has been written off as a result of the matters described above under *Influenza Virus Vaccines Recent Events*, resulting in charges of \$3.0 million and \$18.0 million to cost-of-sales for the three and nine months ended September 30, 2005 respectively.

Revenues decreased for the three months ended September 30, 2005 as compared with the three months ended September 30, 2004 primarily due to decreased royalty and license fee revenues and product sales. Revenues increased for the nine months ended September 30, 2005 as compared with the nine months ended September 30, 2004 primarily due to increased revenues from the joint business arrangement, increased royalty and license fee revenues and increased product sales. The change in total revenues was attributable in part to the movement in exchange rates, in particular the movements in the Euro and British Pound against the U.S. dollar. The movement in exchange rates reduced by approximately 1% our total revenues for the nine months ended September 30, 2005. However, since our Euro and British Pound denominated expenses have also changed due to the movement in exchange rates, our income per share from continuing operations increased \$0.02 per diluted share for the nine months ended September 30, 2005, due to higher expenses compared with revenues denominated in Euros and British Pounds.

For the three months ended September 30, 2005, product sales decreased as compared with the three months ended September 30, 2004 primarily due to lower influenza vaccine sales because we were unable to supply any BEGRIVAC vaccine doses for the 2005-2006 influenza season due to a product sterility issue. There was \$41.0 million of sales of BEGRIVAC vaccine in the third quarter of 2004. This decrease was offset by increases in our travel vaccines, PROCLEIX® product sales, Meningococcal vaccines, TOBI® tobramycin and BETASERON® interferon beta-1b.

For the nine months ended September 30, 2005, product sales increased compared with the nine months ended September 30, 2004 primarily due to increases in sales of our travel vaccines, Meningococcal vaccines, PROCLEIX® product sales and TOBI® tobramycin, offset primarily by decreases in sales of our influenza vaccines and pediatric and other vaccines as discussed below. Sales of our influenza vaccine decreased primarily due to lower influenza vaccine sales because we were unable to supply any BEGRIVAC vaccine doses for the 2005-2006 influenza season due to a product sterility issue.

For the three months ended September 30, 2005, royalty and license fee revenues decreased compared with the three months ended September 30, 2004 primarily due to recognition of \$46.0 million in



the third quarter of 2004 relating to the Roche settlement, as compared with recognition of \$8.0 million in the third quarter of 2005 relating to the settlement. For the nine months ended September 30, 2005, royalties and license fee revenues increased as compared with the nine months ended September 30, 2004 primarily due to increased BETAFFERON® product royalties and our settlement with the Scottish National Blood Transfusion Service. These increases were partially offset by royalties and license fees recognized from the Roche settlement in the third quarter of 2004. The increase in revenue from the joint business arrangement for the nine months ended September 30, 2005 as compared with the nine months ended September 30, 2004 was primarily due to higher profitability realized by the joint business arrangement.

Gross profit margin increased for the three months ended September 30, 2005 as compared with the three months ended September 30, 2004 primarily due to a \$91.3 million charge to cost of sales resulting from the write-off of our entire FLUVIRIN® inventory in the third quarter of 2004, partially offset by there being no BEGRIVAC vaccine sales for the three months ended September 30, 2005.

Gross profit margin decreased for the nine months ended September 30, 2005 as compared with the nine months ended September 30, 2004 primarily due to increased idle facility costs as a result of the delay in commercial production of FLUVIRIN® vaccine for the 2005-2006 influenza season, FLUVIRIN® vaccine remediation costs and the write-off of the BEGRIVAC product inventory and the resulting loss of BEGRIVAC vaccine sales for the three months ended September 30, 2005. These decreases were primarily offset by a \$91.3 million charge to cost of sales resulting from the write-off of our entire Fluvirin inventory in the third quarter of 2004.

Gross profit margins do not include amortization expense of intangible assets from acquired developed products related to business combinations.

The main components of the increase in research and development expenses for the nine months ended September 30, 2005 as compared with the nine months ended September 30, 2004 relate to development efforts in our oncology franchise, development efforts for CUBICIN® (daptomycin for injection), meningococcal vaccines franchise, flu cell culture, development of new processes and procedures in existing manufacturing facilities for BETAFFERON interferon beta-1b and blood-testing programs. These increases were partially offset by research and development programs that have been discontinued or disposed of prior to the first nine months of 2005.

The increase in selling, general and administrative expenses for the three months ended September 30, 2005 as compared with the three months ended September 30, 2004 was due primarily to pre-launch costs for CUBICIN® (daptomycin for injection), higher employee related expenses and higher corporate governance costs.

The increase in selling, general and administrative expenses for the nine months ended September 30, 2005 as compared with the nine months ended September 30, 2004 was due partially to legal expenses associated with the FLUVIRIN® developments discussed above under *Influenza Virus Vaccines Recent Events*. Such legal expenses were \$15.5 million for the nine months ended September 30, 2005. The increase also reflects \$4.3 million due to the movement in the Euro and British Pound exchange rates. The remaining increase in selling, general and administrative expenses reflects a broad range of activities, significant among them being on-going marketing and pre-launch programs to support the continued growth of our business, investment in geographic penetration, higher employee related costs and corporate governance costs.

The effective tax rate was 21.9% and 27.3% of pretax income from continuing operations for the nine months ended September 30, 2005 and 2004, respectively. The tax rate decreased primarily due to lower expected taxable incomes, year to year, in certain high tax jurisdictions, as well as increased benefits of U.S. research credits. Such items are not expected to recur in future years. The effective tax rate may be

affected in future periods by changes in management's estimates with respect to our deferred tax assets and other items affecting the overall tax rate.

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

Our critical accounting policies, which incorporate our more significant judgments and estimates used in the preparation of our Condensed Consolidated Financial Statements, are the same as those described in Part II, Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the year ended December 31, 2004.

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

### **Results of Operations**

#### *Blood-testing*

	Three Months Ended September 30,		Nine Months Ended September 30,		\$ Change Three Months	Nine Months	% Change Three Months	Nine Months
	2005	2004	2005	2004				
	(\$ in 000 s, except percentages)							
Product sales, net:								
PROCLEIX® products	\$ 70,677	\$ 63,629	\$ 201,212	\$ 186,104	\$ 7,048	\$ 15,108	11.1 %	8.1 %
Ortho-Clinical Diagnostics	7,023	7,098	21,473	19,940	(75 )	1,533	(1.1 )%	7.7 %
	77,700	70,727	222,685	206,044	6,973	16,641	9.9 %	8.1 %
Revenue from joint business arrangement	36,093	34,017	103,154	92,910	2,076	10,244	6.1 %	11.0 %
Collaborative agreement revenues	1,579	1,616	5,589	6,005	(37 )	(416 )	(2.3 )%	(6.9 )%
Royalty and license fee revenues	22,501	34,115	73,695	66,817	(11,614 )	6,878	(34.0 )%	10.3 %
Other revenues	137	243	412	673	(106 )	(261 )	(43.6 )%	(38.8 )%
Total blood-testing Revenues	\$ 138,010	\$ 140,718	\$ 405,535	\$ 372,449	\$ (2,708 )	\$ 33,086	(1.9 )%	8.9 %
Gross profit margin	42	% 43	% 42	% 42	%			
Research and development expenses	\$ 6,211	\$ 8,387	\$ 20,937	\$ 19,754	\$ (2,176 )	\$ 1,183	(25.9 )%	6.0 %
Selling, general and administrative expenses	\$ 11,341	\$ 11,077	\$ 34,044	\$ 30,657	\$ 264	\$ 3,387	2.4 %	11.0 %

#### **Product sales**

*PROCLEIX® Products* On February 27, 2002, the U.S. Food and Drug Administration approved the PROCLEIX® HIV-1/HCV Assay. We have marketed the PROCLEIX® HIV-1/HCV Assay in Europe since 1999. On January 15, 2004, the PROCLEIX® ULTRIO HIV-1/HCV/HBV Assay received European CE marking for use on the semi-automated PROCLEIX® System, and on December 14, 2004

the PROCLEIX ULTRIO Assay received European CE marking for use on the fully automated, high throughput PROCLEIX®TIGRIS® System. Under a collaboration agreement with Gen-Probe, we market and sell the PROCLEIX® HIV-1/ HCV Assay, the PROCLEIX ULTRIO Assay and related instrument systems. In addition to selling directly in the U.S., we also sell in various international markets, directly and through distributors. We record revenue based upon the reported results obtained from the customer from the use of assays to screen donations or upon sale and delivery of the assays, depending on the underlying contract. In the case of equipment sales or leases, we record revenue upon the sale and transfer of the title of the instrument or ratably over the life of the lease term, respectively. For provision of service on the instruments, we recognize revenue ratably over the life of the service agreement.

The increase in product sales for the three months ended September 30, 2005 as compared with the three months ended September 30, 2004 was primarily due to \$5.5 million from the conversion to the PROCLEIX® ULTRIO Assay from the PROCLEIX® HIV-1/HCV Assay outside of the U.S. and continued penetration into several markets abroad and \$1.4 million due to an increase in donations in the United States. The increase in product sales for the nine months ended September 30, 2005 as compared with the nine months ended September 30, 2004 was primarily due to \$13.6 million from the conversion to the PROCLEIX® ULTRIO Assay from the PROCLEIX® HIV-1/HCV Assay outside the U.S. and from continued penetration into several markets abroad.

Under a collaboration agreement with Gen-Probe, we market and sell the PROCLEIX® HIV-1/ HCV Assay, the PROCLEIX ULTRIO Assay and related instrument systems. The Food and Drug Administration, or FDA, notified Gen-Probe on October 3, 2005 that it considers the PROCLEIX® TIGRIS® system not substantially equivalent to the PROCLEIX enhanced semi-automated system (eSAS) for screening donated human blood with the PROCLEIX ULTRIO assay. The FDA made this determination in response to Gen-Probe's 510(k) application for the TIGRIS system. We understand that Gen-Probe is in discussions with the FDA to resolve the outstanding issues, and we are not in direct communication with the FDA regarding this matter.

**Revenue from joint business arrangement** The increase in revenue from the joint business arrangement for the three months ended September 30, 2005 as compared with the three months ended September 30, 2004 was primarily due to \$5.6 million from an increase in profitability realized by the joint business arrangement offset by a decline of \$4.2 million in royalties. The increase in revenue from the joint business arrangement for the nine months ended September 30, 2005 as compared with the nine months ended September 30, 2004 was primarily due to \$14.5 million from higher profitability realized by the joint business arrangement offset by a decline of \$5.9 million in royalties.

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

**Royalty and license fee revenues** Our blood-testing segment earns royalties from third parties based on their sales of immunodiagnostic and nucleic acid testing probe diagnostic products utilizing our hepatitis C virus (HCV) and HIV-related (HIV) patents, for use in the blood screening and plasma fractionation markets. Our blood-testing segment also earns license fees related to our HCV and HIV patents for technologies used by third parties to develop products for use in the blood screening and plasma fractionation markets.

The decrease in royalty and license fee revenues for the three months ended September 30, 2005 as compared with the three months ended September 30, 2004 was primarily due to (i) \$10.1 million



recognized in the third quarter of 2004 for deferred revenues and a non-refundable portion of the Roche settlement reached in September 2004 as discussed below under Other Royalty and license fee revenues *Roche Settlement*, and (ii) \$7.9 million in the third quarter of 2004 due to recognition of a portion of the license fee under our license agreements with the German Red Cross for the use of our HIV-1 and hepatitis C virus (HCV) technology for use in molecular probe home brew blood screening. These decreases were partially offset by (i)\$2.7 million of royalties recognized in the third quarter of 2005 from the Roche settlement reached in September 2004 as discussed below under Other Royalty and license fee revenues *Roche Settlement*, (ii)\$1.9 million in the third quarter of 2005 from increased royalties from Roche due to rate increases resulting from certain countries entering the European Union (EU) and an increase in reported donations and (iii) \$1.5 million in the third quarter of 2005 in royalties from our licensing agreement reached in 2004 with Laboratory Corporation of America Holdings (LabCorp) for our HCV intellectual property for nucleic acid testing.

The increase in royalty and license fee revenues for the nine months ended September 30, 2005 as compared with the nine months ended September 30, 2004 was primarily due to (i) \$10.7 million of royalties from the Roche settlement, (ii) \$5.2 million in royalties from Roche due to rate increases resulting from certain countries entering the EU and an increase in reported donations, (iii) \$4.7 million in fees and royalties from our licensing agreement with LabCorp, (iv) \$2.7 million from a settlement with the SNBTS regarding our HCV and HIV patents and (v) \$2.1 million in royalty fees from the blood transfusion centers of the German Red Cross. These increases were partially offset by (i) \$10.1 million recognized in the third quarter of 2004 for deferred revenues and a non-refundable portion of the Roche settlement reached in September 2004 as discussed below under Other Royalty and license fee revenues *Roche Settlement*, and (ii) \$7.9 million in the third quarter of 2004 due to recognition of a portion of the license fee under our license agreements with the German Red Cross for the use of our HIV-1 and hepatitis C virus (HCV) technology for use in molecular probe home brew blood screening.

Royalty and license fee revenues may fluctuate based on the nature of the related agreements, the timing of receipt of license fees and the expiration of patents. Results in any one period are not necessarily indicative of results to be achieved in the future. Also, the license agreements typically provide for certain milestone payments and various royalties on future product sales if the licensee commercializes a product using our technology. However, we have no assurance that the licensee will meet their development objectives or commercialize a product using our technology. In addition, our ability to generate additional royalty and license fee revenues may depend, in part, on our ability to market and capitalize on our technologies.

**Gross profit margin** The decrease in gross profit margin for the three months ended September 30, 2005 as compared with the three months ended September 30, 2004 was primarily due to additional support and service costs associated with our fully automated, high throughput PROCLEIX®TIGRIS® System. Gross profit margin was consistent for the nine months ended September 30, 2005 as compared with the nine months ended September 30, 2004. Blood-testing gross profit margin may fluctuate in future periods as the blood-testing product and customer mix changes.

**Research and development expenses** The decrease in research and development expenses for the three months ended September 30, 2005 as compared with the three months ended September 30, 2004 was primarily due to \$2.4 million decrease in costs relating to our nucleic acid testing products. The increase in research and development expenses for the nine months ended September 30, 2005 as compared with the nine months ended September 30, 2004 was primarily due to \$4.6 million for research activities focused primarily on vCJD partially offset by a \$3.5 million decrease in costs relating to our nucleic acid testing products. Research and development expenses may fluctuate from period to period depending upon the stage of certain projects and the level of pre-clinical and clinical trial-related activities.

**Selling, general, and administrative expenses** Selling, general, and administrative expenses were consistent for the three months ended September 30, 2005 as compared with the three months ended September 30, 2004. The increase in selling, general and administrative expenses for the nine months ended September 30, 2005 as compared with the nine months ended September 30, 2004 was primarily due to \$2.5 million from the geographic expansion of our customer base for the PROCLEIX® HIV-1/HCV Assay in international markets.

We expect continued growth in selling, general and administrative expenses related to nucleic acid testing technology and products as our sales opportunities expand in new markets through anticipated additional nucleic acid testing adoption.

### Vaccines

	Three Months Ended September 30,		Nine Months Ended September 30,		\$ Change Three Months	Nine Months	% Change Three Months	Nine Months
	2005	2004 Restated	2005	2004 Restated				
	(\$ in 000 s, except percentages)							
Product sales, net:								
Influenza vaccines:								
Other Influenza vaccines	\$ 60,321	\$ 93,486	\$ 63,400	\$ 106,953	\$ (33,165 )	\$ (43,553 )	(35.5)%	(40.7 )%
FLUVIRIN® vaccine				2,445		(2,445 )		(100.0)%
Influenza vaccines	60,321	93,486	63,400	109,398	(33,165 )	(45,998 )	(35.5)%	(42.0 )%
Meningococcal vaccines	11,635	8,865	34,393	18,430	2,770	15,963	31.2 %	86.6 %
Travel vaccines	35,012	26,434	123,785	75,705	8,578	48,080	32.5 %	63.5 %
Pediatric and other vaccines	45,800	44,491	115,420	143,292	1,309	(27,872 )	2.9 %	(19.5 )%
	152,768	173,276	336,998	346,825	(20,508 )	(9,827 )	(11.8)%	(2.8 )%
Collaborative agreement revenues	999	2,230	4,240	7,410	(1,231 )	(3,170 )	(55.2)%	(42.8 )%
Royalty and license fee revenues	1,263	1,213	3,448	3,888	50	(440 )	4.1 %	(11.3 )%
Other revenues	1,802	3,006	7,558	12,563	(1,204 )	(5,005 )	(40.1)%	(39.8 )%
Total Vaccines revenues	\$ 156,832	\$ 179,725	\$ 352,244	\$ 370,686	\$ (22,893 )	\$ (18,442 )	(12.7)%	(5.0 )%
Gross profit margin	45 %	9 %	21 %	21 %				
Research and development expenses	\$ 34,942	\$ 30,985	\$ 102,885	\$ 97,313	\$ 3,957	\$ 5,572	12.8 %	5.7 %
Selling, general and administrative expenses	\$ 42,320	\$ 42,288	\$ 122,657	\$ 115,343	\$ 32	\$ 7,314	0.1 %	6.3 %
Amortization expense	\$ 6,121	\$ 14,326	\$ 35,482	\$ 44,352	\$ (8,205 )	\$ (8,870 )	(57.3)%	(20.0 )%
Impairment loss on acquired intangible assets	\$ 14,522	\$	\$ 14,522	\$	\$ 14,522	\$ 14,522	100 %	100 %

**Product sales** We sell influenza, meningococcal, travel, pediatric and other vaccines. Our vaccines are sold in the U.S., Germany, Italy, and the United Kingdom, as well as in other international markets.

**Influenza vaccines** As described above under *Influenza Virus Vaccines Recent Events*, as a result of recent developments with respect to FLUVIRIN® and BEGRIVAC vaccines, we had no FLUVIRIN® or BEGRIVAC vaccine sales in the three and nine months ended September 30, 2005. Sales of FLUVIRIN® influenza vaccine were \$2.4 million for the nine months ended September 30, 2004 from the 2003-2004 influenza season. Sales of BEGRIVAC influenza vaccine were \$41.0 million for the three and nine months ended September 30, 2004. The decrease in sales of our other influenza vaccines for the three months ended September 30, 2005 as compared with the three months ended September 30, 2004 was primarily due to there being no BEGRIVAC vaccine sales for the three months ended September 30, 2005. This decrease was offset by an increase in sales of our other influenza vaccine products.

The decrease in sales of our other influenza vaccines for the nine months ended September 30, 2005 as compared with the nine months ended September 30, 2004 was primarily due to (i) there being no BEGRIVAC vaccine sales for the nine months ended September 30, 2005 and (ii) a manufacturing



upgrade of facilities that produce influenza vaccine for the southern hemisphere. For the nine months ended September 30, 2004, sales of our other influenza vaccines to the southern hemisphere were \$9.9 million. These decreases were offset by an increase in sales of our other influenza vaccine products to the northern hemisphere for the nine months ended September 30, 2005.

*Meningococcal vaccines* The increase in meningococcal vaccines sales for the three months ended September 30, 2005 as compared with the three months ended September 30, 2004 was primarily due to \$5.4 million increase in tender sales of MENJUGATE® vaccine in Spain. This increase was partially offset by a \$2.3 million decrease in tender sales of MENJUGATE® vaccine in the United Kingdom and a \$1.2 million decrease in tender sales of MENJUGATE® vaccine in Canada. The increase in meningococcal vaccines sales for the nine months ended September 30, 2005 as compared with the nine months ended September 30, 2004 was primarily due to (i) \$12.1 million of MENZB meningococcal B vaccine sales to the Ministry of Health in New Zealand, (ii) \$5.4 million increase in tender sales of MENJUGATE® vaccine in Spain and (iii) a \$2.5 million increase in tender sales of MENJUGATE® vaccine to Canada. These increases are partially offset by a \$2.7 million decrease tender sales of MENJUGATE® vaccine in Australia and a \$2.3 million decrease in tender sales of MENJUGATE® vaccine in the United Kingdom.

*Travel vaccines* The increase in travel vaccines sales for the three months ended September 30, 2005 as compared with the three months ended September 30, 2004 was primarily due to (i) \$4.6 million from increased demand for our rabies vaccines in the U.S., primarily due to a product recall from a competitor, and a price increase and (ii) \$3.3 million from increased demand for our rabies vaccines in Europe, primarily due to tender sales to Turkey, Hungary and the United Kingdom. The increase in travel vaccines sales for the nine months ended September 30, 2005 as compared with the nine months ended September 30, 2004 was primarily due to: (i) a \$29.9 million increase in tick-borne encephalitis (TBE) vaccine sales. Sales in the first quarter of 2004 were lower than in the first quarter of 2005 by \$12.0 million due to \$15.1 million of sales in the fourth quarter of 2003; TBE vaccines are typically sold in the first half of the year; and in addition, the second and third quarters of 2005 compared with the second and third quarters of 2004 reflected a \$17.9 million increase in the TBE vaccine sales due to growth in the overall market and a number of marketing initiatives, (ii) \$11.3 million from increased demand for our rabies vaccines in the U.S., primarily due to a product recall from a competitor and price increases, and increased sales to Canada, (iii) \$6.4 million from increased demand for our rabies vaccines in Asia and (iv) a \$5.4 million from increased demand for our rabies vaccines in Europe, primarily due to tender sales to Turkey, Hungary and the U.K. These increases were partially offset by a decline of \$1.8 million in sales of Dukoral vaccine due to the divestiture in the second quarter of 2004 of certain vaccines operations in Sweden acquired in our acquisition of PowderJect.

*Pediatric and other vaccines* Sales of our pediatric and other vaccines increased for the three months ended September 30, 2005 as compared with the three months ended September 30, 2004. This increase was primarily due to a \$15.7 million increase related to the timing of sales for diphtheria, tetanus and pertussis vaccines. This increase is partially offset by (i) a \$8.8 million decrease of polio vaccine sales due to product write-offs and product unavailability as a result of manufacturing upgrades, (ii) a \$1.0 million decrease due to the timing of tender sales for our measles, mumps and rubella vaccines and (iii) a \$4.6 million decrease from the interruption of production of certain vaccines in our Liverpool plant to focus on our remediation efforts at that plant. Sales of our pediatric and other vaccines decreased for the nine months ended September 30, 2005 as compared with the nine months ended September 30, 2004 primarily due to (i) a \$19.8 million decline in polio vaccines and measles, mumps and rubella vaccines sales due to product write-offs and a lack of product availability as a result of manufacturing upgrades (ii) an \$8.8 million decrease due to the timing of tender sales for our polio vaccines and measles, mumps and rubella vaccines, (iii) a \$6.7 million decline due to the planned divestiture of certain vaccines operations in Sweden in the second quarter of 2004 acquired from our acquisition of PowderJect and (iv) a \$12.7 million decrease from the interruption of production of certain vaccines in our Liverpool plant to focus on our





remediation efforts at that plant. These decreases were partially offset by a \$21.1 million increase related to the timing of sales for diphtheria, tetanus and pertussis vaccines.

Certain of our vaccine products are seasonal, particularly our influenza vaccines, which have higher sales primarily in the second half of the year. Our TBE vaccine is also seasonal with higher sales typically in the first half of the year. Certain of our vaccines require regulatory approval for production or sale of the product and sales may fluctuate depending on these regulatory approvals. We expect increased competition for our influenza vaccines business in the future as a result of the recent influenza vaccines developments. For more information on this, see *Influenza Virus Vaccines Recent Events* above. In addition, we expect MENJUGATE® vaccine sales to continue to fluctuate as public health authorities consider adoption of broad vaccination programs and competitive pressures continue to increase.

On October 27, 2005, we announced that we won a \$62.5 million contract to supply the U.S. government with pre-pandemic influenza vaccine for a stockpile to protect against the H5N1 avian influenza virus strain. Under the agreement with the Department of Health and Human Services (HHS), we will provide a bulk stockpile of H5N1 influenza vaccine, which we will produce at our Liverpool manufacturing facility using the U.S.-licensed commercial-scale manufacturing process. Production of the H5N1 stockpile vaccine under this agreement will not affect production of our annual FLUVIRIN® influenza virus vaccine.

**Collaborative agreement revenues** We recognize collaborative agreement revenues for fees received as we perform research services and achieve specified milestones. Collaborative agreement revenues for the three months ended September 30, 2005 as compared with the three months ended September 30, 2004 decreased due to \$1.2 million from a milestone payment in the third quarter of 2004 related to an agreement to supply MeNZB meningococcal B vaccine to the Ministry of Health in New Zealand. Collaborative agreement revenues for the nine months ended September 30, 2005 as compared with the nine months ended September 30, 2004 decreased primarily due to \$2.4 million in lower milestone payments related to an agreement to supply MeNZB meningococcal B vaccine to the Ministry of Health in New Zealand.

Collaborative agreement revenues tend to fluctuate based on the amount and timing of research services performed, the status of projects under collaboration and the achievement of milestones. Due to the nature of our collaborative agreement revenues, results in any one period are not necessarily indicative of results to be achieved in the future. In addition, the collaborative agreements typically provide for certain milestone payments and various royalties on future product sales if the collaborative partners commercialize a product using our technology. Also, our ability to generate additional collaborative agreement revenues may depend, in part, on our ability to initiate and maintain relationships with potential and current collaborative partners.

**Other revenues** Other revenues recognized in our vaccines segment primarily consist of grant revenues and contract manufacturing revenues and may fluctuate due to the nature of the revenues recognized and the timing of events giving rise to these revenues.

**Gross profit margin** Gross profit margin increased for the three months ended September 30, 2005 as compared with the three months ended September 30, 2004 primarily due to a \$91.3 million charge to cost of sales resulting from the write-off of our entire Fluvirin inventory in the third quarter of 2004, partially offset by no BEGRIVAC vaccine sales for the three months ended September 30, 2005.

Gross profit margin was negatively impacted for the nine months ended September 30, 2005 primarily due to (i) \$27.0 million of FLUVIRIN® vaccine remediation costs and \$36.0 million increase in idle facility costs as our Liverpool facility had limited FLUVIRIN® vaccine production during the nine months ended September 30, 2005 due to FLUVIRIN® vaccine remediation activities, (ii) an \$18.0 million charge for the write-off of BEGRIVAC product inventory due to product sterility issues and (iii) lack of BEGRIVAC

sales for the nine months ended September 30, 2005. Gross profit margin was negatively impacted for the nine months ended September 30, 2004 due to there being no FLUVIRIN® sales for the 2004-2005 influenza season and a \$91.3 million charge to cost of sales resulting from the write-off of our entire FLUVIRIN® inventory in the third quarter of 2004.

Vaccines gross profit margin does not include amortization expense of intangible assets from acquired developed products related to business combinations. Such amortization expense is included in the caption amortization expense of intangible assets acquired in business combinations and asset purchases.

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

**Research and development expenses** The increase in research and development expenses for the three months ended September 30, 2005 as compared with the three months ended September 30, 2004 was primarily due to \$2.3 million from advancing our quadrivalent meningococcal vaccine candidate for serogroups A,C,W and Y. The increase in research and development expenses for the nine months ended September 30, 2005 as compared with the nine months ended September 30, 2004 was primarily due \$6.6 million from advancing our quadrivalent meningococcal vaccine candidate for serogroups A,C,W and Y, and \$3.0 million from our flu cell culture development program. These increases were partially offset by the second quarter of 2004 divestiture of certain research and development operations, acquired in the acquisition of PowderJect. The divested operations included \$4.2 million in research and development expenses for the nine months ended September 30, 2004.

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 expenses** The increase in selling, general and administrative expenses for the three months ended September 30, 2005 as compared with the three months ended September 30, 2004 was due to (i) \$1.2 million for corporate governance costs and (ii) \$0.7 million for executive severance. These increases were partially offset by (i) a \$1.4 million decrease in marketing activities focused on international markets. The increase in selling, general and administrative expenses for the nine months ended September 30, 2005 as compared with the nine months ended September 30, 2004 was due to (i) \$3.2 million due to the movement in the Euro and British pound to U.S. Dollar exchange rate, (ii) \$3.4 million for corporate governance costs, (iii) an additional \$2.5 million from the establishment of sales and marketing operations in the U.S., (iv) \$2.4 million for executive severance and (v) \$1.3 million from marketing activities focused on international markets. These increases were partially offset by a reduction of \$4.1 million as a result of the planned divestiture of certain PowderJect operations in the second quarter 2004 and \$2.2 million from the recovery of bad debt.

**Amortization expenses** The decrease in amortization expense for the three and nine months ended September 30, 2005 as compared with the three and nine months ended September 30, 2004 was due to lower amortization expense related to certain developed product technologies from our acquisition of PowderJect which are amortized under the estimated sales method. The estimated sales method considers forecasted FLUVIRIN® sales during each influenza season through the remaining period of the benefit. Related amortization was \$4.1 million and \$30.1 million as compared to \$12.3 million and \$34.9 million during the three and nine months ended September 30, 2005 and 2004, respectively, reflecting updated forecasted FLUVIRIN® sales.

**Impairment loss on acquired intangible assets** In the third quarter of 2005, we recognized an impairment loss of \$14.5 million on acquired intangible assets from our acquisition of PowderJect related to a ARILVAX , a yellow fever vaccine. This impairment loss was due to a focus of our resources towards the influenza market, resulting in a reduction of the expected activity for ARILVAX . ARILVAX remains in our portfolio of trademarks and we may re-enter the yellow fever vaccine market in the future with this product.



**Biopharmaceuticals**

	Three Months Ended September 30,		Nine Months Ended September 30,		\$ Change Three Months	Nine Months	% Change	
	2005	2004	2005	2004			Three Months	Nine Months
(\$ in 000 s, except percentages)								
Product sales, net:								
BETASERON® interferon beta-1b	\$ 36,927	\$ 35,171	\$ 101,693	\$ 96,933	\$ 1,756	\$ 4,760	5.0 %	4.9 %
TOBI® tobramycin	57,890	55,734	167,425	159,600	2,156	7,825	3.9 %	4.9 %
PROLEUKIN® aldesleukin	31,028	31,739	92,290	98,664	(711 )	(6,374 )	(2.2 )%	(6.5 )%
Other	10,862	8,902	26,822	29,770	1,960	(2,948 )	22.0 %	(9.9 )%
	136,707	131,546	388,230	384,967	5,161	3,263	3.9 %	0.8 %
Collaborative agreement revenues	571	278	1,300	1,052	293	248	105.4 %	23.6 %
Royalty and license fee revenues	17,321	15,412	55,739	47,892	1,909	7,847	12.4 %	16.4 %
Other revenues	531	1,201	8,251	9,127	(670 )	(876 )	(55.8 )%	(9.6 )%
Total Biopharmaceutical revenues	\$ 155,130	\$ 148,437	\$ 453,520	\$ 443,038	\$ 6,693	\$ 10,482	4.5 %	2.4 %
Gross profit margin.	71 %	67 %	70 %	72 %				
Research and development expenses	\$ 65,721	\$ 63,252	\$ 198,992	\$ 183,627	\$ 2,469	\$ 15,365	3.9 %	8.4 %
Selling, general and administrative expenses	\$ 34,881	\$ 33,322	\$ 109,619	\$ 98,496	\$ 1,559	\$ 11,123	4.7 %	11.3 %
Amortization expense	\$ 6,240	\$ 6,240	\$ 18,755	\$ 18,725	\$	\$ 30	0.0 %	0.2 %

**Product sales** Biopharmaceutical product sales in 2005 and 2004 consisted principally of BETASERON® interferon beta-1b, TOBI® tobramycin and PROLEUKIN® aldesleukin products.

**BETASERON® interferon beta-1b** We manufacture interferon beta-1b, which is marketed by Schering AG and its affiliates, including Berlex Laboratories, Inc. (collectively, Schering), under the trade names BETASERON® (in the U.S and other non-European markets) and BETAFERON® (in Europe). Boehringer Ingelheim also supplies BETAFERON® interferon beta-1b to Schering for sale in Europe. For product we manufacture, we recognize a portion of revenue for product sales upon shipment to Schering and the remainder based on a contractual percentage of sales by Schering, both of which we record as product sales. For product manufactured by Boehringer Ingelheim and marketed by Schering in Europe under the trade name BETAFERON®, we receive royalties calculated at the same percentage of sales less the amount paid or incurred by Schering for supply costs, which we record in royalty and license fee revenues.

The increase in BETASERON® product sales for the three months ended September 30, 2005 as compared with the three months ended September 30, 2004 primarily related to (i) \$3.4 million from price increases, (ii) \$2.0 million from a shift of revenue from royalties to product sales as Schering began to sell product manufactured by us in additional European markets and (iii) \$1.9 million from the timing of clinical products. These increases were partially offset by \$3.8 million from reduced shipments to Berlex and \$2.7 million from inventory ordering patterns. The increase in BETASERON® product sales for the nine months ended September 30, 2005 as compared with the nine months ended September 30, 2004 primarily related to (i) \$5.4 million from price increases, (ii) \$2.0 million from a shift of revenue from royalties to product sales as Schering began to sell product manufactured by us in additional European markets, (iii) \$1.3 million from the timing of clinical products and (iv) \$0.7 million due to the benefit of the movement in the Euro to U.S. Dollar exchange rate. These increases were partially offset by \$5.5 million from reduced shipments to Berlex and \$1.8 million from inventory ordering patterns.



**TOBI® tobramycin solution for inhalation** We sell TOBI® solution directly in the U.S. and certain international markets. The increase in sales for the three months ended September 30, 2005 as compared with the three months ended September 30, 2004 was primarily due to (i) \$4.7 million due to price increases and (ii) \$2.1 million due to increased patient demand in both the United States and Europe. These increases were partially offset by \$4.6 million reduction due to wholesaler ordering patterns. The increase in sales for the nine months ended September 30, 2005 as compared with the nine months ended September 30, 2004 was primarily due to (i) \$9.1 million due to price increases, (ii) \$8.4 million due to increased patient demand in both the United States and Europe and (iii) \$1.5 million due to the benefit of the movement in the Euro to U.S. dollar exchange rate. These increases were partially offset by \$10.4 million reduction due to wholesaler ordering patterns and \$0.8 million for a government rebate adjustment.

**PROLEUKIN® (aldesleukin)** The decrease in PROLEUKIN® (aldesleukin) product sales for the three months ended September 30, 2005 as compared with the three months ended September 30, 2004 was primarily due to (i) \$2.7 million due to a decrease in patient demand as a result of increased clinical trial activity and (ii) \$1.1 million for wholesaler inventory ordering patterns. These decreases were partially offset by (i) \$3.0 million for price increases. The decrease in PROLEUKIN® (aldesleukin) product sales for the nine months ended September 30, 2005 as compared with the nine months ended September 30, 2004 was primarily due to (i) \$6.5 million due to a decrease in patient demand as a result of increased clinical trial activity, (ii) \$3.5 million for wholesaler inventory ordering patterns and (iii) \$1.6 million for a government rebate adjustment. These decreases were partially offset by \$4.8 million for price increases.

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

Wholesale ordering patterns, reimbursement and government pressures, competition, foreign currency exchange rates and the level of rebates may influence future biopharmaceutical sales.

**Royalty and license fee revenues** Our biopharmaceuticals segment earns royalties on third party sales of several products, including BETA FERON® interferon beta-1b and recombinant insulin and glucagon products. Our biopharmaceuticals segment also earns license fees for technologies, such as hepatitis C virus-related patents, used by third parties to develop therapeutic products.

**BETA FERON® interferon beta-1b** BETA FERON® product royalties were \$13.4 million for each of the three months ended September 30, 2005 and 2004, respectively, and \$45.8 million and \$38.8 million for the nine months ended September 30, 2005 and 2004, respectively.

BETA FERON® product royalties were consistent for the three months ended September 30, 2005 as compared with the three months ended September 30, 2004. The increase in demand of \$1.7 million and \$0.8 million from price increases was partially offset by \$1.7 million from a shift of revenue from royalties to product sales as Schering began to sell product manufactured by us in additional European markets. The increase in BETA FERON® product royalties for the nine months ended September 30, 2005 as compared with the nine months ended September 30, 2004 was primarily due to (i) \$4.0 million from an increase in demand and (ii) \$2.5 million from price increases. These increases were partially offset by \$1.7 million from a shift of revenue from royalties to product sales as Schering began to sell product manufactured by us in additional European markets.

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

Royalty and license fee revenues may fluctuate based on the nature of the related agreements, the timing of receipt of license fees and the expiration of patents. Results in any one period are not necessarily indicative of results to be achieved in the future. Also, the license agreements typically provide for certain milestone payments and various royalties on future product sales if the licensees commercialize a product





using our technology. However, we have no assurance that the licensees will meet their development objectives or commercialize a product using our technology. In addition, our ability to generate additional royalty and license fee revenues may depend, in part, on our ability to market and capitalize on the value of our technologies.

#### **Other revenues**

*Contract manufacturing revenues* Our biopharmaceuticals segment recognized contract manufacturing revenues of \$0.4 million and \$1.1 million for the three months ended September 30, 2005 and 2004, respectively. Contract manufacturing revenues were \$7.4 million and \$8.6 million for the nine months ended September 30, 2005 and 2004, respectively. The fluctuation resulted from the timing of contract manufacturing activities.

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

Other revenues recognized in our biopharmaceuticals segment may fluctuate due to the nature of the revenues recognized and the timing of events giving rise to these revenues. There can be no assurance that we will be successful in obtaining additional revenues or that these revenues will not decline.

**Gross profit margin** The increase in gross profit margin for the three months ended September 30, 2005 as compared with the three months ended September 30, 2004 was primarily due to favorable product mix and increased utilization of facilities. The decrease in gross profit margin for the nine months ended September 30, 2005 as compared with the nine months ended September 30, 2004 was primarily due to a planned increase in idle time for manufacturing facilities and ongoing process improvement efforts.

Biopharmaceutical gross profit margin does not include amortization expense of intangible assets from acquired developed products related to business combinations. Such amortization expense is included in the caption "amortization expense of intangible assets acquired in business combinations and asset purchases".

Biopharmaceutical gross profit margin may fluctuate significantly in future periods due to production yields and increased cost to produce the BETASERON® pre-filled diluent syringe and as the biopharmaceutical product and customer mix changes.

**Research and development expenses** The increase in research and development expenses for the three months ended September 30, 2005 as compared with the three months ended September 30, 2004 was primarily due to (i) \$2.4 million for the progression of phase I clinical studies of our oncology compound CHIR-258, (ii) \$0.9 million for activities related to the development of tifacogin and (iii) \$5.3 million for other research and development activities, primarily related to early-stage oncology compounds. These increases were partially offset by (i) a \$2.4 million decrease in expenses for the development of PULMINIQ (cyclosporine, USP) inhalation solution, (ii) a \$1.5 million decrease in expenses related to the SILCAAT trial, as discussed below and (iii) a \$1.4 million decrease in expenses for development activities related to CUBICIN® (daptomycin for injection) for treatment of complicated skin and soft tissue infections.

The increase in research and development expenses for the nine months ended September 30, 2005 as compared with the nine months ended September 30, 2004 was primarily due to (i) \$6.1 million for the progression of phase I clinical studies of our oncology compound CHIR-258, (ii) \$2.4 million for development activities related to CUBICIN® (daptomycin for injection) for treatment of complicated skin and soft tissue infections, (iii) a \$1.7 million increase in expense related to the development of new processes and performance of test runs related to installed equipment of our existing manufacturing facilities to support the supply of BETAFERON® interferon beta-1b to Schering, (iv) \$1.4 million for the progression of phase I clinical studies of our oncology compound CHIR-12.12, (v) \$1.3 million for activities



related to the development of tifacogin and (vi) \$13.5 million for other research and development activities, primarily related to early-stage oncology compounds. These increases are partially offset by (i) a \$5.4 million decrease in expenses related to the SILCAAT trial, as discussed below, (ii) a \$2.7 million decrease in expenses for the development of PULMINIQ®(cyclosporine, USP) inhalation solution and (iii) a \$3.0 million decrease related to the discontinued development of tezacitabine in the first quarter of 2004 based on an analysis of the data from a Phase II trial in patients with gastro esophageal cancer.

In the fourth quarter 2002, we reached an agreement in principle to transfer responsibility for the SILCAAT trial, a Phase III study for recombinant human interleukin-2 (IL-2, aldesleukin), to the National Institutes Allergy and Infectious Disease (NIAID) and the University of Minnesota. Responsibility for the SILCAAT study was transferred to NIAID and University of Minnesota effective February 14, 2003. Under the agreement, we are obligated to fund a maximum of \$18.0 million over the lifetime of the trial and to supply clinical materials and certain other support services of which \$18.0 million has been paid through December 31, 2004.

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 expenses** The increase in selling, general and administrative expenses for the three months ended September 30, 2005 as compared with the three months ended September 30, 2004 was primarily due to pre-launch costs for CUBICIN® (daptomycin for injection). The increase in selling, general and administrative expenses for the nine months ended September 30, 2005 as compared with the nine months ended September 30, 2004 was primarily due to (i) \$6.8 million for pre-launch costs for CUBICIN® (daptomycin for injection), (ii) \$1.3 million for other worldwide marketing activities, (iii) \$1.1 million of pre-launch costs for PULMINIQ (cyclosporine, USP) inhalation solution, (iv) \$1.0 million for increased TOBI® sales and marketing activities and (v) \$0.4 million due to movement in the Euro to U.S. Dollar exchange rate.

On July 14, 2005, we received an action letter from the FDA stating that the company's New Drug Application (NDA) for PULMINIQ (cyclosporine, USP) inhalation solution is approvable but that an additional pre-approval study is required to confirm the efficacy of the drug. In the NDA for PULMINIQ, Chiron is seeking an indication to increase survival and prevent chronic rejection in patients receiving allogeneic lung transplants, in combination with standard immunosuppressive therapy. We are evaluating possible next steps for PULMINIQ.

**Other**

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

We view certain other revenues and expenses, particularly certain royalty and license fee revenues primarily related to HIV and HCV-related patents, and unallocated corporate expenses, as not belonging to any one reportable segment. As a result, we have aggregated these items into an Other segment.

	Three Months Ended		Nine Months Ended		\$ Change Three Months	Nine Months	% Change	
	September 30, 2005	2004	September 30, 2005	2004			Three Months	Nine Months
(\$ in 000 s, except percentages)								
Royalty and license fee revenues	\$ 29,641	\$ 60,656	\$ 94,427	\$ 102,787	\$ (31,015)	\$ (8,360)	(51.1)%	(8.1)%
Selling, general and administrative expenses	28,610	25,326	109,482	77,279	3,284	32,203	13.0%	41.7%
Purchased in-process research and development		9,629		9,629	(9,629)	(9,629)	(100)%	(100)%
Interest expense	7,759	7,063	22,932	19,440	696	3,492	9.9%	18.0%
Interest and other income, net	18,514	5,369	66,259	41,252	13,145	25,007	244.8%	60.6%

40

---

**Royalty and license fee revenues** Our other segment earns royalties on third party sales of, and license fees on, several products. The majority of royalty and license fee revenues relate to the use of our HCV and HIV-related patents for diagnostic testing purposes by various third parties.

*Roche settlement* In October 2000, we entered into three license agreements with Roche and several of its affiliated companies related to the settlement of certain litigation in the U.S. and certain other countries for use of our HCV and HIV nucleic acid testing intellectual property. Two agreements relate to *in vitro* diagnostics products. The third agreement relates to blood screening.

Under the hepatitis C virus agreement, we received \$85.0 million, of which we recognized \$40.0 million in the fourth quarter 2000. We deferred the remaining \$45.0 million, which becomes nonrefundable ratably through 2005. In the first quarter 2001, we began recognizing portions of the \$45.0 million based upon the greater of (i) the scheduled quarterly minimum non-refundable amount or (ii) the actual earned credits as royalties on future sales related to Roche's use of our HCV-related patent in its *in vitro* diagnostic products. The agreement also provides for royalties on future sales related to Roche's use of our HCV-related patent in its *in vitro* diagnostic products, which commenced in the first quarter 2001. Royalty revenues under the hepatitis C virus agreement increased for the three months ended September 30, 2005 as compared with the three months ended September 30, 2004, by \$2.6 million and 20.9%. Royalty revenues under the hepatitis C virus agreement increased for the nine months ended September 30, 2005 as compared with the nine months ended September 30, 2004, by \$3.9 million and 10.0%.

The HIV agreement with Roche provides for royalties on future sales related to Roche's use of our HIV-related patent in its *in vitro* diagnostic products, which commenced in the first quarter 2001 when the European Patent Office Board of Technical Appeals upheld our HIV-related patent. Royalty revenues recognized under this agreement decreased by \$31.9 million for the three months ended September 30, 2005 as compared with the three months ended September 30, 2004. This decrease is mainly due to the recognition of \$35.6 million of deferred royalties and license fees and a nonrefundable portion of a royalty payment from the September 10, 2004 settlement with Roche, as discussed below. Royalty revenues recognized under this agreement decreased by \$15.5 million for the nine months ended September 30, 2005 as compared with the nine months ended September 30, 2004. This decrease is mainly due to \$35.6 million of deferred royalties and license fees and a nonrefundable portion of a royalty payment from the September 10, 2004 settlement with Roche, as discussed below. This decrease is partially offset by \$21.2 million in royalties recognized under the September 10, 2004 settlement with Roche, as discussed below, for the nine months ended September 30, 2005.

An HIV-related patent directed to nucleic acid testing methods for HIV-1 was issued in the U.S. on March 13, 2003. This patent will expire seventeen years from the date of issuance. The issuance of the patent triggered a milestone payment to us of \$10.0 million from Roche, which was received in April 2003. As permitted under the terms of its licensing agreement, Roche decided to institute arbitration proceedings in regard to the application of the U.S. patent. We had deferred recognition of the \$10.0 million milestone payment, interest, royalties received and royalties accrued under the patent until the resolution of this dispute. On September 10, 2004, we reached a settlement agreement with Roche. Under the terms of the settlement agreement, the milestone payment along with any royalties received prior to March 31, 2004 became non-refundable. Accordingly, during the third quarter 2004, we recognized \$10.0 million in license fees and \$21.8 million in royalties up until June 30, 2004, which had previously been deferred, of which \$16.3 million has been recognized as revenue in our other segment and \$5.5 million has been recognized as revenue in our blood testing segment. During the third quarter 2004, we also recognized \$0.8 million in interest on the license fee. Also under the settlement agreement, in the first nine months of 2005, we received a lump-sum payment of \$78.0 million in lieu of royalties beyond January 1, 2005. Roche may elect under the terms of the agreement to obtain a partial refund and revert to paying royalties on the sales of its products in North America. The amount of such potential refund ranges

between \$64.0 million and \$0.0 million. The amount of the refund available to Roche decreases in increments over the quarters of 2005 and 2006. As such, Chiron expects to recognize \$64.0 million of the payment as revenue during 2005 and 2006. The remaining \$14.0 million is nonrefundable and was recognized as revenue in the third quarter 2004, of which, \$9.3 million has been recognized as revenue in our other segment and \$4.7 million has been recognized as revenue in our blood-testing segment. Currently, the applicable issued HCV-related patents expire in 2015 for the U.S. and in 2010 for Europe. The applicable issued HIV-related patent in Europe expired in October 2005. For the three months ended September 30, 2005, we recognized \$5.3 million of revenue from this settlement in our other segment and \$2.7 million of revenue from this settlement in our blood-testing segment. For the nine months ended September 30, 2005, we recognized \$21.2 million of revenue from this settlement in our other segment and \$10.8 million of revenue from this settlement in our blood-testing segment. Revenues earned from diagnostic products are included in our other segment and revenues earned from blood screening are included in our blood-testing segment.

The impact on revenues for the three and nine months ended September 30, 2004 from the September 10, 2004 settlement with Roche is summarized below (in thousands).

	Other Segment	Blood-testing Segment	Total
Deferred revenues recognized	\$ 16,313	\$ 5,453	\$ 21,766
Deferred license fee recognized.	10,000		10,000
Non-refundable portion of Roche settlement.	9,333	4,667	14,000
Total royalty and license fee revenue	\$ 35,646	\$ 10,120	\$ 45,766

**Bayer** A cross-license agreement provides for royalties to us on HIV and hepatitis C virus products sold by Bayer Corporation. Royalties increased for the nine months ended September 30, 2005 as compared with the nine months ended September 30, 2004 due to additional royalties of \$2.4 million under our existing license agreement, as amended.

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

Royalty and license fee revenues may fluctuate based on the nature of the related agreements, the timing of receipt of license fees and the expiration of patents. Results in any one period are not necessarily indicative of results to be achieved in the future. In addition, our ability to generate additional royalty and license fee revenues may depend, in part, on our ability to market and capitalize on our technologies.

**Selling, general, and administrative expenses** The increase in selling, general and administrative expenses for the three months ended September 30, 2005 as compared with the three months ended September 30, 2004 was primarily due to (i) \$3.9 million in higher employee related expenses and (ii) \$1.7 million in corporate governance costs. These increases were partially offset by lower facility costs of \$1.9 million. The increase in selling, general and administrative expenses for the nine months ended September 30, 2005 as compared with the nine months ended September 30, 2004 was primarily due to (i) \$15.5 million of legal costs associated with the FLUVIRIN® vaccine-related developments discussed above under *Influenza Virus Vaccines Recent Events*, (ii) \$6.5 million for higher employee related expenses, (iii) \$4.2 million for consulting expenses, (iv) \$5.9 million for corporate governance costs and (v) \$1.8 million in legal costs related to the defense of our patents and technology. These increases were partially offset by lower facility costs of \$5.1 million.

**Purchased in-process research and development** On July 2, 2004, we acquired Sagres Discovery and accounted for the acquisition as an asset purchase. We allocated the purchase price based on fair value of the assets acquired and liabilities assumed. We allocated \$9.6 million of the purchase price to purchased in-process research and development, which we charged to operations in the third quarter 2004. We do not

anticipate that there will be any alternative future use for the purchased in-process research and development.

**Interest expense** Interest expense for the three months ended September 30, 2005 was consistent with interest expense for the three months ended September 30, 2004. The increase in interest expense for the nine months ended September 30, 2005 as compared with the nine months ended September 30, 2004 primarily related to interest expense recognized on the \$385.0 million convertible debentures that were issued on June 22, 2004 partially offset by the lower interest expense recognized on the Liquid Yield Option Notes (LYONs), the majority of which were put to us in June 2004. The \$385.0 million convertible debentures incur interest at a higher rate than the LYONs.

**Interest and other income, net** Interest and other income, net, primarily consisted of interest income on our cash and investment balances and other non-operating gains and losses. We recognized interest income of \$9.2 million and \$6.6 million for the three months ended September 30, 2005 and 2004, respectively. We recognized interest income of \$25.4 million and \$17.5 million for the nine months ended September 30, 2005 and 2004, respectively. These increases were due to higher interest rates in 2005 as compared with 2004.

We recognized gains of \$7.2 million and \$1.0 million for the three months ended September 30, 2005 and 2004, respectively, related to the sale of certain equity securities. We recognized gains of \$35.8 million and \$25.0 million for the nine months ended September 30, 2005 and 2004, respectively, related to the sale of certain equity securities.

In the second quarter of 2005, we recognized a \$6.0 million settlement regarding a dispute with one of our competitors regarding certain Chiron patents.

In the third quarter of 2005, we recognized a \$2.6 million insurance settlement regarding a building fire at our Emeryville campus.

There were no losses attributable to impairment of equity securities for the three months ended September 30, 2005. For the nine months ended September 30, 2005, we recognized losses attributable to the impairment of certain equity securities of \$1.3 million. For the three and nine months ended September 30, 2004, we recognized losses attributable to the impairment of certain equity securities of \$1.4 million.

On December 31, 1998, we completed the sale of our 30% interest in General Injectibles & Vaccines, Inc., a distribution business, to Henry Schein, Inc. and received payment in full of certain advances we made to General Injectibles & Vaccines. The agreement also provided for us to receive additional payments, calculated as a pre-determined percentage of Henry Schein's gross profit, through 2003. We received \$3.5 million for 2003 during the nine months ended September 30, 2004.

**Income taxes** The effective tax rate was 21.9% and 27.3% of pretax income from continuing operations for the nine months ended September 30, 2005 and 2004, respectively. The tax rate decreased primarily due to lower expected taxable incomes, year to year, in certain high tax jurisdictions, as well as increased benefits of U.S. research credits. Such items are not expected to recur in future years. The effective tax rate may be affected in future periods by changes in management's estimates with respect to our deferred tax assets and other items affecting the overall tax rate.

**Discontinued operations** In a strategic effort to focus on our core businesses of blood-testing, vaccines and biopharmaceuticals, we completed the sale of Chiron Diagnostics to Bayer Corporation, or Bayer, in 1998.

In the second quarter of 2004, Chiron and the IRS entered into a settlement agreement closing the open tax years 1996 to 1998. Pursuant to this settlement, we recognized a tax benefit of approximately \$12.5 million for the nine months ended September 30, 2004.

Chiron and Bayer were involved in a dispute with respect to their respective rights to certain royalty refunds receivable for which a settlement was reached in 2004. Under this settlement agreement, we made a settlement payment to Bayer in 2004. This settlement includes an agreement that all outstanding items with Bayer related to the sale of Chiron Diagnostics are resolved and no future indemnity obligations are required. We released previously established reserves deemed to be in excess following this settlement. This settlement resulted in a net gain of \$12.8 million for the nine months ended September 30, 2004. This net gain primarily relates to a tax benefit as a result of the settlement payment to Bayer.

### **New Accounting Standards**

In December 2004, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment* (SFAS 123(R)), which requires the cost resulting from all share-based payment transactions to be recognized in the consolidated financial statements. That cost will be measured based on the fair value of the equity instruments issued or on the fair value of liabilities incurred. Under SFAS 123(R), the fair-value-based method for recognition or disclosure of compensation expense will be applied using the modified prospective application transition method or the modified retrospective application transition method. We currently measure compensation expense for our stock-based employee compensation under the intrinsic method. We are currently evaluating transition methods, option valuation methodologies and assumptions in light of SFAS 123(R), and therefore cannot estimate the impact of our adoption at this time, although we expect that its adoption will have a material impact on our consolidated financial statements. Current option values determined using the Black-Scholes-Merton formula, used for purposes of proforma disclosure, may not be indicative of results from the valuation methodologies we finally adopt. The effective date of SFAS 123(R) is the first reporting period beginning after June 15, 2005. However, on April 14, 2005, the Securities and Exchange Commission (SEC) announced the adoption of a new rule that delays the effective date of SFAS 123(R) for registrants, such as Chiron, that are not small business issuers. The SEC's new rule allows calendar year non-small business issuers to implement SFAS 123(R) at the beginning of 2006, which makes SFAS 123(R) effective for Chiron in the first quarter of 2006.

On October 22, 2004, the American Jobs Creation Act of 2004 (the Act) was signed into law. The Act includes a temporary incentive for U.S. multinationals to repatriate accumulated income earned outside the U.S. at an effective tax rate of 5.25%. On December 21, 2004, the FASB issued Staff Position 109-2, *Accounting and Disclosure Guidance for the Foreign Earnings Repatriation Provisions within the American Jobs Creation Act of 2004* (FSP 109-2). FSP 109-2 allows companies additional time to evaluate the effect of the law on whether unrepatriated foreign earnings continue to qualify for SFAS No. 109's exception to recognizing deferred tax liabilities and would require explanatory disclosures from those who need the additional time. Through September 30, 2005, we have not provided deferred taxes on foreign earnings because such earnings were intended to be indefinitely reinvested outside the U.S. Presently we do not have any plan to repatriate earnings under the Act. Accordingly, we have made no change in our current intention to indefinitely reinvest accumulated earnings of our foreign subsidiaries. If we repatriate these earnings, a tax charge to our consolidated results of operations could occur. We will continue to evaluate the impact of this provision.

### **Liquidity and Capital Resources**

Our capital requirements have generally been funded by cash flow from operations, borrowings from commercial banks and issuance of convertible debt securities and common stock. Our cash, cash equivalents and investments in marketable debt securities, which totaled \$1,017.8 million at September 30, 2005, are invested in a diversified portfolio of fixed income securities, including money market instruments, corporate notes and bonds, and government agency securities issued by financial institutions and other issuers with strong credit ratings. By policy, the amount of credit exposure to any one institution is limited. Investments are generally not collateralized and primarily mature within three years.



The recent events regarding FLUVIRIN® vaccine, as discussed above under Management's Discussion and Analysis of Financial Condition and Results of Operations *Influenza Virus Vaccines Recent Events* will continue to impact our cash flow going forward. As we continue to implement our remediation plan, our efforts will entail additional cash payments, which will be material. The MHRA's lifting of our license suspension is conditioned upon the understanding that our commitment to remediation will continue.

In addition, we have incurred and expect to continue to incur substantial expense relating to the investigation by the U.S. Attorney's Office for the Southern District of New York, the Securities and Exchange Commission investigation and the shareholder class action and derivative private lawsuits and other claims arising out of or related to these developments regarding FLUVIRIN® vaccine. The results of any such investigations, proceedings or disputes could have a material adverse effect on our cash flow.

Our previous inability to supply FLUVIRIN® vaccine may also lead to loss of market share in the 2005-2006 influenza season and future seasons. Following the announcement of our FLUVIRIN® license suspension competitors announced plans to introduce influenza vaccine products in the United States and sought expedited regulatory approval to do so. Even though the license suspension has been lifted, some of our customers may choose to purchase influenza vaccine from other providers as their products become available in the United States. Delays in start-up procedures for ramping up to full production and normal manufacturing issues inherent in the complexity of influenza vaccine production, have adversely affected the amount of FLUVIRIN® vaccine that we are able to produce for the 2005-2006 influenza season and may result in further loss of market share. Loss of market share could have a material adverse effect on cash flow.

The recent events regarding BEGRIVAC vaccine, as discussed above under Management's Discussion and Analysis of Financial Condition and Results of Operations *Influenza Virus Vaccines Recent Events* will impact our cash flow going forward. We will be unable to supply any BEGRIVAC vaccine doses for the 2005-2006 influenza season, which will eliminate any cash flows we would have received from the sale of BEGRIVAC vaccine. Our inability to supply BEGRIVAC vaccine as planned to non-U.S. markets may also lead to loss of market share in future seasons. Loss of market share could have a material adverse effect on cash flow. In addition, while we are in the process of implementing remedial measures to address the product sterility issue, including facility modifications our remediation efforts will entail cash payments for additional capital and other expenditures, which could be material. If we suffer a permanent loss of BEGRIVAC influenza vaccine sales, it could have a material adverse effect on our cash flow.

In addition, certain distributors and other parties with whom we had contracted to supply influenza vaccine may make claims against us as a result of Chiron not supplying influenza vaccine. Any such claims may cause us to incur substantial expense and require significant time and attention from our management. The results of any such claims could have a material adverse effect on our cash flow.

For additional information concerning the risks we face as a result of these influenza vaccine developments, see Factors That May Affect Future Results *Developments with respect to influenza vaccines over the past year will harm our business and results of operations*. For additional information on the U.S. Attorney's investigation, SEC investigation, private lawsuits and other claims, see Part II, Item 1. Legal Proceedings of this Report on Form 10-Q.

Under the terms of the Investment Agreement between Novartis and Chiron, Novartis agreed to guarantee certain Chiron obligations up to a maximum of \$702.5 million. As a result of the exercise of our subscription right as described under Management's Discussion and Analysis of Financial Condition and Results of Operations *Recent Developments*, the maximum amount Novartis is required to guarantee pursuant to the terms of the Investment Agreement has been reduced by \$300.0 million, the amount of our common stock Novartis will be required to subscribe for, to \$402.5 million. Under this agreement, Novartis

has guaranteed \$100.0 million under a U.S. credit facility in which there were no borrowings outstanding at September 30, 2005 and \$173.3 million from a lease commitment for a research and development facility in Emeryville, California.

We believe that our cash, cash equivalents and marketable debt securities, together with funds provided by operations and borrowing and leasing arrangements, will be sufficient to meet our foreseeable operating cash requirements including any cash needed for remediation efforts for our Liverpool plant and Marburg plant, cash utilized for our stock repurchase program and our current contractual obligations. In addition, we believe we could access additional funds from the debt and capital markets should the need arise. As noted above, if we suffer a permanent loss of FLUVIRIN® and/or BEGRIVAC influenza vaccine sales, whether through loss of regulatory approvals, market share or otherwise, it could have a material adverse effect on our cash flow.

**Sources and uses of cash** We had cash and cash equivalents of \$204.4 million and \$201.0 million at September 30, 2005 and 2004, respectively.

*Operating activities* For the nine months ended September 30, 2005, net cash provided by operating activities was \$117.6 million as compared with \$132.6 million for the nine months ended September 30, 2004. The decrease in cash provided by operating activities was primarily due to costs associated with our remediation efforts for our Liverpool plant and legal costs related to the FLUVIRIN® vaccine developments discussed above. Cash provided by operating activities also decreased due to (i) increased selling, general and administrative expenses in the nine months ended September 30, 2005 primarily due to ongoing marketing and pre-launch programs to support the continued growth of our business, investment in geographic penetration, higher employee related costs and corporate governance costs, and (ii) increased research and development expenses in the nine months ended September 30, 2005 primarily due to development efforts in our oncology franchise, development efforts for CUBICIN® (daptomycin for injection), meningococcal vaccines franchise, flu cell culture, development of new processes and procedures in existing manufacturing facilities for BETAFERON interferon beta-1b and blood-testing programs. These decreases were partially offset by a \$78.0 million lump-sum payment received in lieu of royalties beyond January 1, 2005 as part of the Roche settlement reached on September 10, 2004 and increased sales of our travel vaccines, meningococcal vaccines and PROCLEIX® product sales, partially offset by decreases in sales of our pediatric and other vaccines.

*Investing activities* For the nine months ended September 30, 2005, net cash used in investing activities consisted of purchases of investments in marketable debt securities of \$714.2 million, capital expenditures of \$141.0 million, other uses of cash of \$10.4 million, issuance of notes receivable of \$5.0 million, purchases of equity securities and interests in affiliated companies of \$4.3 million and cash paid for acquisitions net of cash acquired of \$3.3 million. Included in net cash paid for acquisitions was \$2.6 million for previously accrued costs in connection with acquisition costs related to the acquisition of PowderJect and \$0.7 million of cash paid for the acquisition of Sagres. Cash used in investing activities was offset by proceeds from maturities of investments in marketable debt securities of \$499.1 million, proceeds from sales of investments in marketable debt securities of \$194.5 million, and proceeds from the sale of equity securities and interests in affiliated companies of \$30.0 million.

For the nine months ended September 30, 2004, net cash used in investing activities consisted of purchases of investments in marketable debt securities of \$724.6 million, capital expenditures of \$134.1 million, cash paid for acquisitions net of cash acquired of \$32.3 million, purchases of equity securities and interests in affiliated companies of \$6.2 million and other uses of cash of \$5.2 million. Included in net cash paid for acquisitions was \$5.6 million for previously accrued costs in connection with the acquisition of PowderJect, \$15.5 million of cash delivered on the divestiture of certain operations in Wisconsin, the U.K., and Sweden and \$11.2 million of cash paid for the acquisition of Sagres. Cash used in investing activities was offset by proceeds from sales of investments in marketable debt securities of \$415.1 million, proceeds

from maturities of investments in marketable debt securities of \$226.0 million, and proceeds from the sale of equity securities and interests in affiliated companies of \$31.4 million and proceeds from notes receivable of \$1.5 million.

*Financing activities* For the nine months ended September 30, 2005, net cash provided by financing activities consisted of \$38.6 million of proceeds from the re-issuance of treasury stock and \$1.0 million of proceeds from the issuance of debt offset by \$0.6 million for the repayment of debt and capital leases.

On March 10, 2005, the Board of Directors authorized Chiron to repurchase 5.0 million shares of Chiron common stock through December 31, 2005. From January 1, 2005 through September 30, 2005, no shares were repurchased.

For the nine months ended September 30, 2004, net cash used in financing activities consisted of \$380.2 million for the repayment of debt and capital leases, \$129.7 million for the acquisition of treasury stock and \$8.3 million for the payment of debt issuance costs. Cash used in financing activities was offset by \$385.0 million of proceeds from issuance of convertible debentures, \$64.2 million of proceeds from the re-issuance of treasury stock and \$5.0 million of proceeds from the issuance of debt.

From time to time, we evaluate a number of business development opportunities. To the extent that we are successful in reaching agreements with third parties, these transactions may involve selling a significant portion of our current investment portfolio, incurring additional debt or issuing additional Chiron shares.

**Borrowing arrangements** Under a revolving, committed, uncollateralized credit agreement with a major financial institution, we can borrow up to \$100.0 million. This credit facility is guaranteed by Novartis AG under a November 1994 Investment Agreement, provides various interest rate options and matures in February 2006. There were no borrowings outstanding under this credit facility at September 30, 2005 and December 31, 2004. In July 2003, we entered into a new six-year lease to rent a research and development facility in Emeryville, California. Under provisions of the November 1994 Investment Agreement, Novartis AG guaranteed payments on this lease commitment to a maximum of \$173.3 million. In December 1999, Chiron and Novartis amended the November 1994 Investment Agreement to reduce the maximum amount of our obligations that Novartis would guarantee from \$725.0 million to \$702.5 million. As a result of the exercise of our subscription right as described under *Management s Discussion and Analysis of Financial Condition and Results of Operations Recent Developments*, the maximum amount Novartis is required to guarantee pursuant to the terms of the Investment Agreement has been reduced by \$300.0 million, the amount of our common stock Novartis will be required to subscribe for, to \$402.5 million. Out of the maximum guarantee of \$402.5 million, the credit agreement and lease discussed above have reduced the amount of our debt Novartis would be required to guarantee by \$273.3 million. There remains \$129.2 million of the guarantee available following the exercise of our subscription right. The Novartis loan guarantee will expire on January 1, 2008 unless certain debt ratings are triggered which would extend the guarantee on a declining basis ratably over the subsequent three-year period.

#### **Off-Balance Sheet Arrangements**

As of September 30, 2005, we did not have any off-balance sheet arrangements.

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

As a global biopharmaceutical company, we are engaged in a rapidly evolving and often unpredictable business. The forward-looking statements contained in this Form 10-Q and in other periodic reports, press releases, presentations and other statements issued by us from time to time reflect our current beliefs and expectations concerning objectives, plans, strategies, future performance and other future events. The

following discussion highlights some of the factors, many of which are beyond our control, which could cause actual results to differ materially.

*Chiron will be subject to business uncertainties and contractual restrictions while the merger with Novartis is pending.*

Uncertainty about the effect of the merger with Novartis on employees, customers and other constituencies may have an adverse effect on Chiron. These uncertainties may impair our ability to attract, retain and motivate key personnel until the merger is consummated, and could cause customers, suppliers, partners and others that deal with us to seek to change existing business relationships. Retention of certain employees may be challenging during the pendency of the merger, as certain employees may experience uncertainty about their future roles after the merger. If key employees depart because of issues relating to the uncertainty and difficulty of integration or a desire not to remain with Novartis after the merger, our business could be harmed. In connection with the pending merger, some distributors, customers and strategic partners could delay or defer decisions, which could negatively impact revenues, earnings and cash flows of Chiron.

In addition, the merger agreement restricts us from taking specified actions without the consent of Novartis, including making certain capital expenditures, entering into material contracts and other matters. These restrictions may prevent us from pursuing attractive business opportunities that may arise prior to the completion of the merger and may impede our growth and limit the development of our projects, which could negatively impact revenues, earnings and cash flows of Chiron.

*Developments with respect to influenza vaccines over the past year will harm our business and results of operations.*

In October 2004, the U.K. regulatory body, the Medicines and Healthcare products Regulatory Agency, or MHRA, suspended our license to manufacture FLUVIRIN® at our Liverpool, U.K. facility. As a result of the suspension of our license, we did not release any FLUVIRIN® vaccine during the 2004-2005 influenza season. On March 2, 2005, the MHRA notified us that it had lifted the license suspension, giving Chiron clearance to initiate full production of FLUVIRIN® vaccine, conditioned on the understanding that Chiron's commitment to its remediation plan will continue and will be subject to further inspections by the MHRA.

On October 17, 2005 we initiated delivery and release of FLUVIRIN® vaccine to customers in the United States for the 2005-2006 influenza season. As of such time, we had received all necessary approvals from the U.S. Food and Drug Administration (FDA) and MHRA to start supplying FLUVIRIN® vaccine to the U.S. market. Continued shipments of FLUVIRIN® vaccine will need to undergo corresponding internal release procedures and standard FDA influenza vaccine lot release procedures.

We received a grand jury subpoena issued by the U.S. Attorney's Office for the Southern District of New York in October 2004 requesting production of certain documents relating to FLUVIRIN® vaccine and the suspension by the MHRA of our license. In February 2005, after having previously commenced an informal inquiry, the Securities and Exchange Commission, or SEC, notified us that it would commence a formal investigation into whether we or our employees violated any federal securities laws in connection with these developments regarding FLUVIRIN® vaccine, and Chiron subsequently received subpoenas from the SEC requesting production of certain documents relating to our Liverpool facility and FLUVIRIN® vaccine. We also received a voluntary request for information from the United States House of Representatives, Energy and Commerce Committee, Subcommittee on Oversight and Investigations requesting production of certain documents. Numerous documents have been collected and produced in response to these requests, and several witnesses have been interviewed by the U.S. Attorney's Office, the SEC staff and Congressional staff. Additional investigations regarding these matters may arise.

In addition, we and certain of our officers and directors have also been named as defendants in several putative shareholder class action and derivative lawsuits alleging various claims arising out of or relating to these developments regarding FLUVIRIN® vaccine, which are described below in Part II, Item 1, Legal Proceedings. Certain distributors and other parties with whom we had contracted to supply FLUVIRIN® vaccine are considering or have communicated claims against us as a result of our inability to supply FLUVIRIN® vaccine, and additional parties may do so in the future. On January 27, 2005, the U.S. Centers for Disease Control and Prevention, or CDC, terminated its contracts with Chiron for the supply of FLUVIRIN® vaccine for default on the basis of Chiron's failure to supply such vaccine to the U.S. government for the 2004-2005 influenza season. The CDC has reserved the right to hold Chiron liable for any excess costs it may have incurred in replacing any FLUVIRIN® vaccine that Chiron failed to deliver and further has reserved all other remedies provided under the contract. It is not possible to predict whether any of these claims will be pursued and, if so, whether those claims will be upheld. Investigations, litigation and disputes have caused us to incur substantial expense and have required significant time and attention from our management and will continue to do so in the future and could result in civil action and/or criminal proceedings against Chiron. The results of any such investigations, proceedings or disputes could have a material adverse effect on our consolidated financial position and results of operations and/or cash flow.

Although the MHRA has lifted its suspension of our license to manufacture FLUVIRIN® vaccine, we expect to incur additional expenses in connection with ongoing FLUVIRIN® vaccine matters, which could be material, including in connection with (1) our continuing remediation efforts at our Liverpool facility; and (2) responding to the U.S. Attorney for the Southern District of New York, the SEC, the United States House of Representatives, Energy and Commerce Committee, Subcommittee on Oversight and Investigations and the private lawsuits and other claims and investigations that exist or may arise.

For additional information on the U.S. Attorney's investigation, SEC investigation, private lawsuits and other claims, see Part II, Item 1. Legal Proceedings of this report on Form 10-Q.

BEGRIVAC vaccine is manufactured at our facility in Marburg, Germany. In July 2005, we reported that we would be unable to supply any BEGRIVAC vaccine doses for the 2005-2006 influenza season due to a product sterility issue and wrote off our existing product inventory resulting in charges of \$3.0 million and \$18.0 million to cost of sales for the three and nine months ended September 30, 2005 respectively. Investigation of the product sterility issue has been completed and implementation of remedial measures and facility modifications is underway. Our inability to supply BEGRIVAC vaccine as planned to non-U.S. markets for the 2005-2006 influenza season or, if remedial efforts are delayed or not successful, future seasons could have a material adverse effect on our business and results of operations. In addition, it is possible that distributors and other parties with whom we had contracted to supply influenza vaccine may make claims against us as a result of Chiron not supplying influenza vaccine. Any such claims may cause us to incur substantial expense and require significant time and attention from our management. The results of any such claims could have a material adverse effect on our consolidated financial position and results of operations and/or cash flow.

We did not release any FLUVIRIN® vaccine during the 2004-2005 influenza season. As a result, our results of operations for 2004 were materially adversely affected by these matters. In addition, we will not release any BEGRIVAC vaccine during the 2005-2006 influenza season. Additional issues with respect to influenza vaccines could cause us to have to recognize an impairment charge with respect to the goodwill, certain other intangible assets and property, including without limitation the Liverpool plant resulting from the PowderJect acquisition and the new influenza vaccines manufacturing facility under construction in Liverpool, which could have a material adverse effect on our results of operations.

Our inability to supply influenza vaccines may also lead to loss of market share in future seasons. Following the announcement of our FLUVIRIN® license suspension, competitors announced plans to



introduce influenza vaccine products in the United States and sought expedited regulatory approval to do so. Even though the license suspension has been lifted, some of our customers may choose to purchase influenza vaccine from other providers as their products become available in the United States. Loss of market share in the United States or foreign markets could have a material adverse effect on our business and results of operations. Delays in start-up procedures for ramping up to full production and normal manufacturing issues inherent in the complexity of influenza vaccine production, have adversely affected the amount of FLUVIRIN® vaccine that we are able to produce for the 2005-2006 influenza season and may result in further loss of market share.

*If we fail to obtain or maintain the regulatory approvals we need to market our products or substantial changes in the regulatory environment occur, our business may suffer.*

We must obtain and maintain regulatory approval in order to market most of our products. Generally, these approvals are on a product-by-product and country-by-country basis. In the case of influenza vaccines, the failure to obtain or maintain our licenses, or delays imposed by regulatory actions, could lead to the loss of our entire inventory during any given season since each year's vaccines are manufactured to meet specific strains of influenza. In the case of therapeutic products, a separate approval is required for each therapeutic indication. Product candidates that appear promising based on early, and even large-scale, clinical trials may not receive regulatory approval. Furthermore, the results of clinical trials often are susceptible to varying interpretations that may delay, limit or prevent approval or result in the need for additional pre-marketing or post-marketing studies. In addition, regulations may be amended from time to time. Revised regulations may require us to reformulate products on a country or regional basis, obtain additional regulatory approvals, or accept additional risks that our products will not maintain market acceptance or be eligible for third party insurance coverage. Increased regulatory scrutiny and restrictions regarding marketing practices for products that are subject to government reimbursement may impact the sales of such products. There is no guarantee that we will be able to meet conditions to obtain or maintain regulatory approval or to satisfy new regulatory requirements and may suffer a loss of revenue as a result.

*If our focus on the research and development of emerging technologies does not result in the creation of commercial products, our business could be harmed.*

We focus our research and development activities on areas in which we have particular strengths and on technologies that appear promising. These technologies often are on the cutting edge of modern science. As a result, the outcome of any research or development program is highly uncertain. Only a very small fraction of these programs ultimately result in commercial products or even product candidates. Product candidates that initially appear promising often fail to yield successful products. In many cases, preclinical or clinical studies will show that a product candidate is not efficacious (that is, it lacks the intended therapeutic or prophylactic effect), or that it raises safety concerns or has other side effects, which outweigh the intended benefit. Success in preclinical or early clinical trials (which generally focus on safety issues) may not translate into success in large-scale clinical trials (which are designed to show efficacy), often for reasons that are not fully understood. Further, success in clinical trials will likely lead to increased investment, adversely affecting short-term profitability, to bring such products to market. And even after a product is approved and launched, general usage or post-marketing studies may identify safety or other previously unknown problems with the product which may result in regulatory approvals being suspended, limited to narrow indications or revoked, or which may otherwise prevent successful commercialization.

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

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

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

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

We operate in a highly competitive environment, and the competition is expected to increase. Competitors include large pharmaceutical, chemical and blood testing companies, compounding pharmacies, and biotechnology companies. Some of these competitors, particularly large pharmaceutical and blood testing companies, have greater resources than us. Accordingly, even if we are successful in launching a product, we may find that a competitive product dominates the market for any number of reasons, including:

- The possibility that the competitor may have launched its product first;
- The competitor may have greater access to certain raw materials;
- The competitor may have more efficient manufacturing processes;
- The competitor may adapt more quickly to technological change;
- The competitor may have greater marketing capabilities;
- The competitive product may have therapeutic or other advantages; or
- New competitors may enter into markets where we currently have significant competitive advantage.

The technologies applied by our competitors and us are rapidly evolving, and new developments frequently result in price competition and product obsolescence. In addition, we may be impacted by



competition from generic forms of our products, substitute products or imports of products from lower priced markets.

*Conflicts with or decisions by third parties we collaborate with could harm our business.*

An important part of our business strategy depends upon collaborations with third parties, including research collaborations and joint efforts to develop, commercialize new products and manufacture, market and distribute existing products. As circumstances change, Chiron and our strategic partners may develop conflicting priorities or other conflicts of interest or decide not to extend existing collaborations. We may experience significant delays and incur significant expenses in resolving these conflicts and may not be able to resolve these matters on acceptable terms. Even without conflicts of interest, we may disagree with our strategic partners as to how best to realize the value associated with a current product or a product in development. In some cases, the strategic partner may have responsibility for formulating and implementing key strategic or operational plans. In addition, merger and acquisition activity within the pharmaceutical and biotechnology industries may affect our strategic partners, causing them to reprioritize their efforts related to the research collaborations and other joint efforts with us. Decisions by corporate partners on key clinical, regulatory, marketing (including pricing), inventory management and other issues may prevent successful commercialization of the product or otherwise impact our profitability.

*If any of our third party suppliers or manufacturers cannot adequately meet our needs, our business could be harmed.*

We use raw materials and other supplies that generally are available from multiple commercial sources. Certain manufacturing processes, however, use materials that are available from sole sources, or that are in short supply, or are difficult for the supplier to produce and certify in accordance with our specifications. From time to time, concerns are raised with respect to potential contamination of biological materials that are supplied to us. These concerns can further tighten market conditions for materials that may be in short supply or available from limited sources. Moreover, regulatory approvals to market our products may be conditioned upon obtaining certain materials from specified sources. Our ability to substitute material from an alternate source may be delayed pending regulatory approval of such alternate source. Although we work to mitigate the risks associated with relying on sole suppliers, there is a possibility that material shortages could impact production.

We purchase bulk powdered tobramycin, the primary basic raw material in TOBI<sup>®</sup> tobramycin, from two of the principal worldwide suppliers of the drug. We anticipate that either one of these suppliers alone will be able to supply sufficient quantities to meet current needs; however, there can be no assurance that these suppliers will be able to meet future demand in a timely and cost-effective manner. As a result, our operations could be adversely affected by an interruption or reduction in the supply of bulk tobramycin powder.

We have entered into contracts with third parties for the production and packaging of TOBI<sup>®</sup> tobramycin. Over time, we can use alternative production and packaging sources. However, if the contracted third parties become unable to produce or package sufficient quantities of TOBI solution due to work stoppages or other factors, our operations could be disrupted until alternative sources are secured. We have entered into contracts with third parties for the packaging of the pre-filled diluent syringe for BETASERON<sup>®</sup> interferon beta-1b. Over time, we can use alternative packaging sources. However, if the contracted third parties become unable to produce or package sufficient quantities of the pre-filled diluent syringe for BETASERON<sup>®</sup> interferon beta-1b due to work stoppages or other factors, our operations could be disrupted until alternative sources are secured.

In connection with the production of our influenza vaccine products, we must purchase large quantities of chicken eggs. For FLUVIRIN<sup>®</sup> vaccine, we purchase those eggs and incubation services from

a single supplier in the United Kingdom and, pursuant to the contract with that supplier, we have agreed to make specified purchases from that supplier through 2009, subject to our right to terminate this agreement earlier upon payment of a termination fee. If our supplier were to fail to supply eggs in sufficient quantities or quality, including as a result of any health or other issues related to the chickens, our business would be materially adversely affected.

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

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

Third parties, including competitors, have patents and patent applications in the U.S. and other significant markets that may be useful or necessary for the manufacture, use or sale of certain products and products in development by our strategic partners and us. It is likely that third parties will obtain these patents in the future. Certain of these patents may be broad enough to prevent or delay us and our strategic partners from manufacturing or marketing products important to our current and future business. We cannot accurately predict the scope, validity and enforceability of these patents, if granted, the extent to which we may wish or need to obtain licenses to these patents, and the cost and availability of these licenses. If we do not or cannot obtain these licenses, products may be withdrawn from the market or delays could be encountered in market introduction while an attempt is made to design around these patents, or we could find that the development, manufacture or sale of such products is foreclosed. We could also incur substantial costs in licensing or challenging the validity and scope of these patents.

*Because most of our products are based on technologies that are unfamiliar to the healthcare community, they may not be accepted by healthcare providers and patients, which could harm our business.*

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

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

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

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

*Sales of our products and profitability may be adversely affected by pricing policies and applicable laws and the availability and amount of reimbursement from third parties, such as the government and insurance companies.*

In the U.S., Europe and other significant markets, sales of our products and our profitability may be affected by the pricing policies and applicable laws of, and the availability and amount of reimbursement from, the government or other third parties, such as insurance companies. It is difficult to predict the pricing and reimbursement status of newly approved, novel biotechnology products, and it may be challenging to meet the current pricing and reimbursement policies for existing products, which may be complex, subject to change and limit our revenues. In certain foreign markets, governments have issued more extensive regulations relating to the pricing and profitability of pharmaceutical companies, which can be expected to limit our revenues from certain products. There have been proposals in the U.S. (at both the federal and state level) to implement such controls. If the United States Congress enacts legislative proposals addressing parallel importation currently being deliberated, revenues from certain products may be affected further by this change in U.S. policy. The growth of managed care in the U.S. also has placed pressure on the pricing of healthcare products. These pressures can be expected to continue.

*If we market products in a manner that violates state, federal or foreign laws that govern pharmaceuticals and health care products, including FDA, FTC, and health care fraud and abuse laws, we may be subject to civil or criminal penalties, including the potential for exclusion from federal, state and foreign programs.*

The federal laws and regulations administered by the FDA and FTC place restrictions on the promotion of medical products. FDA law and regulations prohibit the marketing and promotion of unapproved drug and device products and unapproved uses of approved drug and device products. FTC and FDA also place restrictions on the promotion of approved drugs and devices to ensure that marketing material is not false or misleading. In addition to these restrictions on the marketing of pharmaceutical products without regulatory approval, other types of state and federal health care fraud and abuse laws have been applied in recent years to restrict certain marketing practices in the healthcare industry, and to otherwise determine the eligibility of pharmaceutical manufacturers to have their products reimbursed by Medicare, Medicaid, and other federal and state programs. These laws include anti-kickback statutes, false claims statutes, and others. In addition, the foreign business operations of Chiron are impacted by certain United States laws and regulations. These include prohibitions on payments to foreign officials and restrictions on exports to certain foreign nations or commerce with certain debarred parties. Likewise, various foreign laws may restrict the manner in which healthcare products are marketed in other countries.

The federal anti-kickback statute prohibits, among other things, knowingly offering, paying, soliciting, or receiving remuneration to induce or in return for purchasing, ordering, recommending, or arranging for the purchase, order, or lease of any health care item reimbursable under Medicare, Medicaid, or other federally funded health care programs. This statute has been interpreted broadly to apply to arrangements

between drug manufacturers on one hand and prescribers, purchasers, pharmacies, Group Purchasing Organizations, and pharmacy benefit and formulary managers on the other, along with such indirect purchasers as health plans. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain activities from prosecution, the exemptions and safe harbors are drawn narrowly. Activities that fall outside of a safe harbor are not necessarily illegal, but practices that involve direct or indirect remuneration intended to induce prescribing, purchasing, or recommending of products may be subject to governmental scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability.

Federal false claims laws generally prohibit a person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. Recently, several pharmaceutical and other health care companies have been subject to investigative and enforcement activity under these laws, including qui tam suits filed by whistleblowers, for a variety of alleged inappropriate promotional and marketing activities, such as providing free product to customers with the expectation that the customers would bill federal programs for the product; engaging in off-label promotion that caused claims to be submitted to federal and state programs for non-covered off-label uses; and submitting inflated best price and otherwise incorrect pricing data for Medicaid rebate or other price reporting purposes. In some cases, the manufacturers have been alleged to have aided and abetted in the submission of false claims. In addition, state Attorneys General and private class action plaintiffs have filed civil suits under the federal RICO statute and a variety of state consumer protection laws claiming that pharmaceutical companies reported inflated average wholesale prices to pricing services used by the federal programs to set reimbursement rates, and that as a result, Medicare beneficiaries, Medicaid programs and private payers overpaid for drugs. Still other manufacturers have been subject to enforcement activity for alleged violations of such federal statutes as the Prescription Drug Marketing Act, involving pharmaceutical sampling practices. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Sanctions under federal, state and foreign laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

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

In connection with our research and manufacturing activities, we utilize some hazardous materials. We believe we take great care to ensure we have appropriate procedures and permits in place for storing and handling such hazardous materials. We could be subject to loss of our permits, government fines or penalties and/or other adverse governmental action if such hazardous materials are stored, handled or released into the environment in violation of law or any permit. A substantial fine or penalty, the payment of significant environmental remediation costs or the loss of a permit or other authorization to operate or engage in our ordinary course of business could result in material, unanticipated expenses and the possible inability to satisfy customer demand.

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

We seek to obtain patents on many of our inventions. Without the protection of patents, competitors may be able to use our inventions to manufacture and market competing products without being required to undertake the lengthy and expensive development efforts made by us and without having to pay royalties or otherwise compensate us for the use of the invention. We have no assurance that patents and patent applications owned or licensed to us will provide substantial protection. Important legal questions

remain to be resolved as to the extent and scope of available patent protection for biotechnology products and processes in the U.S. and other important markets. We do not know how many of our pending patent applications will be granted, or the effective coverage of those that are granted. In the U.S. and other important markets, the issuance of a patent is neither conclusive as to its validity nor the enforceable scope of its claims. We have engaged in significant litigation to determine the scope and validity of certain of our patents and expect to continue to do so. An adverse outcome of litigation could result in the reduction or loss of royalty revenues. Engaging in patent litigation against one party may place significant royalty revenues received or to be received from other parties at risk. Even if we are successful in obtaining and defending patents, there can be no assurance that these patents will provide substantial protection. The length of time necessary to resolve patent litigation successfully may allow infringers to gain significant market advantage. Third parties may be able to design around the patents and develop competitive products that do not use the inventions covered by our patents. Many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties (for example, the third party's product is needed to meet a threat to public health or safety in that country, or the patent owner has failed to work the invention in that country, or the third party has patented improvements). In addition, most countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may be limited to monetary relief and may be unable to enjoin infringement, which could materially diminish the value of the patent. In addition, royalty revenues may decline as patents expire.

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

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

- Use of cash resources;
- Potentially dilutive issuances of equity securities;
- The incurrence of debt and contingent liabilities, impairment losses or restructuring charges;
- Large write-offs and difficulties in assessment of the relative percentages of in-process research and development expense that can be immediately written off as compared to the amount which must be amortized over the appropriate life of the asset;
- Amortization expenses related to other intangible assets; and
- Impairment of the value of tangible and intangible assets resulting from management's decision to discontinue a line of business or product previously acquired by Chiron or from changes in business conditions.

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

- Challenges associated with managing an increasingly diversified business and international business;
- Difficulties in assimilating the operations, products, technology, information systems or personnel of the acquired company;
- Diversion of management's attention from other business concerns;
- Inability to maintain uniform standards, controls, procedures and policies;

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

Legal risks may include requirements to obtain the consent of our stockholders or a third party, or the approval of various regulatory authorities.

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

*If we cannot initiate and maintain revenue-generating relationships with third parties, we may not be able to grow our revenues in the near to medium-term.*

Many products in our current pipeline are in relatively early stages of research or development. Our ability to grow earnings in the near- to medium-term may depend, in part, on our ability to initiate and maintain other revenue generating relationships with third parties, such as licenses to certain of our technologies, and on our ability to identify and successfully acquire rights to later-stage products from third parties. We may fail to establish such other sources of revenue.

*Our international sales and operations involve additional risks that could increase our expenses, adversely affect our operating results and require increased time and attention of our management.*

We derive a substantial portion of revenue from sales outside of the U.S. and have significant research, development, manufacturing and marketing operations outside of the U.S. Our planned growth is contingent upon the successful expansion of our international revenue. These international operations are subject to risks in addition to those faced by our U.S. operations, including:

- fluctuations in currency exchange rates and economic instability such as higher interest rates and inflation;
- difficulties in hedging foreign currency transaction exposures;
- difficulties in staffing, managing, training and operating our international operations;
- difficulties in coordinating the activities of our geographically dispersed and culturally diverse operations;
- costs and delays associated with coordinating operations in multiple languages;
- potential loss of proprietary information due to laws that may be less protective of our intellectual property rights; and
- exposure to different and evolving legal standards (particularly with respect to product marketing, pricing and competition).

*Our level of debt could limit cash flow available for our operations and could adversely affect our ability to service our debt or obtain additional financing, if necessary.*

As of September 30, 2005, our total debt including current portion, was \$939.8 million. Our level of debt could restrict our operations and make it more difficult for us to satisfy our obligations under the 2033 and the 2034 convertible debentures (the debentures). Among other things, our level of debt may:

- Limit our ability to obtain additional financing for working capital, capital expenditures, strategic acquisitions and general corporate purposes;



- Require us to dedicate all or a substantial portion of our cash flow to service our debt, which will reduce funds available for other business purposes, such as capital expenditures or acquisitions;
- Limit our flexibility in planning for or reacting to changes in the markets in which we compete;
- Place us at a competitive disadvantage relative to our competitors with less leverage;
- Render us more vulnerable to general adverse economic and industry conditions; and
- Make it more difficult for us to satisfy our financial obligations, including those relating to the debentures and our other debt obligations.

We and our subsidiaries may still be able to incur substantially more debt. The terms of our credit facility, the indenture governing the debentures and the agreements governing our other debt permit additional borrowings. Our incurrence of additional debt could further exacerbate the risks described above.

Our ability to satisfy our obligations under the debentures and our other debt agreements will depend on our future operating performance, which will be subject, in part, to factors beyond our control, including general economic and business conditions. If we are unable to generate sufficient cash flow to service our debt, we may be required to refinance all or a portion of our debt, including the debentures, obtain additional financing, sell some of our assets or operations, reduce or delay capital expenditures, or revise or delay our strategic plans. If we are required to take any of these actions, it could have a material adverse effect on our business, financial condition and results of operations. In addition, we cannot assure you that we would be able to take any of these actions, that these actions would enable us to continue to satisfy our capital requirements or that these actions would be permitted under the terms of our various debt instruments, including the indenture governing the debentures.

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

On October 30, 2005, we entered into a merger agreement with Novartis AG and Novartis Corporation, pursuant to which Chiron will become a wholly owned subsidiary of Novartis Corporation. Apart from the transactions contemplated by the merger agreement, we have an alliance with Novartis AG, a life sciences company headquartered in Basel, Switzerland. Under a series of agreements between Chiron and Novartis, which will continue in force while our merger with Novartis is pending or if the merger is not completed, and as a result of subsequent stock issuances by Chiron, Novartis' ownership interest in Chiron was approximately 42% as of September 30, 2005. The governance agreement between Chiron and Novartis contains provisions that require the approval of Novartis before we enter into certain corporate transactions. These transactions generally include significant debt or equity issuances, debt or equity repurchases, most mergers and acquisitions, the payment of cash dividends, amendments to Chiron's certificate of incorporation or by-laws, and other transactions that would adversely impact the rights of Novartis, or discriminate against Novartis, as a Chiron stockholder. In addition, a majority of the independent directors must approve any material transactions between Chiron and Novartis. These provisions may limit our ability to enter into transactions with third parties otherwise viewed as beneficial to Chiron. In addition, as discussed under *Chiron will be subject to business uncertainties and contractual restrictions while the merger with Novartis is pending*, our merger agreement with Novartis contains additional and more restrictive limitations on our operations while the merger agreement is in effect. All of our shares owned by Novartis are eligible for sale in the public market subject to compliance with the applicable securities laws. We have agreed that, upon Novartis' request, we will file one or more registration statements under the Securities Act in order to permit Novartis to offer and sell shares of our common stock, including shares that Novartis will be required to purchase from us pursuant to the exercise of our subscription rights under the subscription agreement. Sales of a substantial number of shares of our



common stock by Novartis in the public market could adversely affect the market price of our common stock.

*Our stock price could be volatile.*

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

- Fluctuations in earnings from period to period;
- Results of clinical trials conducted by us or by our competitors;
- Announcements by us or our competitors regarding product development efforts, including the status of regulatory approval applications;
- Impact from the recent influenza vaccines developments;
- The outcome of legal proceedings, including claims filed by us against third parties to enforce our patents and claims filed by third parties against us relating to patents held by the third parties;
- The launch of competing products;
- The resolution of (or failure to resolve) disputes with strategic partners;
- Corporate restructuring by us;
- Adoption of new U.S or foreign laws;
- The sale of a substantial number of shares held by our existing stockholders;
- Licensing activities by us; and
- The acquisition or sale by us of products, products in development or businesses.

In connection with our research and development collaborations, from time to time we may invest in equity securities of our strategic partners. The price of these securities also is subject to significant volatility and may be affected by, among other things, the types of events that affect our stock. Changes in the market price of these securities may impact our profitability.

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

We pay taxes principally in the U.S., Germany, Italy, 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 our future tax provision. Specifically, on October 22, 2004, the American Jobs Creation Act of 2004 (the Act) was signed into law. The Act includes an elimination of the tax benefit of the Extraterritorial Income Exclusion over 2005 and 2006.

We have negotiated a number of rulings regarding income and other taxes that are subject to periodic review and renewal. If such rulings are not renewed or are substantially modified, income taxes payable in particular jurisdictions could increase. While we believe that all material tax liabilities are reflected properly in our balance sheet, we are presently under audit in several jurisdictions and may be subject to further audits in the future, and we have no assurance that we will prevail in all cases in the event the taxing authorities disagree with our interpretations of the tax law. In addition, we have assumed liabilities for all income taxes incurred prior to the sales of our former subsidiaries, including PowderJect Vaccines, Inc., SBL Vaccin AB, and PowderJect Research Limited. Future levels of research and development spending, capital investment and export sales will impact our entitlement to related tax credits and benefits which have the effect of lowering our effective tax rate.



*Our earnings results may be inconsistent and cause volatility in our stock price.*

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

- Inventory management practices, including wholesale ordering patterns;
- The level of pre-clinical and clinical trial-related activities;
- Seasonality of certain vaccine products;
- The tender driven nature of certain vaccine products;
- The nature of our collaborative, royalty and license arrangements and other revenue sources;
- Foreign currency exchange rate fluctuations; and
- The level of product reserves due to various issues, including seasonality patterns, excess and obsolete inventory, and production yields.

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

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

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

It is possible that the application of certain current accounting standards may change due to environmental factors, which may necessitate a change in our standard practice related to these accounting standards. In particular, effective January 1, 2006 we will be required to adopt SFAS No. 123(R) requiring us to apply a fair-value based method to account for costs related to share-based payments including stock options and employee stock purchase plans. We expect the adoption of SFAS 123(R) to materially impact our results of operations.

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

**Market risk management** Our cash flow and earnings are subject to fluctuations due to changes in foreign currency exchange rates, changes in interest rates and changes in the fair value of equity securities held for sale. We attempt to limit our exposure to some or all of these market risks through the use of various financial and derivative instruments. During the first nine months of 2005, we added a new hedging instrument to our foreign currency hedging strategy. We purchased \$54.4 million of British Pound denominated fixed-income securities to create a hedge against a portion of our British Pound currency exposures. We manage our exposures to market risks as discussed in further detail in Part II, Item 7A, **Quantitative and Qualitative Disclosures About Market Risk** in our annual Report on Form 10-K for the year ended December 31, 2004.



**Item 4. Controls and Procedures**

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

**(b) Changes in internal controls** Except as set forth below, there have been no significant changes in Chiron's internal controls over financial reporting that have materially affected, or are reasonably likely to materially affect internal controls over financial reporting during the most recent fiscal quarter.

The management of Chiron assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2004. In performing the assessment management identified three material weaknesses in internal control over financial reporting as of December 31, 2004. As a result of the material weaknesses described below, management determined that, as of December 31, 2004, the Company's system of internal control over financial reporting was not effective based on the criteria in *Internal Control - Integrated Framework*.

The first material weakness pertains to both the design and operating effectiveness of controls relating to revenue recognition at our vaccines subsidiary in Germany. Specifically, controls pertaining to the communication and evaluation of any special terms and other actions of the sales organization affecting revenue recognition were not effective. As a result, on March 8, 2005, the Audit Committee of the Board of Directors, following discussion with and upon the recommendation of management and following discussion with Chiron's independent auditors, concluded that the previously issued financial statements for the second and third quarters of 2004 should be restated to correct certain errors contained therein and should not be relied upon. The identified errors affected product revenue, cost of goods sold, accounts receivable, and unearned revenue for the Company's vaccines segment. In addition to the restatement of the financial statements for the second and third quarters of 2004, adjustments were recorded in the consolidated financial statements for year ended December 31, 2004 to correct the identified errors.

The second material weakness pertains to both the design and operating effectiveness of controls relating to the annual income tax provision. Specifically, there were errors in the annual tax provision for the year ended December 31, 2004 as a result of ineffective controls relating to the design and use of analytical tools to analyze and calculate the tax provision, the reconciliation of certain tax accounts, and the review of those reconciliations. These errors affected income tax expense and income tax asset and liability accounts. Adjustments were recorded in the consolidated financial statements for year ended December 31, 2004 to correct the identified errors.

The third material weakness pertains to both the design and operating effectiveness of controls relating to the timely determination of the appropriate accrual for legal services. Specifically, procedures to estimate the accrual for unbilled services and controls over the timely recording of invoices payable were not effective. Errors resulting from these deficiencies affected operating expenses, intangible assets and accrued liabilities. Adjustments were recorded in the consolidated financial statements for year ended December 31, 2004 to correct the identified errors.

During the first, second and third quarters of fiscal year 2005, and in connection with the preparation of our condensed consolidated financial statements for the quarters ended March 31, June 30 and September 30, 2005, as applicable, we designed and implemented additional controls and procedures

relating to revenue recognition at our vaccines subsidiary in Germany to address the first material weakness identified above. Such additional controls and procedures included, among others:

- During the first quarter, providing our sales force with training regarding the applicable accounting principles and procedures for the communication of special terms and conditions and the impact of their activities on our revenue recognition;
- During the first, second and third quarters, review of a significant sample of supporting sales documentation, including customer agreements, to identify sales transactions with special terms and conditions to determine that the sales were recognized in accordance with applicable accounting principles; and
- During the third quarter, implementation of additional procedures and controls to further enhance detection of customer agreements that have special terms and conditions in order to help ensure that such terms and conditions are considered in evaluating revenue recognition.

In addition, during the first, second and third quarters of 2005, and in connection with the preparation of our condensed consolidated financial statements for the quarters ended March 31, June 30 and September 30, 2005, as applicable, we designed and implemented additional controls and procedures relating to the timely recording of legal services invoices payable and estimating the accrual for unbilled legal services to address the third material weakness identified above. Such additional controls and procedures included, among others:

- Designing of new procedures for invoice processing and procedures for the accrual of unbilled services and communication of the new procedures to individuals integral to the process; and
- During the first quarter, completion of training and awareness workshops relating to the new processes.

In addition, we have established a remediation plan to address the ineffective controls related to the annual tax provision process. The remediation plan includes additional controls and revisions to the tax provision process, the implementation of new analytical tools in order to enhance the analysis and calculation of the tax provision and additional training of personnel responsible for the tax provision process. During the third quarter of 2005, we completed the design of revised controls and procedures and are in the process of implementing a new analytical tool. In addition, personnel responsible for the tax provision process have completed a portion of the training.

## PART II

### Item 1. Legal Proceedings

We are party to certain lawsuits and legal proceedings, which are described in Part I, Item 3. *Legal Proceedings* of our Annual Report on Form 10-K for the year ended December 31, 2004. The following is a description of material developments during the period covered by this Quarterly Report and certain other events and should be read in conjunction with the Annual Report on Form 10-K for the year ended December 31, 2004 and the Quarterly Reports on Form 10-Q for the quarters ended March 31, 2005 and June 30, 2005.

#### *Average Wholesale Price Litigation*

In February 2005, the State of Illinois through its Attorney General filed a complaint in the Circuit Court of Cook County, Illinois, County Department, Chancery Division, against numerous biotechnology and pharmaceutical companies, including Chiron, in connection with setting average wholesale prices for various products that are reimbursed by Medicare and Illinois Medicaid. The Attorney General alleges that defendants violated the Illinois Consumer Fraud and Deceptive Business Practices Act, the Illinois Public Assistance Fraud Act, and the Illinois Whistleblower Reward and Protection Act, and seeks declaratory relief as well as damages. In August 2005, the matter was transferred to the In Re Pharmaceutical Industry Average Wholesale Price Litigation in the United States District Court for the District of Massachusetts.

In October 2005, the State of Mississippi through its Attorney General filed a complaint in the Chancery Court of Hinds County, Mississippi, First Judicial District, against numerous biotechnology and pharmaceutical companies, including Chiron, in connection with setting average wholesale prices for various products that are reimbursed by Medicare and Mississippi Medicaid. The Attorney General alleges that defendants violated the Mississippi Medicaid Fraud Control Act, the Mississippi Regulation of Business for Consumer Protection Act, and certain Mississippi state common law provisions, and seeks declaratory relief as well as damages.

It is not known when or on what basis these matters will be resolved.

#### *FLUVIRIN<sup>®</sup> influenza virus vaccine*

For a discussion of developments related to FLUVIRIN<sup>®</sup> influenza virus vaccine, see *Item 2 Management's Discussion and Analysis of Financial Condition and Results of Operations, Factors That May Affect Future Results*.

#### A. FLUVIRIN<sup>®</sup> vaccine Securities Class Actions

Between October 2004 and December 2004, five securities class action lawsuits were filed against Chiron and certain Chiron officers on behalf of purchasers of Chiron securities for class periods ranging from July 23, 2003 through October 13, 2004. Four of the suits were filed in the United States District Court for the Northern District of California. One action, although originally filed in the United States District Court for the Eastern District of Pennsylvania, was later transferred to the United States District Court for the Northern District of California. In March 2005, the Court named lead counsel and plaintiff, and in April 2005, lead plaintiff filed a consolidated complaint. The consolidated complaint alleges, among other things, that the defendants violated certain provisions of the federal securities laws by making false and misleading statements from July 23, 2003 through October 5, 2004 concerning the amount of FLUVIRIN<sup>®</sup> vaccine Chiron projected to produce and Chiron's historical and forecasted financial results, and seeks unspecified monetary damages and other relief from all defendants. The trial is scheduled to begin on May 1, 2006.

## B. FLUVIRIN® vaccine Shareholder Derivative Actions

Between October 2004 and November 2004, six shareholder derivative complaints were filed in the Superior Court of the State of California for the County of Alameda, naming Chiron as a nominal party and naming certain current and former Chiron officers and directors and Novartis AG as defendants in connection with the suspension of Chiron's license to manufacture FLUVIRIN® vaccine. One complaint also named Chiron as a defendant and sought relief from Chiron, including an equitable accounting. In December 2004, the six derivative actions were consolidated for discovery and trial under the caption *In re Chiron Corporation Derivative Litigation* (the *Derivative Action*). In February 2005, lead plaintiff filed a consolidated complaint, and in May 2005 filed an amended consolidated complaint alleging that defendants are liable for breach of their fiduciary duties of loyalty and care and other duties allegedly owed to Chiron in connection with Chiron's acquisition of its Liverpool, England facility and the British regulatory agency's decision to suspend temporarily Chiron's license to manufacture FLUVIRIN® vaccine at the Liverpool facility, and seeking unspecified monetary damages and other relief from all defendants. The complaints did not seek any affirmative relief from Chiron. In July 2005, the Court granted without prejudice Chiron's and Novartis' motions to dismiss the amended consolidated complaint based on three agreements entered in 1994 between Chiron and Novartis, all of which contain mandatory forum selection clauses requiring that any claims arising out of or relating to the agreements must be adjudicated in Delaware. Regarding the directors and officers, the Court also dismissed those claims implicated by the 1994 agreements, and stayed the remaining claims pending resolution of the action it is anticipated plaintiffs will file in Delaware. In September 2005, plaintiffs filed an appeal before the Superior Court of the State of California for the County of Alameda.

## C. Other FLUVIRIN® vaccine Legal Matters

In August 2005, Celltech Pharma (Celltech) filed a complaint against Chiron Vaccines and Chiron Behring GmbH & Co. KG (collectively, Chiron) in the Tribunal de Commerce of Nanterre in France. Celltech alleges that Chiron breached its alleged undertaking to provide Fluvirin to Celltech for the 2004/2005 influenza season in France, and seeks damages.

In December 2004, Belisario and Kimberly Bolanos filed suit against Chiron in the Superior Court of the State of California for the County of Alameda, alleging they suffered injuries as a result of a flu shot Mr. Bolanos received and seeking monetary damages. In August 2005, plaintiffs agreed to dismiss the suit without prejudice to pursue potential administrative remedies and Chiron agreed to toll the statute of limitations with regard to other certain claims.

### *Novartis AG Proposed Acquisition Shareholder Suits*

Between September 1 and September 13, 2005, twelve class action lawsuits were filed by Chiron shareholders against Chiron, Novartis AG (Novartis), and members of Chiron's Board of Directors (collectively, the Defendants) regarding Novartis' September 1, 2005 offer to acquire the approximately 58% of Chiron shares that Novartis does not already own for \$40 per share (the Novartis Offer). Eight of the suits were filed in the Superior Court of the State of California in Alameda County (the California Court) by i) Ronald Abramoff, Harold Adelson, Beverly McCalla, Joan Weisberg, and David Jaroslawicz; ii) Edith Auman; iii) Joseph Fisher, MD, P.C. New Profit Sharing Trust, Trustee Joseph Fisher, MD; iv) William Lattarulo; v) Steven Rosenberg and The Harold Grill IRA; vi) Tracie Scotto; vii) Albert Stein; and viii) William Steiner (the California Plaintiffs). The remaining four suits were filed in the Court of Chancery of the State of Delaware in and for New Castle County (the Delaware Court) by ix) Judy Longcore; x) Paulena Partners L.L.C.; xi) Sylvia Piven; and xii) the Thomas Stone Irrevocable Trust (the Delaware Plaintiffs). Both the California and Delaware Plaintiffs allege that Defendants breached their fiduciary duties or aided in the breach of those duties in connection with the Novartis Offer. Two of the Delaware Plaintiffs also allege that certain provisions of the 1994 Governance Agreement between Chiron



and Novartis are invalid and unenforceable under Delaware law. The complaints seek injunctive relief to prevent the Novartis Offer from being consummated, declaratory relief, unspecified monetary damages and other relief from all Defendants. In October 2005, the California Court consolidated the eight California actions and appointed lead plaintiffs and lead counsel. In November 2005, the Delaware Court consolidated the four Delaware actions and appointed lead plaintiffs and lead counsel. The California Plaintiffs have agreed to stay the California Litigation until (i) an announcement, if any, that Chiron and Novartis have agreed to consummate a merger or acquisition; or (ii) Novartis exercises certain arbitration processes contained in the Governance Agreement.

It is not known when or on what basis these matters will be resolved.

#### ***Sysmex Corporation***

In March 2001, Chiron filed a complaint and petition for preliminary injunction with the Osaka District Court in Japan against Sysmex Corporation ( Sysmex ) seeking damages and an injunction against Sysmex 's manufacture and sale of the Ranream HCV II Ex kit for infringing Chiron 's Japanese Patent No. 2733138 (the 138 patent ) claiming hepatitis C virus immunodiagnostic technology. Sysmex denied the infringement allegations and filed two invalidation appeals with the Japanese Patent Office Board of Appeals against the 138 patent. In February 2003, the Japanese Patent Office Board of Appeals, ruling on one of the invalidation appeals, found that the 138 patent was invalid. In May 2003, Chiron filed an appeal of the invalidation judgment before the Tokyo High Court. Furthermore, the second invalidation appeal was stayed pending Chiron 's appeal to the Tokyo High Court. In January 2005, the Tokyo High Court upheld the judgment of the Japanese Patent Office Board of Appeals, and in August 2005, the Japanese Supreme Court declined to hear Chiron 's appeal. The matter is thus concluded.

#### **Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

(c) Our Board of Directors authorized the repurchase of our common stock on the open market to offset the dilution associated with the issuance of new shares under the stock option and stock purchase plans and the granting of share rights. On March 10, 2005, the Board of Directors authorized Chiron to repurchase 5.0 million shares of Chiron common stock through December 31, 2005. There were no stock repurchases in the third quarter of 2005.

#### **Item 3. Defaults Upon Senior Securities**

None.

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

None.

#### **Item 5. Other Information**

None.

65

---

**Item 6. Exhibits.**

(a) Exhibits

**Exhibit**

<b>Number</b>	<b>Exhibit</b>
2.01	Agreement and Plan of Merger, dated as of October 30, 2005, among Novartis Corporation, Novartis Biotech Partnership, Inc., Chiron and Novartis AG, incorporated by reference to Exhibit 2.01 of Chiron's report on Form 8-K filed with the Commission on November 1, 2005.
3.01	Restated Certificate of Incorporation of Chiron, as filed with the Office of the Secretary of State of Delaware on August 17, 1987, incorporated by reference to Exhibit 3.01 of Chiron's report on Form 10-K for fiscal year 1996.
3.02	Certificate of Amendment of Restated Certificate of Incorporation of Chiron, as filed with the Office of the Secretary of State of Delaware on December 12, 1991, incorporated by reference to Exhibit 3.02 of Chiron's report on Form 10-K for fiscal year 1996.
3.03	Certificate of Amendment of Restated Certificate of Incorporation of Chiron, as filed with the Office of the Secretary of State of Delaware on May 22, 1996, incorporated by reference to Exhibit 3.04 of Chiron's report on Form 10-Q for the period ended June 30, 1996.
3.04	Bylaws of Chiron, as amended and restated, incorporated by reference to Exhibit 99.1 of Chiron's current report on Form 8-K filed with the Commission on March 10, 2005.
4.01	Indenture between Chiron and State Street Bank and Trust Company, dated as of June 12, 2001, incorporated by reference to Exhibit 4.01 of Chiron's report on Form 10-Q for the period ended June 30, 2001.
4.02	Registration Rights Agreement between Chiron and Merrill Lynch & Co., Inc., and Merrill Lynch, Pierce, Fenner & Smith, Incorporated, incorporated by reference to Exhibit 4.02 of Chiron's report on Form 10-Q for the period ended June 30, 2001.
4.03	Form of Liquid Yield Option Note due 2031 (Zero Coupon Senior) (included as exhibits A-1 and A-2 to the Indenture filed as Exhibit 4.01 to Chiron's report on Form 10-Q for the period ended June 30, 2001), incorporated by reference to Exhibit 4.03 of Chiron's report on Form 10-Q for the period ended June 30, 2001.
4.04	Indenture between Chiron and U.S. Bank National Association, as trustee, dated as of July 30, 2003, incorporated by reference to Exhibit 4.1 of Chiron's registration statement on Form S-3 filed with the Commission on September 23, 2003.
4.05	Registration Rights Agreement dated as of July 30, 2003, between Chiron and Morgan Stanley & Co., Goldman, Sachs & Co., Banc of America Securities LLC and BNP Paribas Securities Corp., incorporated by reference to Exhibit 4.3 of Chiron's registration statement on Form S-3 filed with the Commission on September 23, 2003.
4.06	Form of Convertible Debentures (included in Exhibit 4.04), incorporated by reference to Exhibit 4.2 of Chiron's registration statement on Form S-3 filed with the Commission on September 23, 2003.
4.07	Indenture between Chiron and U.S. Bank National Association, as trustee, dated as of June 22, 2004, incorporated by reference to Exhibit 4.07 of Chiron's report on Form 10-Q for the period ended June 30, 2004.
4.08	Registration Rights Agreement dated as of June 22, 2004, between Chiron, Credit Suisse First Boston, LLC and Morgan Stanley & Co., Goldman, Sachs & Co., Incorporated, incorporated by reference to Exhibit 4.08 of Chiron's report on Form 10-Q for the period ended June 30, 2004.

66

Edgar Filing: CHIRON CORP - Form 10-Q

- 4.09 Specimen of Convertible Debentures (included as Exhibit A to the Indenture referenced as Exhibit 4.07 of Chiron's report on Form 10-Q for June 30, 2004) issued on June 22, 2004, incorporated by reference to Exhibit 4.09 of Chiron's report on Form 10-Q for the period ended June 30, 2004.
- 10.511 Audit Committee Charter, as amended and restated as of September 14, 2005.
- 10.628 Letter agreement dated October 20, 2005 between Howard H. Pien and Chiron, incorporated by reference to Exhibit 99.1 of Chiron's current report on Form 8-K filed with the Commission on October 26, 2005.\*
- 31.1 Certification of the Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
- 31.2 Certification of the Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
- 32.1 Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2 Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

---

\* Indicates management contract or compensatory plan, contract or arrangement.

**CHIRON CORPORATION**  
**September 30, 2005**  
**SIGNATURES**

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

DATE: November 3, 2005

CHIRON CORPORATION

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

DATE: November 3, 2005

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