CHIRON CORP
Form 10-Q/A
April 06, 2005

# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# FORM 10-Q/A

**(Mark one)**

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

**For the quarterly period ended September 30, 2004**

**OR**

**o** **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** | **94-2754624** |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |
| **4560 Horton Street, Emeryville, California** | **94608** |
| (Address of principal executive offices) | (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 ý No o

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

Yes ý No o

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 29, 2004** |
|---|---|
| Common Stock, $0.01 par value | 186,839,927 |

**EXPLANATORY NOTE**

This Form 10Q/A (the Report ) is being filed to amend Chiron Corporation s (the Company ) Quarterly Report on Form 10-Q filed on November 2, 2004 (the Original Report ), as previously amended on December 16, 2004, for the quarterly period ended September 30, 2004 to reflect the restatement of the Company s previously issued financial statements as of and for the three and nine month periods ended September 30, 2004, and the notes related thereto, as described below, and to make related changes. The information in this Report as of the date of the Original Report does not reflect subsequent results, events or developments. Such subsequent results, events or developments include, among others, the information and events subsequently described in our Quarterly Reports on Form 10-Q, our Annual Reports on Form 10-K and our Current Reports on Form 8-K. For a description of such subsequent results, events or developments, please read our Exchange Act Reports filed with the Securities and Exchange Commission since the date of the Original Report, which update and supersede information contained in the Original Report and this Report.

Chiron has determined that certain sales of a 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. See Note 1 to Chiron s Condensed Consolidated Financial Statements, included herein, for additional discussion.

Chiron has reflected the results of the restatement for the fiscal year ended December 31, 2004 in its Annual Report on Form 10-K for such year, filed with the SEC on March 16, 2005 and has restated its interim financial statements in this Report and in an additional Quarterly Report on Form 10-Q/A for the quarterly period ended June 30, 2004.

In 2004, the Emerging Issues Task Force (EITF) reached a consensus on EITF Issue No. 04-8 The Effect of Contingently Convertible Instruments on Diluted Earnings per Share, that the dilutive effect of contingently convertible debt instruments ( CoCo s ) must be included in diluted earnings per share regardless of whether the triggering contingency has been satisfied, if dilutive. Adoption of Issue No. 04-8 would be on a retroactive basis and would require restatement of prior period diluted earnings per share. Chiron adopted EITF Issue No. 04-08 in the fourth quarter of 2004. The adoption of EITF Issue No. 04-08 did not result in additional dilution to our diluted earnings per share from our $500.0 million convertible debentures due 2033 nor from our $385.0 million convertible debentures due 2034 for the three and nine months ended September 30, 2004, as discussed in Note 2 to Chiron s Condensed Consolidated Financial Statements.

**CHIRON CORPORATION**

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**Item 1. Financial Statements**

**CHIRON CORPORATION**

**CONDENSED CONSOLIDATED BALANCE SHEETS**

**(Unaudited)**

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

| | September 30, 2004 Restated | December 31, 2003 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 200,983 | $ 364,270 |
| Short-term investments in marketable debt securities | 343,507 | 174,212 |
| Total cash and short-term investments | 544,490 | 538,482 |
| Accounts receivable, net of allowances | 397,802 | 382,933 |
| Current portion of notes receivable | | 1,479 |
| Inventories, net of reserves | 218,589 | 199,625 |
| Assets held for sale | 2,754 | 2,992 |
| Current net deferred income tax assets | 60,232 | 50,204 |
| Derivative financial instruments | 7,599 | 9,463 |
| Other current assets | 65,229 | 72,471 |
| Total current assets | 1,296,695 | 1,257,649 |
| Noncurrent investments in marketable debt securities | 467,813 | 560,292 |
| Property, plant, equipment and leasehold improvements, at cost: | | |
| Land and buildings | 371,382 | 366,275 |
| Laboratory, production and office equipment | 644,087 | 615,814 |
| Leasehold improvements | 116,602 | 112,200 |
| Construction-in-progress | 186,310 | 144,162 |
| | 1,318,381 | 1,238,451 |
| Less accumulated depreciation and amortization | (566,988) | (548,701) |
| Property, plant, equipment and leasehold improvements, net | 751,393 | 689,750 |
| Purchased technologies, net | 221,122 | 236,707 |
| Goodwill | 820,086 | 787,587 |
| Other intangible assets, net | 447,608 | 486,889 |
| Investments in equity securities and affiliated companies | 113,325 | 121,576 |
| Equity method investments | 709 | 953 |
| Noncurrent notes receivable | 7,500 | 7,500 |
| Noncurrent derivative financial instruments | | 7,391 |
| Other noncurrent assets | 57,080 | 38,875 |
| | $ 4,183,331 | $ 4,195,169 |

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, 2004 Restated | December 31, 2003 |
|---|---|---|
| **LIABILITIES AND STOCKHOLDERS EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 113,045 | $ 102,201 |
| Accrued compensation and related expenses | 78,470 | 83,311 |
| Current portion of capital lease | 944 | 570 |
| Current portion of unearned revenue | 37,802 | 47,873 |
| Income taxes payable | 4,746 | 15,270 |
| Other current liabilities | 159,886 | 187,688 |
| Total current liabilities | 394,893 | 436,913 |
| Long-term debt | 940,295 | 926,709 |
| Capital lease | 157,014 | 157,677 |
| Noncurrent derivative financial instruments | 4,928 | |
| Noncurrent net deferred income tax liabilities | 101,288 | 107,496 |
| Noncurrent unearned revenue | 30,525 | 45,564 |
| Other noncurrent liabilities | 86,462 | 69,448 |
| Minority interest | 8,498 | 7,002 |
| Total liabilities | 1,723,903 | 1,750,809 |
| Commitments and contingencies | | |
| Stockholders equity: | | |
| Common stock | 1,917 | 1,917 |
| Additional paid-in capital | 2,527,877 | 2,503,195 |
| Deferred stock compensation | (15,572) | (12,871) |
| Retained earnings (Accumulated deficit) | 16,269 | (46,634) |
| Accumulated other comprehensive income | 171,460 | 216,302 |
| Treasury stock, at cost (4,999,000 shares at September 30, 2004 and 4,567,000 shares at December 31, 2003) | (242,523) | (217,549) |
| Total stockholders equity | 2,459,428 | 2,444,360 |
| | $ 4,183,331 | $ 4,195,169 |

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

**CHIRON CORPORATION**

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

**(Unaudited)**

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2004 Restated | 2003 | 2004 Restated | 2003 |
| Revenues: | | | | |
| Product sales, net | $ 375,549 | $ 432,674 | $ 937,836 | $ 897,222 |
| Revenues from joint business arrangement | 34,017 | 26,058 | 92,910 | 79,985 |
| Collaborative agreement revenues | 4,124 | 7,816 | 14,467 | 15,554 |
| Royalty and license fee revenues | 111,396 | 66,237 | 221,384 | 186,537 |
| Other revenues | 4,450 | 7,688 | 22,363 | 32,482 |
| Total revenues | 529,536 | 540,473 | 1,288,960 | 1,211,780 |
| Operating expenses: | | | | |
| Cost of sales (excludes amortization expense related to acquired developed products) | 238,526 | 174,380 | 494,455 | 357,389 |
| Research and development | 103,000 | 97,519 | 301,736 | 269,564 |
| Selling, general and administrative | 114,531 | 105,818 | 326,128 | 259,086 |
| Amortization expense | 20,566 | 19,821 | 63,077 | 35,135 |
| Purchased in-process research and development | 9,629 | 122,700 | 9,629 | 122,700 |
| Other operating expenses | 1,280 | 4,779 | 8,040 | 7,729 |
| Total operating expenses | 487,532 | 525,017 | 1,203,065 | 1,051,603 |
| Income from operations | 42,004 | 15,456 | 85,895 | 160,177 |
| Interest expense | (7,063) | (6,222) | (19,440) | (12,523) |
| Interest and other income, net | 5,369 | 5,239 | 41,252 | 31,170 |
| Minority interest | (504) | (443) | (1,583) | (1,424) |
| Income from continuing operations before income taxes | 39,806 | 14,030 | 106,124 | 177,400 |
| Provision for income taxes | 12,359 | 34,183 | 28,938 | 75,025 |
| Income (loss) from continuing operations | 27,447 | (20,153) | 77,186 | 102,375 |
| Gain (loss) from discontinued operations | (450) | 1,174 | 24,854 | 3,138 |
| Net income (loss) | $ 26,997 | $ (18,979) | $ 102,040 | $ 105,513 |
| Basic earnings (loss) per share: | | | | |
| Income (loss) from continuing operations | $ 0.15 | $ (0.11) | $ 0.41 | $ 0.55 |
| Net income (loss) | $ 0.14 | $ (0.10) | $ 0.54 | $ 0.57 |
| | | | | |
| Diluted earnings (loss) per share: | | | | |
| Income (loss) from continuing operations | $ 0.14 | $ (0.11) | $ 0.40 | $ 0.54 |
| Net income (loss) | $ 0.14 | $ (0.10) | $ 0.53 | $ 0.55 |

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

**CHIRON CORPORATION**

**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME**

**(Unaudited)**

**(In thousands)**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2004 Restated | 2003 | 2004 Restated | 2003 |
| Net income (loss) | $ 26,997 | $ (18,979) | $ 102,040 | $ 105,513 |
| Other comprehensive income (loss): | | | | |
| Change in foreign currency translation adjustment during the period | 2,960 | 21,182 | (34,452) | 66,300 |
| Unrealized gains (losses) from investments: | | | | |
| Net unrealized holding gains (losses) arising during the period, net of tax (provision) benefit of ($5,977) and ($1,984) for the three months ended September 30, 2004 and 2003, respectively, and ($3,865) and ($3,268) for the nine months ended September 30, 2004 and 2003, respectively | (2,680) | 4,200 | 4,864 | 6,840 |
| Reclassification adjustment for net gains included in net income, net of tax (provision) of ($400) for the three months ended September 30, 2004, and ($9,753) and ($3,626) for the nine months ended September 30, 2004 and 2003, respectively | (625) | | (15,254) | (5,744) |
| Net unrealized gains (losses) from investments | (3,305) | 4,200 | (10,390) | 1,096 |
| Other comprehensive income (loss) | (345) | 25,382 | (44,842) | 67,396 |
| Comprehensive income | $ 26,652 | $ 6,403 | $ 57,198 | $ 172,909 |

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, | |
|---|---|---|
| | **2004 Restated** | **2003** |
| Net cash provided by operating activities | $ 132,633 | $ 253,933 |
| Cash flows from investing activities: | | |
| Purchases of investments in marketable debt securities | (724,616) | (622,650) |
| Proceeds from sales of investments in marketable debt securities | 415,100 | 748,041 |
| Proceeds from maturities of investments in marketable debt securities | 225,959 | 364,737 |
| Capital expenditures | (134,079) | (81,372) |
| Purchases of equity securities and interests in affiliated companies | (6,216) | (4,270) |
| Proceeds from sale of equity securities and interests in affiliated companies | 31,421 | 12,545 |
| Cash paid for acquisitions, net of cash acquired | (32,289) | (804,728) |
| Other, net | (3,688) | (12,249) |
| Net cash used in investing activities | (228,408) | (399,946) |
| Cash flows from financing activities: | | |
| Net repayment of short-term borrowings | | (2,344) |
| Repayment of debt and capital leases | (380,159) | (62,341) |
| Payments to acquire treasury stock | (129,665) | (132,675) |
| Proceeds from re-issuance of treasury stock | 64,178 | 85,995 |
| Proceeds from issuance of debt | 4,996 | 536 |
| Payment of bond issuance costs | (8,285) | |
| Proceeds from issuance of convertible debentures | 385,000 | 500,000 |
| Proceeds from put options | | 2,144 |
| Net cash (used in) provided by financing activities | (63,935) | 391,315 |
| Effect of exchange rate changes on cash and cash equivalents | (3,577) | 6,655 |
| Net (decrease) increase in cash and cash equivalents | (163,287) | 251,957 |
| Cash and cash equivalents at beginning of the period | 364,270 | 247,950 |
| Cash and cash equivalents at end of the period | $ 200,983 | $ 499,907 |

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

**CHIRON CORPORATION**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**September 30, 2004**

**(Unaudited)**

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

*Basis of Presentation*

The information presented in the Condensed Consolidated Financial Statements at September 30, 2004, and for the three and nine months ended September 30, 2004 and 2003, is unaudited but includes adjustments, consisting only of all normal recurring adjustments, which Chiron Corporation believes to be necessary for fair presentation of the periods presented.

The Condensed Consolidated Balance Sheet amounts at December 31, 2003, have been derived from audited financial statements. Historically, Chiron s operating results have varied considerably from period to period due to the nature of Chiron s collaborative, royalty and license arrangements and the seasonality of certain vaccine products. In addition, the mix of products sold and the introduction of new products will affect comparability from quarter to quarter. As a consequence, Chiron s interim results in any one quarter are not necessarily indicative of results to be expected for a full year. This information should be read in conjunction with Chiron s audited Consolidated Financial Statements as of and for the year ended December 31, 2003, which are included in the Annual Report on Form 10-K filed by Chiron with the Securities and Exchange Commission.

*Restatement of Financial Statements*

Chiron determined that certain sales of a 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 of the restatement, in the third quarter of 2004, product sales were increased by $5.6 million, cost of sales were increased by $0.9 million and income taxes were increased by $1.2 million. This resulted in a $3.5 million increase in income from continuing operations and net income and a $0.01 increase of diluted income from continuing operations per share ($0.14 per share instead of the $0.13 per share as previously reported). On the September 30, 2004 consolidated balance sheet, the current portion of unearned revenue increased by $7.6 million and income taxes payable decreased by $1.9 million.

As a result of the restatement, in the second quarter of 2004, product sales were reduced by $13.9 million, cost of sales were reduced by $1.5 million and income taxes were reduced by $3.1 million. This resulted in a $9.3 million reduction in income from continuing operations and net income and a $0.05 reduction of diluted income from continuing operations per share ($0.12 per share instead of the $0.17 per share as previously reported).

As a result of the restatement, for the nine months ended September 30, 2004, product sales were reduced by $8.3 million, cost of sales were reduced by $0.6 million and income taxes were reduced by $1.9 million. This resulted in a $5.8 million reduction in income from continuing operations and net income and a $0.03 reduction of diluted income from continuing operations per share ($0.40 per share instead of the $0.43 per share as previously reported).

*Principles of Consolidation*

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

On July 8, 2003, Chiron acquired PowderJect Pharmaceuticals plc, a company based in Oxford, England that develops and commercializes vaccines. Chiron included PowderJect Pharmaceuticals operating results in its consolidated operating results beginning July 8, 2003. PowderJect Pharmaceuticals is part of Chiron s vaccines segment.

Chiron is a limited partner in several venture capital funds. Chiron is obligated to pay up to $60.0 million over ten years in equity contributions to these venture capital funds, of which approximately $38.4 million was paid through September 30, 2004. Chiron accounts for these investments under the equity method of accounting.

*New Accounting Pronouncements*

In October 2004, the Emerging Issues Task Force (EITF) reached a consensus on EITF Issue No. 04-8 The Effect of Contingently Convertible Instruments on Diluted Earnings per Share, that the dilutive effect of contingent convertible debt instruments ( CoCo s ) must be included in diluted earnings per share regardless of whether the triggering contingency has been satisfied, if dilutive. Adoption of Issue No. 04-8 would be on a retroactive basis and would require restatement of prior period diluted earnings per share, subject to certain transition provisions. It is effective for all periods ending after December 15, 2004. Accounting pursuant to this Issue would not result in additional dilution to Chiron s diluted earnings per share for the three and nine months ended September 30, 2004 from Chiron s $500.0 million convertible debentures due 2033 ( 2033 Debentures ) nor from Chiron s $385.0 million convertible debentures due 2034 ( 2034 Debentures ).

Financial Accounting Standards Board (or FASB) Interpretation No. 46 (or FIN 46), Consolidation of Variable Interest Entities, an interpretation of Accounting Research Bulletin No. 51 as revised, requires a variable interest entity (or VIE) to be consolidated by a company if that company absorbs a majority of the VIE s expected losses, receives a majority of the entity s expected residual returns, or both, as a result of ownership, contractual or other financial interest in the VIE. Prior to the adoption of FIN 46, VIEs were generally consolidated by companies owning a majority voting interest in the VIE. The consolidation requirements of FIN 46 applied immediately to VIEs created after January 31, 2003; however, the FASB deferred the effective date for VIEs created before February 1, 2003 to the quarter ended March 31, 2004 for calendar year companies. Adoption of the provisions of FIN 46 prior to the deferred effective date was permitted.

Chiron adopted the remaining provisions of FIN 46 in the first quarter of 2004. The adoption of these provisions did not have a material effect on Chiron s condensed consolidated financial statements.

On March 31, 2004, the FASB issued an Exposure Draft (ED), Share-Based Payment An Amendment of FASB Statements No. 123 and 95. The proposed Statement addresses the accounting for transactions in which an enterprise receives employee services in exchange for (a) equity instruments of the enterprise or (b) liabilities that are based on the fair value of the enterprise s equity instruments or that may be settled by the issuance of such equity instruments. The proposed Statement would eliminate the ability to account for share-based compensation transactions using Accounting Principles Board Opinion No. 25 (APB 25) Accounting for Stock Issued to Employees, and generally would require instead that such transactions be accounted for using a fair-value based method. As proposed, companies would be required to recognize an expense for compensation cost related to share-based payment arrangements including stock options and employee stock purchase plans. As proposed, the new rules would be applied on a modified prospective basis as defined in the ED, and would be effective for Chiron beginning July 1, 2005. Chiron is currently evaluating option valuation methodologies and assumptions in light of the evolving accounting standards related to employee stock options. Current estimates of option values using the Black-Scholes method may not be indicative of results from valuation methodologies ultimately adopted in the final rules.

*Use of Estimates and Reclassifications*

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

Chiron s blood-testing segment includes Chiron s one-half share in the pretax operating earnings generated by the joint business contractual arrangement with Ortho-Clinical Diagnostics, Inc., a Johnson & Johnson company. Chiron accounts separately for research and development and manufacturing cost reimbursements and certain product sale revenues received from Ortho-Clinical Diagnostics, but relating to the joint business contractual arrangement. Chiron s joint business arrangement with Ortho-Clinical Diagnostics is a contractual arrangement and is not a separate and distinct legal entity. Through Chiron s joint business contractual arrangement with Ortho-Clinical Diagnostics, Chiron sells a line of immunodiagnostic tests to detect hepatitis viruses and retroviruses and provides supplemental tests and microplate and chemiluminescent instrument systems to automate test performance and data collection. Prior to the first quarter 2003, Chiron accounted for revenues relating to non-U.S. affiliate sales on a one-quarter lag, with an adjustment of the estimate to actual in the subsequent quarter. More current information of non-U.S. affiliate sales of Chiron s joint business contractual arrangement became available in the first quarter 2003, and as a result, Chiron is able to recognize revenues relating to non-U.S. affiliate sales on a one-month lag. The effect of this change, net of tax, was an increase to net income by $3.2 million for revenue from the joint business contractual arrangement for the nine months ended September 30, 2003.

Chiron currently owns a facility in London, England for international operations. This facility became available for sale in the fourth quarter of 2003. Chiron has committed to a plan to sell this facility and is actively marketing this facility. This facility is classified as Assets held for sale in the Condensed Consolidated Balance Sheet at September 30, 2004.

Chiron, prior to filing its financial statements on Form 10-Q, publicly releases an unaudited condensed balance sheet and statement of operations. Between the date of Chiron s earnings release and the filing of Form 10-Q, reclassifications may be required. These reclassifications, when made, have no effect on income from continuing operations, net income or earnings per share. There has been no such reclassification in the third quarter of 2004.

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

*Inventories*

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

Subsequent to the third quarter of 2004, the UK regulatory body, the Medicines and Healthcare products Regulatory Agency (MHRA), sent Chiron a letter prohibiting Chiron from releasing any Fluvirin doses manufactured at Chiron s Liverpool facility since March 2, 2004. In that letter, the MHRA asserted that Chiron s manufacturing process did not comply with U.K. good manufacturing practices regulations. In addition to prohibiting release of existing Fluvirin doses, the MHRA letter also suspended Chiron s license to manufacture further influenza virus vaccine in its Liverpool facility for three months. Chiron has not released any Fluvirin into any territory. Chiron wrote-off the entire inventory of Fluvirin product in the third quarter 2004, resulting in a $91.3 million charge to cost of sales.

Inventories, net of reserves consisted of the following:

| | September 30, 2004 | December 31, 2003 |
|---|---|---|
| Finished goods | $ 55,153 | $ 38,640 |
| Work-in-process | 116,596 | 105,359 |
| Raw materials | 46,840 | 55,626 |
| | $ 218,589 | $ 199,625 |

*Income Taxes*

The effective tax rate for the three and nine months ended September 30, 2004 was 31.0% and 27.3% respectively, of pretax income from continuing operations, including the charge for purchased in-process research and development related to the Sagres acquisition. See discussion in Note 4 Acquisitions . The effective tax rate for the three and nine months ended September 30, 2003 was 243.6% and 42.3% respectively, of pretax income from continuing operations, including the charge for purchased in-process research and development related to the PowderJect acquisition. The charges for the purchased in-process research and development in 2003 and 2004 are not tax deductible. The effective tax rate for the three and nine months ended September 30, 2004 and 2003 was 25% of pretax income from continuing operations, after excluding the impact of the purchased in-process research and development charges. 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.

*Stock-Based Compensation*

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

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

| | | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|---|
| | | 2004 | 2003 | 2004 | 2003 |
| | | (in thousands, except per share data) | | | |
| Net income (loss): | | | | | |
| As reported | | $ 26,997 | $ (18,979) | $ 102,040 | $ 105,513 |
| Add: | Stock-based employee compensation expense included in reported net income (loss), net of related tax effects | 1,118 | 1,091 | 3,807 | 3,743 |
| Less: | Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects | 23,778 | 20,741 | 68,055 | 58,786 |
| | Pro forma | $ 4,337 | $ (38,629) | $ 37,792 | $ 50,470 |
| Basic net income (loss) per share: | | | | | |
| As reported | | $ 0.14 | $ (0.10) | $ 0.54 | $ 0.57 |
| Pro forma | | $ 0.02 | $ (0.21) | $ 0.20 | $ 0.27 |
| Diluted net income (loss) per share: | | | | | |
| As reported | | $ 0.14 | $ (0.10) | $ 0.53 | $ 0.55 |
| Pro forma | | $ 0.02 | $ (0.21) | $ 0.20 | $ 0.27 |

*Comprehensive Income*

For the three and nine months ended September 30, 2004 and 2003, the foreign currency translation component of comprehensive income relates to permanent investments in non-U.S. subsidiaries, and accordingly, was not adjusted for income taxes.

*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 Retained earnings / Accumulated deficit. Chiron charged losses of $9.0 million and $39.1 million for the three and nine months ended September 30, 2004, respectively, and $8.9 million and $40.3 million for the three and nine months ended September 30, 2003, respectively, to Retained earnings / Accumulated deficit in the Condensed Consolidated Balance Sheets.

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

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

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

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2004 | 2003 | 2004 | 2003 |
| Income (loss) (Numerator): | | | | |
| Income (loss) from continuing operations | $ 27,447 | $ (20,153) | $ 77,186 | $ 102,375 |
| Shares (Denominator): | | | | |
| Weighted-average common shares outstanding | 187,368 | 186,685 | 187,751 | 186,658 |
| Effect of dilutive securities: | | | | |
| Stock options and equivalents | 2,646 | | 3,150 | 3,828 |
| Put options | | | | 2 |
| Weighted-average common shares outstanding, plus impact from assumed conversions | 190,014 | 186,685 | 190,901 | 190,488 |
| Basic earnings (loss) per share | $ 0.15 | $ (0.11) | $ 0.41 | $ 0.55 |
| Diluted earnings (loss) per share | $ 0.14 | $ (0.11) | $ 0.40 | $ 0.54 |

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2004 | 2003 | 2004 | 2003 |
| Income (loss) (Numerator): | | | | |
| Net income (loss) | $ 26,997 | $ (18,979) | $ 102,040 | $ 105,513 |
| Shares (Denominator): | | | | |

| | | | | |
|---|---|---|---|---|
| Weighted-average common shares outstanding | 187,368 | 186,685 | 187,751 | 186,658 |
| Effect of dilutive securities: | | | | |
| Stock options and equivalents | 2,646 | | 3,150 | 3,828 |
| Put options | | | | 2 |
| Weighted-average common shares outstanding, plus impact from assumed conversions | 190,014 | 186,685 | 190,901 | 190,488 |
| Basic earnings (loss) per share | $ 0.14 | $ (0.10) | $ 0.54 | $ 0.57 |
| Diluted earnings (loss) per share | $ 0.14 | $ (0.10) | $ 0.53 | $ 0.55 |

For the three and nine months ended September 30, 2004, stock options to purchase 11.7 million and 10.1 million shares with exercise prices greater than the average market prices of common stock were excluded from the respective computations of diluted earnings per share as their inclusion would be antidilutive. For the three and nine months ended September 30, 2003, stock options to purchase 4.2 million and 10.7 million shares with exercise prices greater than the average market prices of common stock were excluded from the respective computations of diluted earnings (loss) 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 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 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 that 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, 2004, the assumed conversion of the 2034 Debentures was not dilutive.

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 Liquid Yield Option Notes (LYONs) were excluded from the computations of diluted earnings per share, as their inclusion would be antidilutive. For each of the three and nine months ended September 30, 2003, 5.2 million shares of common stock that would be issued upon conversion of the LYONs were excluded from the computation of diluted earnings (loss) per share, as their inclusion would be antidilutive. During the second quarter of 2004, Chiron was required to purchase a significant portion of the LYONs as discussed in Note 8 Debt Obligations .

**Note 3 Discontinued Operations**

In a strategic effort to focus on its core businesses of blood-testing, vaccines and biopharmaceuticals, Chiron completed the sale of Chiron Diagnostics and Chiron Vision in 1998 and 1997, respectively.

Chiron and Bayer Corporation, or 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 excess following this settlement. This settlement resulted in a net gain of $12.8 million, which was included in Gain (loss) from discontinued operations 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.

In the second quarter 2004, Chiron and the IRS entered into a settlement agreement closing the open tax years 1996 to 1998. Pursuant to this settlement agreement Chiron recognized a tax benefit of approximately $12.5 million, which was included in Gain (loss) from discontinued operations for the nine months ended September 30, 2004.

In the third quarter 2003, Chiron reversed approximately $1.2 million, net of tax, related to unutilized reserves for Chiron Diagnostics, which was included in Gain (loss) from discontinued operations for the three and nine months ended September 30, 2003.

In the first quarter 2003, Chiron and Bayer reached a settlement agreement relating to certain claims raised by Bayer under the Stock Purchase Agreement dated September 17, 1998, between Chiron and Bayer for Chiron Diagnostics. Under this settlement agreement, Chiron was required to make a payment to Bayer during the first quarter 2003. Pursuant to this settlement, Chiron recorded a charge, net of adjustment to its previously provided reserve for indemnity obligations, of $7.6 million, offset by an income tax benefit of $9.0 million, resulting in a net gain of $1.4 million which was included in Gain (loss) from discontinued operations for the nine months ended September 30, 2003.

**Note 4 Acquisitions**

**Sagres Discovery** On July 2, 2004, Chiron acquired Sagres Discovery (Sagres), a privately held company headquartered in Davis, California, which focuses on the discovery and validation of targets with potential application to the development of cancer therapeutics. Chiron acquired Sagres for a preliminary purchase price of $12.0 million.

Sagres is part of Chiron s biopharmaceuticals segment. Chiron accounted for the acquisition as an asset purchase and included Sagres s operating results in its consolidated operating results beginning on July 2, 2004. The components of the preliminary purchase price and allocation thereof based on estimated fair values are summarized in the following table (in thousands). The preliminary purchase price reflects acquisition costs, which include contractual severance, direct acquisition costs and facility exit costs. Chiron is in the process of finalizing certain estimates including those for severance and facility exit costs for certain research facilities; thus both the preliminary purchase price and the allocation of the preliminary purchase price are subject to change.

| | | |
|---|---|---|
| Consideration and acquisition costs: | | |
| Cash paid for asset purchase | $ | 10,057 |
| Cash payable for asset purchase | | 837 |
| Acquisition costs paid as of September 30, 2004 | | 1,082 |
| Acquisition costs not yet paid as of September 30, 2004 | | 47 |
| Total preliminary purchase price | $ | 12,023 |

| | | |
|---|---|---|
| Allocation of preliminary purchase price: | | |
| Assets acquired | $ | 1,698 |
| Liabilities assumed | | (724) |
| Deferred tax assets | | 1,420 |
| Purchased in-process research and development | | 9,629 |
| Total preliminary purchase price | $ | 12,023 |

Chiron allocated the preliminary purchase price based on the fair value of the assets acquired and liabilities assumed. Chiron allocated a portion of the preliminary purchase price to purchased in-process research and development, which it charged to earnings in the third quarter 2004.

For acquisition costs related to Sagres, Chiron paid $1.1 million for the nine months ended September 30, 2004. These payments are reflected in the Condensed Consolidated Statement of Cash Flows as a component of Cash paid for acquisitions, net of cash acquired for the nine months ended September 30, 2004.

The deferred tax assets primarily related to future utilization of net operating loss carryforwards. Chiron acquired federal and state net operating loss carryforwards of approximately $25.0 million and $20.6 million, respectively and federal and state business credits attributed to Sagres of approximately $1.7 million and $1.3 million, respectively. The available utilization of such net operating loss and business tax credit carryforwards is limited in any one year to approximately $0.2 million per annum over the next twenty years under provisions of the Internal Revenue Code. As such, a significant portion of Sagres s net operating loss carryforwards is expected to expire unutilized.

**PowderJect Pharmaceuticals plc** On July 8, 2003, Chiron acquired PowderJect Pharmaceuticals, a company based in Oxford, England that develops and commercializes vaccines. Chiron acquired all of the outstanding shares of common stock of PowderJect Pharmaceuticals for 550 pence per ordinary share, which, including estimated acquisition costs, resulted in a total purchase price of approximately $940.3 million.

During the second quarter 2004, Chiron completed the planned divestiture of certain research operations in Madison, Wisconsin and Oxford, England and certain vaccines operations in Sweden. The divestiture of these operations included the disposition of net assets of $14.7 million (which included $15.5 million of cash), deferred taxes of $9.4 million, and exit liabilities of $21.6 million. The net impact of the divestiture resulted in an increase to goodwill of $2.5 million in the second quarter 2004. Also, during the second quarter of 2004, Chiron adjusted the previously recorded obligation related to an assumed defined benefit plan, which resulted in an increase to goodwill of $8.1 million.

During the third quarter 2004, Chiron revised estimates of exit costs associated with certain contractual obligations under supply and research agreements related to the divested research operations and other direct acquisition costs. Also, during the third quarter 2004, Chiron revised estimates of exit costs associated with the divestiture of certain research operations in Madison, Wisconsin. The net impact of the revision of these estimates resulted in an increase to goodwill of $14.0 million, an increase to acquisition costs of $14.5 million and a decrease to current liabilities assumed of $0.5 million. As a result of these adjustments to exit costs, the purchase price was revised to $940.3 million.

PowderJect Pharmaceuticals is part of Chiron s vaccines segment. Chiron accounted for the acquisition as a business combination and included PowderJect Pharmaceuticals operating results in its consolidated operating results beginning July 8, 2003.

The components of the purchase price, and the allocation thereof based on estimated fair values are summarized in the following table (in thousands).

| | | |
|---|---|---|
| Consideration and acquisition costs: | | |
| Cash paid for common stock | $ | 831,026 |
| Cash paid for options on common stock | | 59,153 |
| Acquisition costs paid as of September 30, 2004 | | 22,340 |
| Acquisition costs not yet paid as of September 30, 2004 | | 27,827 |
| Total purchase price | $ | 940,346 |

| | | |
|---|---|---|
| Allocation of purchase price: | | |
| Cash and cash equivalents | $ | 76,685 |
| Short-term marketable securities | | 8,840 |
| Accounts receivable, net | | 39,600 |
| Inventories | | 64,924 |
| Property, plant and equipment | | 60,589 |
| Goodwill | | 527,492 |
| Acquired intangible assets | | 335,500 |
| Other assets | | 4,876 |
| Income taxes payable | | (17,741) |
| Current liabilities | | (53,810) |
| Net deferred tax liability | | (69,566) |
| Long-term liabilities | | (82,343) |
| Purchased in-process research and development | | 45,300 |
| Total purchase price | $ | 940,346 |

Chiron allocated the purchase price based on the fair value of the assets acquired and liabilities assumed. Chiron allocated a portion of the purchase price to purchased in-process research and development, which it charged to earnings in 2003. Purchased in-process research and development represented the valuation of acquired, to-be-completed research projects. Purchased in-process research and development was determined using the income approach, which is based on the premise that the value of a security or asset is the present value of the future earning capacity that is available for distribution to the subject investors in the security or asset. In valuing the purchased in-process research and development, Chiron used probability-of-success-adjusted cash flows and a 14% discount rate. Cash flows from projects including those relating to (i) certain travel vaccines and (ii) vaccines for allergies were assumed to commence between 2004 and 2012. Given the high risk associated with the development of new drugs, Chiron probability-adjusted the revenue and expense forecasts to reflect the risk of advancement through the regulatory approval process based on the stage of development in the regulatory process. Such a valuation requires significant estimates and assumptions. Chiron believes that the fair value assigned to purchased in-process research and development is based on reasonable assumptions. To assist in determining the value of the purchased in-process research and development, a third-party valuation was obtained as of the acquisition date.

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

Income taxes payable of $17.7 million relates to current tax liabilities associated with PowderJect Pharmaceuticals at the date of acquisition. The net deferred tax liability of $69.6 million is comprised of current and non-current deferred tax assets of $31.1 million primarily related to net operating losses incurred from April 1, 2003 through the acquisition date, reserves and depreciation timing differences and a non-current deferred tax liability of $100.7 million related to acquired intangibles.

For acquisition costs related to PowderJect Pharmaceuticals, Chiron paid $5.6 million and $5.5 million for the nine months ended September 30, 2004 and September 30, 2003, respectively. For the acquisition of PowderJect Pharmaceuticals, cash paid for common stock and options on common stock was $890.2 million for the nine months ended September 30, 2003. These payments are reflected in the Condensed Consolidated Statement of Cash Flows as a component of Cash paid for acquisitions, net of cash acquired for the nine months ended September 30, 2004 and 2003, respectively.

Chiron paid $1.0 million and $0.2 million related to severance payments included in acquisition costs for PathoGenesis Corporation and Matrix Pharmaceutical, respectively, for the nine months ended September 30, 2003. These payments are reflected in the Condensed Consolidated Statement of Cash Flows as a component of Cash paid for acquisitions, net of cash acquired for the nine months ended September 30, 2003.

**Note 5 Roche Settlement**

In October 2000, Chiron entered into three license agreements with F. Hoffmann-La Roche Limited (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 Chiron s hepatitis C virus and HIV nucleic acid testing intellectual property. Two agreements relate to *in vitro* diagnostics products. The third agreement relates to blood screening, which was superseded in May 2001 by two new agreements, one for hepatitis C virus and one for HIV.

An HIV-related patent directed to nucleic acid testing methods for HIV-1 was issued in the U.S. on March 13, 2003. This patent will expire seventeen years from the date of issuance. The issuance of the patent triggered a milestone payment to Chiron of $10.0 million from 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. Chiron 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, Chiron 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, for the three months ended September 30, 2004, Chiron has 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 Chiron s other segment and $5.5 million has been recognized as revenue in Chiron s blood testing segment. Chiron also recognized $0.8 million in interest on the license fee. Also under the settlement agreement, in the first quarter of 2005, Chiron is entitled to receive 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 refund available decreases in equal quarterly increments over the eight quarters of 2005 and 2006. As such, Chiron expects to recognize $64.0 million of the payment as revenue over those eight quarters. The remaining $14.0 million is nonrefundable and was recognized as revenue for the three months ended September 30, 2004, of which $9.3 million has been recognized as revenue in Chiron s other segment and $4.7 million has been recognized as revenue in Chiron s blood testing segment.

The one time impact on revenues for the three and nine months ended September 30, 2004 from these items 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 one time royalty and license fee revenue | $ 35,646 | $ 10,120 | $ 45,766 |

**Note 6 Intangible Assets**

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

| | September 30, 2004 | | | December 31, 2003 | | |
|---|---|---|---|---|---|---|
| | Gross Carrying Value | Accumulated Amortization | Net Carrying Value | Gross Carrying Value | Accumulated Amortization | Net Carrying Value |
| Purchased technologies | $ 332,434 | $ 111,312 | $ 221,122 | $ 332,543 | $ 95,836 | $ 236,707 |
| Patents | $ 126,847 | $ 68,620 | $ 58,227 | $ 119,675 | $ 61,747 | $ 57,928 |
| Trademarks | 60,750 | 22,824 | 37,926 | 61,082 | 20,507 | 40,575 |
| Licenses and technology rights | 48,783 | 34,121 | 14,662 | 49,087 | 27,818 | 21,269 |
| Developed product technologies | 350,828 | 59,642 | 291,186 | 347,233 | 23,093 | 324,140 |
| Customer relationships | 28,334 | 10,896 | 17,438 | 28,824 | 9,952 | 18,872 |
| Know how(1) | 12,868 | 6,615 | 6,253 | 13,090 | 6,023 | 7,067 |
| Databases | 7,100 | 1,893 | 5,207 | 7,100 | 1,538 | 5,562 |
| Other | 34,992 | 18,283 | 16,709 | 26,328 | 14,852 | 11,476 |
| Total other intangible assets | $ 670,502 | $ 222,894 | $ 447,608 | $ 652,419 | $ 165,530 | $ 486,889 |
| Total intangible assets subject to amortization | $ 1,002,936 | $ 334,206 | $ 668,730 | $ 984,962 | $ 261,366 | $ 723,596 |

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

Aggregate amortization expense is as follows (in thousands):

| | |
|---|---|
| For the nine months ended September 30, 2004 | $ 71,668 |
| For the remaining three months in the year ended December 31, 2004 (estimated) | 23,883 |
| For the year ended December 31, 2004 (estimated) | $ 95,551 |
| For the year ended December 31, 2005 (estimated) | $ 96,449 |
| For the year ended December 31, 2006 (estimated) | $ 100,881 |
| For the year ended December 31, 2007 (estimated) | $ 98,735 |
| For the year ended December 31, 2008 (estimated) | $ 74,231 |
| For the year ended December 31, 2009 (estimated) | $ 50,580 |

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, 2003 | $ 187,492 | $ 600,095 | $ 787,587 |
| PowderJect adjustment (See Note 4) | | 24,531 | 24,531 |
| Effect of exchange rate changes | | 7,968 | 7,968 |
| Balance as of September 30, 2004 | $ 187,492 | $ 632,594 | $ 820,086 |

Chiron performed its annual impairment test for goodwill in the third quarter 2004, as of July 1, 2004. Subsequent to the third quarter 2004, given the developments with respect to Fluvirin discussed in Note 9 Commitments and Contingencies, Chiron considered the impact of recent Fluvirin developments on goodwill. Based on this revised analysis, Chiron has no indication of an impairment loss. Chiron will continue to monitor goodwill for any impairment associated with future developments related to the Fluvirin matters.

**Note 7 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, Inc., a Johnson & Johnson company. Chiron s alliance with Gen-Probe is focused on developing and commercializing nucleic acid testing products using Transcription-Mediated Amplification technology to screen donated blood and plasma products for viral infection. Chiron s joint business arrangement with Ortho-Clinical Diagnostics is operated under a contractual arrangement and is not a separate and distinct legal entity. Through Chiron s joint business contractual arrangement with Ortho-Clinical Diagnostics, Chiron sells a line of immunodiagnostic tests to detect hepatitis viruses and retroviruses and provides supplemental tests and microplate and chemiluminescent instrument systems to automate test performance and data collection. The 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 international markets. The vaccines segment is also involved in the development of novel vaccines and vaccination technology. The biopharmaceuticals segment consists of therapeutic products and services, with an emphasis on the treatment of cancer and infectious diseases, using the development and acquisition of technologies related to therapeutic proteins and small molecules. The biopharmaceuticals segment earns royalties on third party sales of several products, including Betaferon® and recombinant insulin and glucagons products 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 Note 1 Basis of Presentation and Summary of Significant Accounting Policies above and in Chiron s Annual Report on Form 10-K for the year ended December 31, 2003. Chiron evaluates the performance of its segments based on each segment s income (loss) from continuing operations excluding certain special items such as purchased in-process research and development, which is shown as a reconciling item in the table below.

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2004 | 2003 | 2004 | 2003 |
| *Revenues* | | | | |
| Blood-testing: | | | | |
| Product sales, net: | | | | |
| Procleix® System | $ 63,629 | $ 53,663 | $ 186,104 | $ 141,767 |
| Ortho-Clinical Diagnostics | 7,098 | 6,235 | 19,940 | 19,766 |
| Total product sales, net | 70,727 | 59,898 | 206,044 | 161,533 |
| Revenues from joint business arrangement | 34,017 | 26,058 | 92,910 | 79,985 |
| Collaborative agreement revenues | 1,616 | 2,103 | 6,005 | 6,393 |
| Royalty and license fee revenues | 34,115 | 20,576 | 66,817 | 59,372 |
| Other revenues | 243 | | 673 | |
| Total blood-testing revenues | 140,718 | 108,635 | 372,449 | 307,283 |
| | | | | |
| Vaccines: | | | | |
| Product sales, net: | | | | |
| Flu vaccines | 93,486 | 183,250 | 109,398 | 191,286 |
| Meningococcus vaccines | 8,865 | 10,642 | 18,430 | 31,876 |
| Travel vaccines | 26,434 | 11,229 | 75,705 | 59,981 |
| Pediatric and other vaccines | 44,491 | 57,598 | 143,292 | 133,537 |
| Total product sales, net | 173,276 | 262,719 | 346,825 | 416,680 |
| Collaborative agreement revenues | 2,230 | 4,349 | 7,410 | 4,516 |
| Royalty and license fee revenues | 1,213 | 3,023 | 3,888 | 9,550 |
| Other revenues | 3,006 | 2,679 | 12,563 | 8,688 |
| Total vaccines revenues | 179,725 | 272,770 | 370,686 | 439,434 |
| | | | | |
| Biopharmaceuticals: | | | | |
| Product sales, net | | | | |
| Betaseron® | 35,171 | 29,010 | 96,933 | 88,788 |
| TOBI® | 55,734 | 43,022 | 159,600 | 122,740 |
| Proleukin® | 31,739 | 29,859 | 98,664 | 85,223 |
| Other | 8,902 | 8,166 | 29,770 | 22,258 |
| Total product sales, net | 131,546 | 110,057 | 384,967 | 319,009 |
| Collaborative agreement revenues | 278 | 1,364 | 1,052 | 4,645 |
| Royalty and license fee revenues | 15,412 | 23,523 | 47,892 | 62,098 |
| Other revenues | 1,201 | 5,009 | 9,127 | 23,794 |
| Total biopharmaceuticals revenues | 148,437 | 139,953 | 443,038 | 409,546 |
| | | | | |
| Other: | | | | |
| Royalty and license fee revenues | 60,656 | 19,115 | 102,787 | 55,517 |
| Total revenues | $ 529,536 | $ 540,473 | $ 1,288,960 | $ 1,211,780 |

| | | | | |
|---|---|---|---|---|
| *Income (loss) from continuing operations* | | | | |
| Blood-testing | $ 80,690 | $ 56,994 | $ 203,538 | $ 169,997 |
| Vaccines | (65,528) | 69,848 | (161,880) | 65,340 |
| Biopharmaceuticals | 1,683 | 15,663 | 29,709 | 48,959 |
| Other | 34,788 | (4,349) | 24,157 | (1,419) |
| Segment income from operations | 51,633 | 138,156 | 95,524 | 282,877 |
| Operating expense reconciling item: | | | | |
| Purchased in-process research and development | (9,629) | (122,700) | (9,629) | (122,700) |
| Income from operations | 42,004 | 15,456 | 85,895 | 160,177 |
| Interest expense | (7,063) | (6,222) | (19,440) | (12,523) |
| Interest and other income, net | 5,369 | 5,239 | 41,252 | 31,170 |
| Minority interest | (504) | (443) | (1,583) | (1,424) |
| Income from continuing operations before income taxes | $ 39,806 | $ 14,030 | $ 106,124 | $ 177,400 |

**Note 8 Debt Obligations**

*Convertible Debentures*

On June 22, 2004, Chiron issued $385.0 million aggregate principal amount of convertible debentures, which mature on June 30, 2034. The convertible debentures accrue interest at a rate of 2.75% per year and interest is payable on June 30 and December 30 commencing on December 30, 2004. The debentures are senior, unsecured obligations of Chiron and rank equal in right of payment with all of Chiron s existing and future unsecured and unsubordinated indebtedness.

The holders of the debentures may convert their debentures when certain Chiron common stock price targets have been met at certain times, if the trading price for the debentures falls below certain levels for a specified period of time, if the debentures have been called for redemption, if the credit rating assigned to Chiron s long-term senior debt is below specified levels, upon the occurrence and continuance of specified corporate transactions or in connection with a transaction or event constituting a change in control. The initial conversion rate is 14.9254 shares of Chiron common stock per $1,000 principal amount of debentures. This is equivalent to an initial conversion price of approximately $67.00 per share of Chiron common stock.

If the 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 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 that 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 a change in control occurs on or prior to July 5, 2010, under certain circumstances, holders of the debentures will receive a make whole premium on debentures tendered for repurchase and for debentures converted in connection with a change in control. The amount of the make whole premium will be based on the price paid per share of Chiron common stock in a transaction constituting a change in control and is payable in Chiron common stock.

The holders of the debentures may require Chiron to repurchase for cash all or part of the debentures on June 30, 2010, June 30, 2014, June 30, 2019, June 30, 2024 and June 30, 2029. The repurchase price will be equal to 100% of the principal amount of the debentures to be repurchased, plus accrued and unpaid interest, if any, up to the repurchase date.

On or after July 5, 2010, Chiron may redeem for cash all or part of the debentures at a redemption price equal to 100% of principal amount of the debentures to be redeemed, plus accrued and unpaid interest, if any, up to the redemption date.

Bond issuance costs in connection with the issuance of the debentures amounted to approximately $8.6 million and are being amortized to interest expense on a straight-line basis, which approximates the effective interest method, over six years, which represents the period from the issue date to the earliest put date. Bond issuance costs are recorded in Other intangible assets, net in the Condensed Consolidated Balance Sheets at September 30, 2004.

*Liquid Yield Option Notes*

In June 2001, Chiron issued zero coupon Liquid Yield Option Notes (LYONs) with a face value of $730.0 million and a yield to maturity of 2.0%. The LYONs were carried net of an original issue discount of $328.2 million, which was being accreted to interest expense over the life of the LYONs using the effective interest method. No beneficial conversion feature existed at the time of the issuance of the LYONs. The LYONs mature on June 12, 2031, at a face value of $1,000 per note. The LYONs are uncollateralized and unsubordinated, and rank equal in right of payment to Chiron s existing and future uncollateralized and unsubordinated indebtedness.

On June 12, 2004, certain LYONs holders, at their option, tendered $649.9 million in aggregate principal amount at maturity for purchase by Chiron. The purchase price for the LYONs was $584.31 in cash per $1,000 in principal amount at maturity. The aggregate purchase price for all the LYONs validly surrendered for purchase was $379.7 million. At September 30, 2004, there remains outstanding $80.1 million in aggregate principal amount at maturity and an accreted balance of $47.1 million for the LYONs.

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

| Date | | Price |
|---|---|---|
| June 12, 2006 | $ | 608.04 |
| June 12, 2011 | $ | 671.65 |
| June 12, 2016 | $ | 741.92 |
| June 12, 2021 | $ | 819.54 |
| June 12, 2026 | $ | 905.29 |

*Other Loans Payable*

Chiron has entered into various agreements with a governmental body in Italy for which Chiron may borrow up to 8.6 million Euros ($10.6 million at September 30, 2004) for research purposes. Under these facilities, Chiron has an outstanding balance of 5.1 million Euros ($6.4 million) as of September 30, 2004 with interest rates that range from 2% to 6% and maturities that range from 2010 to 2013.

**Note 9 Commitments and Contingencies**

In March 2004, Chiron entered into a worldwide, exclusive, multi-product, collaborative arrangement with XOMA Ltd. for the development and commercialization of antibody products for the treatment of cancer. Under the terms of the arrangement, the parties agreed to jointly research, develop, and commercialize multiple antibody product candidates. Under the arrangement, the parties agreed to share development and commercialization expenses, including preclinical and clinical development, manufacturing and worldwide marketing costs, as well as revenues, generally on a 70-30 basis, with Chiron s share being 70% and XOMA s share being 30%. Chiron agreed to make an initial payment of $10.0 million, which has been paid as of September 30, 2004, and to make a loan facility of up to $50.0 million available to XOMA, starting on January 1, 2005 to fund XOMA s share of development expenses. The collaboration will initially focus on preclinical, process development and scale up work, with a potential Investigative New Drug (IND) filing anticipated early in the collaboration.

On June 1, 2004, Chiron renewed its lease for a manufacturing facility in Emeryville, California from June 1, 2004 through September 30, 2015 with two 3-year options to renew at the end of the lease term and with a right to cancel the lease as of May 31, 2014 without a cancellation fee. Chiron is obligated to pay approximately $17.5 million up until May 31, 2014.

Chiron is subject to indemnification provisions under its agreements with other companies in its ordinary course of business, typically with business partners, contractors, clinical sites, insurers and customers. Under these provisions, Chiron generally indemnifies and holds harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of Chiron s activities. These indemnification provisions generally survive termination of the underlying agreement. In some cases, the maximum potential amount of future payments Chiron could be required to make under these indemnification provisions is unlimited. The estimated fair value of the indemnity obligations of these agreements is minimal. Accordingly, Chiron has no liabilities recorded for these agreements as of September 30, 2004. Chiron has not incurred material costs to defend lawsuits or settle claims related to these indemnification agreements.

During the third quarter of 2004, in conducting final internal release procedures for Fluvirin influenza virus vaccine, Chiron s quality systems identified lots that did not meet product sterility specifications. As a result, Chiron determined at that time to delay releasing any Fluvirin doses pending completion of internal investigations. Subsequent to the third quarter, the UK regulatory body, the Medicines and Healthcare products Regulatory Agency (MHRA), sent Chiron a letter prohibiting Chiron from releasing any Fluvirin doses manufactured at its Liverpool facility since March 2, 2004. In that letter, the MHRA asserted that Chiron s manufacturing process did not comply with U.K. good manufacturing practices regulations. In addition to prohibiting release of existing Fluvirin doses, the MHRA letter also suspended Chiron s license to manufacture further influenza virus vaccine in its Liverpool facility for three months. Following its own investigation, the U.S. Food and Drug Administration, or FDA, announced that it would not permit release of any Fluvirin from our Liverpool facility into the United States. The MHRA could extend the license suspension or even make it permanent. Chiron estimates that Fluvirin production must begin by March 2005 in order for Chiron to be able to release the product in September 2005, so any significant extension of the suspension could result in Chiron being unable to release Fluvirin for the 2005-2006 season, which would harm its business and results of operations. Chiron cannot predict with any certainty if or when it will be able to resume production of Fluvirin at its Liverpool facility. In addition, while Chiron is still in the process of assessing the appropriate corrective steps, its remediation efforts could entail additional capital and other expenditures, which could be material. Chiron s inability to supply Fluvirin may also lead to loss of market share. As a result of the license suspension, competitors have announced plans to introduce influenza vaccine products in the United States and are seeking expedited regulatory approval to do so. Even if the license suspension expires, some of Chiron s customers may choose to purchase flu vaccine from other providers as their products become available in the United States. Loss of market share could have a material adverse effect on its business and results of operations. Chiron is subject to investigations and litigation in connection with the events described above. Chiron has received a grand jury subpoena issued by the U.S. Attorney s Office for the Southern District of New York requesting production of certain documents and materials relating to Chiron s influenza virus vaccine and the suspension by the MHRA of Chiron s license. The Securities and Exchange Commission is also conducting an informal inquiry into whether Chiron has violated any federal securities laws. Additional investigations regarding these matters may arise, including Congressional investigations. In addition, Chiron and certain of its officers and directors have also been named as defendants in several putative class action and shareholder derivative lawsuits arising out of these developments. Investigations and litigation could cause Chiron to incur substantial expense, require significant time and attention from Chiron s management and result in civil and/or criminal penalties against Chiron. The results of any such investigations or proceedings could have a material adverse effect on Chiron s consolidated financial position and results of operations or cash flows.

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

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

***Forward-Looking Statements***

*This 10-Q contains forward-looking statements regarding our expectations, hopes or intentions regarding the future, including statements relating to sales growth, product development initiatives, new product marketing, acquisitions, competition, in- and out-licensing activities and expected cost savings that involve risks and uncertainties and are subject to change. You should read the discussion below in conjunction with Part I, Item 1., Financial Statements, of this 10-Q and Part II, Items 7., 7A. and 8., Management s Discussion and Analysis of Financial Condition and Results of Operations, Quantitative and Qualitative Disclosures About Market Risk and Financial Statements and Supplementary Data, respectively, of our Annual Report on Form 10-K for the year ended December 31, 2003. The forward-looking statements contained in this 10-Q reflect our current beliefs and expectations on the date of this 10-Q. Actual results, performance or outcomes may differ from current expectations. Many factors could cause actual results, performance and outcomes to differ materially from those expressed or implied by these forward-looking statements. In particular, many factors related to recent developments with respect to our influenza vaccine Fluvirin® could cause actual results, performance or outcomes to differ materially. These include, among other things, (1) uncertainty with respect to our ability to deliver Fluvirin in time for the 2005-2006 or future seasons, (2) possible additional adverse developments with respect to Fluvirin resulting from investigations or discussions with or actions taken or required by applicable regulatory authorities, such as the U.K. Medicines and Healthcare products Regulatory Agency and the U.S. Food and Drug Administration, including further suspension or revocation of our license to manufacture Fluvirin at our Liverpool facility, (3) possible additional adverse developments resulting from discussions with or actions taken or required by other governmental authorities and agencies, such as the U.S. Department of Health and Human Services and the Centers for Disease Control, (4) significant expenses arising out of remediation efforts with respect to our Liverpool facility and in connection with the investigation by the U.S. Attorney s Office for the Southern District of New York, the inquiry by the Securities and Exchange Commission and putative class action and shareholder derivative lawsuits related to the Fluvirin recent developments and (5) additional significant competition in the U.S. influenza vaccines market stemming from the recent developments with respect to Fluvirin. Our actual performance may also differ from current expectations due to the outcome of clinical trials, regulatory review and approvals generally, manufacturing capabilities, intellectual property protections and defenses, stock-price and interest-rate volatility and marketing effectiveness. In particular, there can be no assurance that we will increase sales of existing products, successfully develop and receive approval to market new products or achieve market acceptance for such new products. There can be no assurance that our out-licensing activity will generate significant revenue, or that our in-licensing activities will fully protect us from claims of infringement by third parties. In addition, we may engage in business opportunities, the successful completion of which is subject to certain risks, including stockholder and regulatory approvals and the integration of operations. We have discussed the important factors, which we believe could cause actual results to differ from what is expressed in the forward-looking statements, under the caption Factors That May Affect Future Results in this 10-Q. We do not undertake an obligation to update the forward-looking information contained in this 10-Q.*

**Restatement of Financial Statements**

As discussed in Note 1 to our Condensed Consolidated Financial Statements, we determined that certain sales of a 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 determined to restate the financial statements included in our Quarterly Reports on 10-Q for such quarters. The restatement is reflected in management s discussion and analysis of financial condition and results of operations below.

**Overview**

We are a global pharmaceutical company that participates in three healthcare markets: blood-testing, vaccines and biopharmaceuticals. We are focused on developing products for cancer, which include immune-based therapies, antibodies and novel small molecule anti-cancer agents and infectious disease, which have a range of products spanning all three of our business units. Our revenues consist of product sales, revenues from a joint business contractual arrangement, collaborative agreement revenues, royalty and license fee revenues and other revenues, primarily consisting of contract manufacturing and grant revenues.

The blood-testing segment consists of an alliance with Gen-Probe and our one-half share in the pretax operating earnings generated by the joint business contractual arrangement with Ortho-Clinical Diagnostics, Inc., a Johnson & Johnson company. Our alliance with Gen-Probe is focused on developing and commercializing nucleic acid testing products using transcription-mediated amplification technology to screen donated blood and plasma products for viral infection. Our joint business arrangement with Ortho-Clinical Diagnostics is operated under a contractual arrangement and is not a separate and distinct legal entity. Through our joint business contractual arrangement with Ortho-Clinical Diagnostics, we sell a line of immunodiagnostic tests to detect hepatitis viruses and retroviruses and provide supplemental tests and microplate and chemiluminescent instrument systems to automate test performance and data collection. The blood-testing segment also earns royalties from third parties based on their sales of immunodiagnostic and nucleic acid testing probe diagnostic products utilizing our hepatitis C virus and HIV-related patents, for use in blood screening and plasma fractionation markets.

The vaccines segment consists of flu vaccines, including Fluvirin® and other flu vaccines, meningococcal vaccines, travel vaccines, which include rabies and tick-borne encephalitis vaccines, Arilvax and Dukoral , and pediatric and other vaccines. We sell these vaccines primarily in the U.S., Germany, Italy and the United Kingdom, as well as in other international markets. Our vaccines segment is also involved in the development of other novel vaccines and vaccination technology. We acquired Fluvirin,

Arilvax and Dukoral as part of our July 8, 2003 acquisition of PowderJect Pharmaceutical plc, or PowderJect, a company based in Oxford, England. We accounted for that acquisition under the purchase method of accounting and included PowderJect s operating results in our consolidated operating results beginning July 8, 2003.

During the third quarter 2004, in conducting final internal release procedures for our Fluvirin influenza virus vaccine, our quality systems identified lots that did not meet product sterility specifications. As a result, we determined at that time to delay releasing any Fluvirin doses pending completion of internal investigations. Subsequent to the third quarter, the U.K. regulatory body, the Medicines and Healthcare products Regulatory Agency, or MHRA, sent us a letter prohibiting us from releasing any Fluvirin doses manufactured at our Liverpool facility since March 2, 2004. In that letter, the MHRA asserted that our manufacturing process did not comply with U.K. good manufacturing practices regulations. In addition to prohibiting release of existing Fluvirin doses, the MHRA letter also suspended our license to manufacture further influenza virus vaccine in our Liverpool facility for three months. Following its own investigation, the U.S. Food and Drug Administration, or FDA, announced that it would not permit release of any Fluvirin from our Liverpool facility into the United States. Following our announcements of these events, we were served with a grand jury subpoena issued by the U.S. Attorney s Office for the Southern District of New York requesting production of certain documents and materials relating to our influenza virus vaccine and the suspension by the MHRA of our license. In addition, the Securities and Exchange Commission, or SEC, has informed us that it had opened an informal inquiry to determine whether we have violated certain provisions of the federal securities laws and requesting that we voluntarily provide certain documents and materials, including materials relating to Fluvirin and the suspension of our license to manufacture Fluvirin. We and certain of our officers and directors have also been named as defendants in several putative class action and shareholder derivative lawsuits arising out of these developments.

These recent developments with respect to Fluvirin had the following immediate impact on our results of operations for the three and nine months ended September 30, 2004:

we had no sales of Fluvirin during these periods (other than, with respect to the nine months ended September 30, $2.4 million in late 2003-2004 season sales), while Fluvirin sales were $103.3 million for the three and nine months ended September 30, 2003; and

we wrote-off our entire inventory of Fluvirin, resulting in a $91.3 million charge to cost of sales and a decrease in diluted earnings per share of approximately $0.36 for each of the three and nine months ended September 30, 2004.

In addition to the above, we do not expect to release any Fluvirin during the fourth quarter of 2004 or for the 2004-2005 flu season and cannot predict with any certainty if or when we will be able to resume production of Fluvirin at our Liverpool facility. We cannot provide any assurances that we will be able to provide Fluvirin for the 2005-2006 season. As a result, we expect that our results of operations for the fourth quarter 2004 will be materially adversely affected by these matters and possibly beyond. If we are unable to provide Fluvirin for the 2005-2006 season or afterward, we may also have to recognize an impairment charge with respect to the goodwill, certain other intangible assets and the Liverpool plant resulting from the PowderJect acquisition and the new flu vaccines manufacturing facility under construction in Liverpool, which could have a material adverse effect on our results of operations. As a result of these developments, if we are able to resume production and distribution of Fluvirin from our Liverpool facility, we may experience loss of market share in the U.S. flu vaccine market as competitors seek to introduce their influenza products into the United States and as governmental authorities and agencies face increased pressure to diversify their sources of flu vaccine and find and approve alternative suppliers of flu vaccine, which could further materially adversely affect our results of operations going forward. We also expect to incur expenses in connection with these Fluvirin matters, which could be material, including in connection with (1) our remediation efforts at our Liverpool facility; and (2) responding to the U.S. Attorney for the Southern District of New York, the SEC, the private lawsuits and other claims and investigations that may arise. For additional information concerning the risks we face as a result of these Fluvirin developments, see Factors That May Affect Future Results The recent developments with respect to

Fluvirin will harm our business and results of operations. For additional information on the U.S. Attorney s investigation, SEC inquiry and private lawsuits, see Part II, Item 1 of this report on Form 10-Q.

The biopharmaceuticals segment consists of therapeutic products and services, with an emphasis on the treatment of cancer and infectious diseases. Our in-house capabilities span three types of therapeutics, including small molecules, therapeutic proteins and monoclonal antibodies. Our products include TOBI® (tobramycin solution for inhalation) for pseudomonal lung infections in cystic fibrosis patients, Proleukin® (aldesleukin) for cancer (metastatic melanoma and renal cell carcinoma), and Betaseron® (interferon beta-1b) for multiple sclerosis. The biopharmaceuticals segment also includes collaborations with Berlex Laboratories, Inc. and its parent company, Schering AG of Germany, related to Betaseron® interferon beta-1b. The biopharmaceuticals segment earns royalties on third party sales of several products, including Betaferon® and recombinant insulin and glucagons products and earns license fees for technologies, such as hepatitis C virus-related patents, used by third parties to develop therapeutic products.

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.

**SELECTED CONSOLIDATED FINANCIAL DATA**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | | $ Change | | % Change | |
|---|---|---|---|---|---|---|---|---|
| | 2004 | 2003 | 2004 | 2003 | Three Months | Nine Months | Three Months | Nine Months |
| | ($ in 000 s, except per share data) | | | | | | | |
| Product sales, net | $ 375,549 | $ 432,674 | $ 937,836 | $ 897,222 | $ (57,125) | $ 40,614 | (13.2)% | 4.5% |
| Royalty and license fee revenues | 111,396 | 66,237 | 221,384 | 186,537 | 45,159 | 34,847 | 68.2% | 18.7% |
| Total revenues | 529,536 | 540,473 | 1,288,960 | 1,211,780 | (10,937) | 77,180 | (2.0)% | 6.4% |
| Cost of sales (excludes amortization expense from acquired developed products) | 238,526 | 174,380 | 494,455 | 357,389 | 64,146 | 137,066 | 36.8% | 38.4% |
| Research and development | 103,000 | 97,519 | 301,736 | 269,564 | 5,481 | 32,172 | 5.6% | 11.9% |
| Selling, general and administrative | 114,531 | 105,818 | 326,128 | 259,086 | 8,713 | 67,042 | 8.2% | 25.9% |
| Purchased in-process research and development | 9,629 | 122,700 | 9,629 | 122,700 | (113,071) | (113,071) | (92.2)% | (92.2)% |
| Income (loss) from continuing operations | 27,447 | (20,153) | 77,186 | 102,375 | 47,600 | (25,189) | 236.2% | (24.6)% |
| Diluted earnings (loss) per share: | | | | | | | | |
| Income (loss) from continuing operations | $ 0.14 | $ (0.11) | $ 0.40 | $ 0.54 | $ 0.25 | $ (0.14) | 227.3% | (25.9)% |
| | | | | | | | | |
| Gross profit margin | 36% | 60% | 47% | 60% | | | | |

Income from continuing operations was $27.4 million, or $0.14 per diluted share and loss from continuing operations was $20.2 million or $0.11 per diluted share for the three months ended September 30, 2004 and 2003, respectively. Income from continuing operations was $77.2 million or $0.40 per diluted share and $102.4 million or $0.54 per diluted share for the nine months ended September 30, 2004 and 2003, respectively. Total revenues were $529.5 million and $540.5 million for the three months ended September 30, 2004 and 2003, respectively, and $1.3 billion and $1.2 billion for the nine months ended September 30, 2004 and 2003, respectively. As described above, there were no sales of Fluvirin during the current quarter. Sales of Fluvirin influenza vaccine were $103.3 million for the three months ended September 30, 2003. In addition, as described above, our entire Fluvirin product inventory has been written-off in the third quarter 2004, resulting in a $91.3 million charge to cost of sales. This charge has resulted in an approximate $0.36 decrease in diluted earnings per share for the three and nine months ended September 30, 2004, respectively. The loss from continuing operations for the three months ended September 30, 2003 was driven by a charge for purchased in-process research and development from our acquisition of PowderJect of $122.7 million that was expensed for the three months ended September 30, 2003. This charge for purchased in-process research and development also negatively impacted the nine months ended September 30, 2003. A contractual decline in the Betaseron® royalty rate, described in more detail below, resulted in $11.4 million and $32.7 million declines in total revenues for the three and nine months ended September 30, 2004. Our total revenues were affected by the movement in exchange rates, in particular the movements in the Euro and British Pound against the U.S. dollar. The movement in exchange rates added approximately 2% and 3% to our total revenues for the three and nine months ended September 30, 2004, respectively. However, since our Euro and British Pound denominated expenses have also increased due to the movement in exchange rates, our earnings per share from continuing operations declined $0.05 and $0.07 per diluted share for the three and nine months ended September 30, 2004, respectively, due to higher expenses compared to revenues denominated in Euros and British Pounds.

For the three months ended September 30, 2004, product sales decreased compared to the three months ended September 30, 2003 as there were no Fluvirin influenza vaccine sales for the current quarter. Product sales increased across our other two business units and with respect to our other vaccine products, in particular our other flu vaccines products, TOBI® tobramycin, Procleix® products, travel vaccines and Betaseron®. For the nine months ended September 30, 2004, product sales increased due to increases in Procleix® products, TOBI®, travel vaccines, Proleukin® and Betaseron®, even though we had no Fluvirin vaccine sales in the current quarter.

For the three and nine months ended September 30, 2004, royalty and licenses fees increased significantly due to the F. Hoffmann-La Roche (Roche) settlement regarding our HIV patent in the U.S. in the three months ended September 30, 2004. The settlement included a $78.0 million lump sum payment, of which $14.0 million was recognized in the third quarter 2004. In addition, the settlement resulted in $31.8 million of previously deferred royalties and license payments being recognized in the three months ended September 30, 2004. The one time impact of

these items from the Roche settlement was an approximate $0.18 increase in diluted earnings per share for the three and nine months ended September 30, 2004, respectively. Also, there was an additional

$7.9 million for the three and nine months ended September 30, 2004 due to recognition of a portion of the license fee under our license agreements with the Blood Transfusion Centers of the German Red Cross (German Red Cross) for use of our HIV-1 and hepatitis C virus (HCV) technology.

The declines in gross profit margins for the three and nine months ended September 30, 2004 as compared with the three and nine months ended September 30, 2003 were primarily due to the write-off of our entire inventory of Fluvirin, resulting in a $91.3 million charge to cost of sales in the third quarter 2004, as well as the fact that there were no Fluvirin vaccine sales in the third quarter 2004. The effect of the Fluvirin charge resulted in a 24% and 9% decrease in our gross margin percentage for the three and nine months ended September 30, 2004.

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

The main components of the increase in research and development expenses for the nine months ended September 30, 2004 as compared to the nine months ended September 30, 2003 include tifacogin, our meningococcal vaccines franchise and our flu cell culture program. These increases were partially offset by the discontinuance of development of tezacitabine and PA-2794.

The increase in selling general and administrative expenses for the nine months ended September 30, 2004 as compared to the nine months ended September 30, 2003 mainly reflects the timing of our acquisition of PowderJect on July 8, 2003. Selling, general and administrative expenses for the nine months ended September 30, 2004 include nine months of selling, general and administrative expenses from PowderJect while the nine months ended September 30, 2003 included three months of such expenses. Selling, general and administrative expenses increased also due to investment in geographic penetration for our products, marketing programs for our products and defense of our patents and technology.

The effective tax rate for the three and nine months ended September 30, 2004 was 31.0% and 27.3% respectively, of pretax income from continuing operations, including the charge for purchased in process research and development related to the Sagres acquisition. The effective tax rate for the three and nine months ended September 30, 2003 was 243.6% and 42.3% respectively, of pretax income from continuing operations including the charge for purchased in-process research and development related to the PowderJect acquisition. The charges for the purchased in-process research and development in 2003 and 2004 are not tax deductible. The effective tax rate for the three and nine months ended September 30, 2004 and 2003 was 25% of pretax income from continuing operations, after excluding the impact of the purchased in-process research and development charges. 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 Chiron s Annual Report on Form 10-K for the year ended December 31, 2003, except for additional discussion in the following two paragraphs.

Purchased in-process research and development We allocate the purchase price of acquisitions based on the fair value of the assets acquired and liabilities assumed. To assist in determining the value of the in-process research and development and certain other intangibles, a third party valuation is typically obtained as of the acquisition date if the acquisition is significant. We generally use the income approach to value in-process research and development. The income approach is based on the premise that the value of a security or asset is the present value of the future earning capacity that is available for distribution to the subject investors in the security or asset. We perform a discounted cash flow analysis, utilizing anticipated revenues, expenses and net cash flow forecasts related to the technology. Given the high risk associated with the development of new drugs, we probability adjust the revenue and expense forecasts to reflect the risk of advancement through the regulatory approval process based on the stage of development in the regulatory process. Such a valuation requires significant estimates and assumptions. We believe the fair value assigned to the in-process research and development is based on reasonable assumptions. However, these assumptions may be incomplete or inaccurate, and unanticipated events and circumstances may occur. Additionally, estimates for the purchase price allocation may change as subsequent information becomes available. 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. On July 8, 2003, we acquired PowderJect and accounted for the acquisition using the purchase method of accounting. We allocated the purchase price based on fair value of the assets acquired and liabilities assumed. We allocated $122.7 million of the purchase price to purchased in-process research and development, which we charged to operations for the nine months ended September 30, 2003. In the fourth quarter of 2003, upon completion of strategic assessments of the value of certain research and development projects, we revised the allocation of a portion of the purchase price resulting in a $77.4 million decrease to purchased in-process research and development which we credited to operations and which was offset against goodwill. We do not anticipate that there will be any alternative future use for the purchased in-process research and development. In valuing the purchased in-process research and development, we used probability-of-success-adjusted cash flow and a 14% discount rate. Cash flows from projects including those related to (i) certain travel vaccines and (ii) vaccines for allergies were assumed to commence between 2004 and 2012.

Product returns and rebates We have extensive historical information on returns and rebates for our products. Historical

information with respect to actual product returns and rebates is the primary factor assessed in estimating product returns and rebates allowances. In determining the allowance for product returns, we primarily use one of the following methodologies depending on the product: (i) we match the actual returns to the actual sale on a product-by-product basis to assess the historical trend for returns, and based on an analysis of the historical trend, the appropriate return percentage for the current period is then applied to current period sales to arrive at the product returns charge against revenue for the period or (ii) for seasonal products we analyze our actual returns over the previous seasons to arrive at the average actual returns percentage, which is then applied to the current season s sales to arrive at the charge against revenue for the current period. In estimating rebates, we use historical trends to analyze rebates against revenue on a product-by-product basis to arrive at an expected rebate percentage. This expected rebate percentage is applied to current period sales to arrive at the rebates expense for the period. If actual product returns and rebates are greater than our estimates, additional product return and rebates accruals may be required. If actual product returns and rebates are less than our estimates, we may have to reverse certain accruals.

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

Our blood-testing segment includes in part our one-half share in the pretax operating earnings generated by the joint business contractual arrangement with Ortho-Clinical Diagnostics, Inc., a Johnson & Johnson company. Our joint business arrangement with Ortho-Clinical Diagnostics is a contractual arrangement and is not a separate and distinct legal entity. Through our joint business contractual arrangement with Ortho-Clinical Diagnostics, we sell a line of immunodiagnostic tests to detect hepatitis viruses and retroviruses and provide supplemental tests and microplate and chemiluminescent instrument systems to automate test performance and data collection. Prior to the first quarter of 2003, we accounted for revenues relating to non-U.S. affiliate sales on a one-quarter lag, with an adjustment of the estimate to actual in the subsequent quarter. More current information of non-U.S. affiliate sales of our joint business contractual arrangement became available for the three months ended March 31, 2003, and as a result, we are able to recognize revenues relating to non-U.S. affiliate sales on a one-month lag. The effect of this change, net of tax, was an increase to net income by $3.2 million for revenues from the joint business arrangement for the nine months ended September 30, 2003.

**Results of Operations**

*Blood-testing*

| | Three Months Ended September 30, | | Nine Months Ended September 30, | | $ Change | | % Change | |
|---|---|---|---|---|---|---|---|---|
| | 2004 | 2003 | 2004 | 2003 | Three Months | Nine Months | Three Months | Nine Months |
| | ($ in 000 s, except percentages) | | | | | | | |
| Product sales, net: | | | | | | | | |
| Procleix® | $ 63,629 | $ 53,663 | $ 186,104 | $ 141,767 | $ 9,966 | $ 44,337 | 18.6% | 31.3% |
| Ortho-clinical Diagnostics | 7,098 | 6,235 | 19,940 | 19,766 | 863 | 174 | 13.8% | 0.9% |
| | 70,727 | 59,898 | 206,044 | 161,533 | 10,829 | 44,511 | 18.1% | 27.6% |
| Revenue from joint business arrangement | 34,017 | 26,058 | 92,910 | 79,985 | 7,959 | 12,925 | 30.5% | 16.2% |
| Collaborative agreement revenues | 1,616 | 2,103 | 6,005 | 6,393 | (487) | (388) | (23.2)% | (6.1)% |
| Royalty and license fee revenues | 34,115 | 20,576 | 66,817 | 59,372 | 13,539 | 7,445 | 65.8% | 12.5% |
| Other revenues | 243 | | 673 | | 243 | 673 | 100.0% | 100.0% |
| Total blood-testing revenues | $ 140,718 | $ 108,635 | $ 372,449 | $ 307,283 | $ 32,083 | $ 65,166 | 29.5% | 21.2% |
| | | | | | | | | |
| Gross profit margin | 43% | 40% | 42% | 42% | | | | |
| Research and development | $ 8,387 | $ 5,947 | $ 19,754 | $ 16,731 | $ 2,440 | $ 3,023 | 41.0% | 18.1% |
| Selling, general and administrative | $ 11,077 | $ 9,661 | $ 30,657 | $ 27,217 | $ 1,416 | $ 3,440 | 14.7% | 12.6% |

**Product sales**

*Procleix*® 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 eSAS system. Under a collaboration agreement

with Gen-Probe, we market and sell the Procleix® HIV-1/ HCV Assay, the Procleix Ultrio Assay and the related instrument system. In addition to selling directly in the U.S., we also sell in various European and Asia / Pacific markets, directly and through distributors. We record revenue based upon the reported results obtained from the customer from the use of assays to screen donations or upon sale and delivery of the assays, depending on the underlying contract. In the case of equipment sales or leases, we record revenue upon the sale and transfer of the title of the instrument or ratably over the life of the lease term, respectively. For 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, 2004 as compared with the three months ended September 30, 2003 was primarily due to $5.6 million from continued penetration into several markets abroad and $4.3 million from the U.S. market primarily due to market share gains in the U.S. for the Procleix® HIV-1/ HCV Assay. The increase in product sales for the nine months ended September 30, 2004 as compared with the nine months ended September 30, 2003 was primarily due to (i) $19.2 million for the introduction of the West Nile virus assay on an investigational-use basis in the U.S. in March 2003, (ii) $15.3 million for the continued penetration into several markets abroad and (iii) $9.5 million for market share gains in the U.S. for the Procleix® HIV-1/ HCV Assay.

**Revenue from joint business arrangement** The increase in revenue from joint business arrangement for the three months ended September 30, 2004 as compared with the three months ended September 30, 2003 was primarily due to $6.8 million for an increase in royalties. The increase in revenue from joint business arrangement for the nine months ended September 30, 2004 as compared with the nine months ended September 30, 2003 was primarily due to (i) $8.0 million for an increase in royalties and (ii) $7.6 million for higher profits from Ortho-Clinical Diagnostics U.S. operations and foreign affiliates. These increases were partially offset by a one-time benefit of $4.3 million for the three months ended March 31, 2003 due to a change in estimate from a three-month lag to a one-month lag relating to non-U.S. affiliate sales.

**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 and HIV-related patents, for use in the blood screening and plasma fractionation markets. Our blood-testing segment also earns license fees related to our hepatitis C virus and HIV-related patents for technologies used by third parties to develop products for use in the blood screening and plasma fractionation markets. The increases in royalty and license fee revenues for the three and nine months ended September 30, 2004 as compared to the three and nine months ended September 30, 2003 were primarily due to (i) $10.1 million for the Roche settlement, as described below and (ii) $7.9 million 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. The increases were partially offset by a $4.0 million one-time payment relating to back royalties, which was recognized in the three months ended September 30, 2003, and was estimated under an agreement with Roche relating to back royalties. In addition, the nine months ended September 30, 2003 included a $7.0 million license fee from Baxter A.G. related to our hepatitis C virus and HIV technology for use in the plasma fractionation market.

*German Red Cross Settlement* We have granted a non-exclusive license to the German Red Cross for use of our HIV-1 and hepatitis C virus (HCV) technology for use in molecular probe home brew blood screening through 2008, for a total license fee payment of $22.8 million. Of this license fee payment, $7.9 million was recognized as royalty and license fee revenues in the current quarter, as discussed above, and the remaining balance is expected to be recognized through 2008, as the cancellation privilege in the related agreements expires. In addition, the German Red Cross has the option to license our patents beyond 2008 upon payment of an additional fee. The licensing terms also cover potential past infringements.

*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 the use of our hepatitis C virus and HIV nucleic acid testing intellectual property. Two agreements relate to *in vitro* diagnostic products. See Other Royalty and license fee revenues below. The third agreement for blood screening was superseded in May 2001 by two new agreements, one for each of hepatitis C virus and HIV.

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. 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. Our blood-testing segment had deferred recognition of 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 royalties received prior to March 31, 2004 became non-refundable. For discussion regarding the impact of this settlement on our in vitro diagnostics products, see Other Royalty and license fee revenue below. Accordingly, for the three months ended September 30, 2004, our blood-testing segment recognized revenue of $5.5 million for royalties up until June 30, 2004, which had previously been deferred. Also under the settlement agreement, in the first quarter of 2005, we are entitled to receive 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. The amount of the refund

available decreases in equal quarterly increments over the eight quarters of 2005 and 2006. As such, we expect to recognize $64.0 million of the payment as revenue over those eight quarters. This revenue will be split between our blood-testing segment and our other segment. The remaining $14.0 million is nonrefundable and was recognized as revenue for the three months ended September 30, 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.

The one time impact on revenues for the three and nine months ended September 30, 2004 from these items from the September 10, 2004 settlement with Roche is summarized under Other Royalty and license fee revenues below.

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

**Gross profit margin** Gross profit margin increased for the three months ended September 30, 2004 as compared with the three months ended September 30, 2003 due to a positive impact by an adjustment to cost of goods sold pursuant to our collaboration agreement with Gen-Probe. The blood-testing gross profit margin benefited from an amendment in November 2003 to the worldwide blood screening collaboration agreement between Chiron and Gen-Probe in order to adopt permanent, fixed revenue shares for each party. Effective January 1, 2004, Gen-Probe s share was set at 45.75% of net revenues for assays, which include a test for the hepatitis C virus. For commercial assays, which do not test for hepatitis C virus, such as the West Nile test, the agreement remains unchanged with each party retaining 50% of the net revenues after deduction of specified expenses.

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

**Research and development** The increases in research and development expenses for the three and nine months ended September 30, 2004 as compared to the three and nine months ended September 30, 2003 were primarily due to (i) $1.0 million related to acquisition of in-process technologies, focused primarily on research into variant Creutzfeldt-Jakob disease (vCJD) and (ii) the remainder of the increase is driven by the continued development of nucleic acid testing products.

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

**Selling, general, and administrative** The increases in selling, general and administrative expenses for the three months ended September 30, 2004 as compared to the three months ended September 30, 2003 were primarily due to (i) $0.6 million from the geographic expansion of our customer base for the Procleix® HIV-1/HCV Assay particularly in Latin America and Asia markets and (ii) $0.5 million from the support and pre-launch costs associated with TIGRIS, a fully automated testing system. The increases in selling, general and administrative expenses for the nine

months ended September 30, 2004 as compared to the nine months ended September 30, 2003 were primarily due to (i) $1.6 million from the geographic expansion of our customer base for the Procleix® HIV-1/HCV Assay particularly in Latin America and Asia markets and (ii) $0.9 million from the support and pre-launch costs associated with TIGRIS, a fully automated testing system.

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 | | % Change | |
|---|---|---|---|---|---|---|---|---|
| | 2004 | 2003 | 2004 | 2003 | Three Months | Nine Months | Three Months | Nine Months |
| | ($ in 000 s, except percentages) | | | | | | | |
| Product sales, net: | | | | | | | | |
| Flu vaccines: | | | | | | | | |
| Other Flu vaccines | $ 93,486 | $ 79,960 | $ 106,953 | $ 87,996 | $ 13,526 | $ 18,957 | 16.9% | 21.5% |
| Fluvirin | | 103,290 | 2,445 | 103,290 | (103,290) | (100,845) | (100.0)% | (97.6)% |
| Flu vaccines | 93,486 | 183,250 | 109,398 | 191,286 | (89,764) | (81,888) | (49.0)% | (42.8)% |
| Meningococcus vaccines | 8,865 | 10,642 | 18,430 | 31,876 | (1,777) | (13,446) | (16.7)% | (42.2)% |
| Travel vaccines | 26,434 | 11,229 | 75,705 | 59,981 | 15,205 | 15,724 | 135.4% | 26.2% |
| Pediatric and other vaccines | 44,491 | 57,598 | 143,292 | 133,537 | (13,107) | 9,755 | (22.8)% | 7.3% |
| | 173,276 | 262,719 | 346,825 | 416,680 | (89,443) | (69,855) | (34.0)% | (16.8)% |
| Collaborative agreement revenues | 2,230 | 4,349 | 7,410 | 4,516 | (2,119) | 2,894 | (48.7)% | 64.1% |
| Royalty and license fee revenues | 1,213 | 3,023 | 3,888 | 9,550 | (1,810) | (5,662) | (59.9)% | (59.3)% |
| Other revenues | 3,006 | 2,679 | 12,563 | 8,688 | 327 | 3,875 | 12.2% | 44.6% |
| Total Vaccines revenues | $ 179,725 | $ 272,770 | $ 370,686 | $ 439,434 | $ (93,045) | $ (68,748) | (34.1)% | (15.6)% |
| | | | | | | | | |
| Gross profit margin | 11% | 58% | 22% | 56% | | | | |
| Research and development | $ 30,985 | $ 35,298 | $ 97,313 | $ 82,693 | $ (4,313) | $ 14,620 | (12.2)% | 17.7% |
| Selling, general and administrative | $ 44,806 | $ 43,419 | $ 119,696 | $ 90,240 | $ 1,387 | $ 29,456 | 3.2% | 32.6% |
| Amortization expense | $ 14,326 | $ 13,604 | $ 44,352 | $ 16,497 | $ 722 | $ 27,855 | 5.3% | 168.8% |

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

*Flu vaccines* As described above under Overview, as a result of recent developments with respect to Fluvirin, we had no Fluvirin sales in the three or nine months ended September 30, 2004 (other than, with respect to the nine months ended September 30, $2.4 million in late 2003-2004 season sales). Sales of Fluvirin influenza vaccine were $103.3 million for the three and nine months ended September 30, 2003. Sales of our remaining flu vaccines increased in the three and nine months ended September 30, 2004 as compared with the three and nine months ended September 30, 2003 primarily due to approximately $5.1 million for the favorable movement in the Euro to U.S. Dollar exchange rate as well as price increases.

*Meningococcus vaccines* The decrease in meningococcus vaccines sales for the three months ended September 30, 2004 as compared to the three months ended September 30, 2003 was primarily due to a reduction of $8.0 million in sales of Menjugate® product due to the timing of outbreaks and vaccination programs in various countries and increased competition for tender sales. This decrease was partially offset by sales in 2004 of $6.2 million of MeNZB meningococcal B vaccine to the Ministry of Health in New Zealand. The decrease in meningococcus vaccines sales for the nine months ended September 30, 2004 as compared to the nine months ended September 30, 2003 was primarily due to a reduction of $19.6 million in sales of Menjugate® product due to the timing of outbreaks and vaccination programs in various countries and increased competition for tender sales of certain meningococcus vaccines, which was partially offset by the $6.2 million MeNZB sales in 2004 to the Ministry of Health in New Zealand.

*Travel vaccines* The increase in travel vaccines sales for the three months ended September 30, 2004 as compared with the three months ended September 30, 2003 was primarily due to (i) $5.4 million driven by increased demand for our rabies vaccines in the U.S., primarily due to a product recall from a competitor and (ii) $8.2 million driven by increased sales of our tick-borne encephalitis vaccines, which is typically sold in the first half of the year. The increase in travel vaccines sales for the nine months ended September 30, 2004 as compared with the nine months ended September 30, 2003 was primarily due to (i) increased demand for our rabies vaccines in the U.S., primarily due to a product recall from a competitor and increased demand for our rabies vaccines in Europe and Asia, in the amount of $12.9 million and (ii) additional sales of travel vaccine products in the amount of $5.1 million reflecting the fact that the nine months ended September 30, 2003 represented only approximately one quarter s worth of sales of certain travel vaccines acquired as part of the PowderJect acquisition. The increase in travel vaccines for the nine months ended September 30, 2004 as compared with the nine months ended September 30, 2003 were partially offset by $9.3 million in lower sales of our tick-borne encephalitis vaccine. Such lower sales of tick-borne encephalitis vaccine for the nine months ended September 30, 2004 were due to higher sales in the fourth quarter of 2003, which is typically sold in the first half of the year.

*Pediatric and other vaccines* Sales of our pediatric and other vaccines decreased for the three months ended September 30, 2004 as compared with the three months ended September 30, 2003 primarily due to (i) a reduction of $7.2 million due to the planned divestiture of certain vaccines operations in Sweden in the second quarter 2004 acquired via our acquisition of PowderJect and (ii) a reduction of $2.9 million due to the timing of tender sales for our

diphtheria, tetanus and pertussis vaccines. Sales of our pediatric and other vaccines increased for the nine months ended September 30, 2004 as compared with nine months September 30, 2003 primarily due to an additional $12.6 million related to the timing of tender sales for our polio vaccines and diphtheria, tetanus and pertussis vaccines, offset partially by $4.5 million due to the timing of tender sales for our measles, mumps and rubella vaccines.

Certain of our vaccine products are seasonal, particularly our flu vaccines, which have higher sales primarily in the second 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. Due to the Fluvirin recent developments described above, we expect no sales of Fluvirin influenza vaccine for the 2004-2005 season. There can be no assurance that we will resume manufacturing or sale of Fluvirin for the 2005-2006 season or future seasons. In addition, we expect Menjugate® sales to continue to fluctuate as public health authorities consider adoption of broad vaccination programs and competitive pressures continue to increase.

We expect competitive pressures related to our Menjugate® product to continue into the future. In addition, we expect increased competition for our flu vaccines business in the future.

**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, 2004 as compared with the three months ended September 30, 2003 decreased primarily due to lower milestone payments 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, 2004 as compared with the nine months ended September 30, 2003 increased primarily due to (i) $1.5 million due to higher milestone payments related to an agreement to supply MeNZB meningococcal B vaccine to the Ministry of Health in New Zealand and (ii) $1.4 million due to increased collaborative agreement revenues following our acquisition of PowderJect.

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

**Royalty and license fee revenues** Our vaccines segment earns royalties on third party sales of, and license fees on, several products.

*GlaxoSmithKline* An agreement with GlaxoSmithKline plc provides for royalties on sales of certain vaccine products. Under this agreement, royalties were $0.8 million and $1.8 million for the three months ended September 30, 2004 and 2003, respectively. Royalties were $2.1 million and $5.2 million for the nine months ended September 30, 2004 and 2003, respectively. These decreases were primarily due to the expiration of various patents under this agreement.

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

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

**Other revenues**

*Grant and contract revenues* Our vaccines segment other revenues included grant and contract revenues of $10.2 million and $6.9 million for the nine months ended September 30, 2004 and 2003, respectively. We have entered into a series of agreements with the U.S. National Institutes of Health to advance our HIV vaccine program into human clinical trials. We recognized grant and contract revenues under these arrangements of $6.8 million and $6.1 million for the nine months ended September 30, 2004 and 2003, respectively.

The balance of other revenues consisted of various other agreements, which individually were not material.

Other revenues recognized in our vaccines segment may fluctuate due to the nature of the revenues recognized and the timing of events giving rise to these revenues.

**Gross profit margin** Gross profit margin declined for the three months ended September 30, 2004 as compared with the three months ended September 30, 2003 due to (i) the fact that there were no sales of Fluvirin in the third quarter of 2004 and (ii) a $91.3 million charge to cost of sales resulting from the write-off of our entire inventory of Fluvirin. Each of these matters is described in more detail under Overview. Gross profit margin for the three months ended September 30, 2004 benefited from higher prices of our other flu vaccines products and increased sales of our rabies vaccine in the U.S. market. Gross profit margin decreased for the nine months ended September 30, 2004 as compared with the nine months ended September 30, 2003 primarily due to the Fluvirin matters described above. Gross profit margin was also negatively impacted by reduced sales and margins of the Menjugate® product and reduced sales of our tick-borne encephalitis vaccine. These decreases were offset by higher prices of our other flu vaccines products and increased sales of our rabies vaccine in the U.S. market.

Vaccines gross profit margin does not include amortization expense from acquired developed products, intangible assets related to business combinations. Such amortization expense is included in the caption amortization expense discussed below.

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** The decrease in research and development expenses for the three months ended September 30, 2004 as compared to the three months ended September 30, 2003 was due to the planned divestiture of certain research operations, associated with our acquisition of PowderJect, in Madison, Wisconsin and Oxford, England during the second quarter of 2004. Research and development expense associated with these operations was approximately $6.3 million for the three months ended September 30, 2003. The increase in research and development expenses for the nine months ended September 30, 2004 as compared to the nine months ended September 30, 2003 was primarily due to the advancement of several programs in our meningococcal franchise (an additional $6.1 million) and flu cell culture (an additional $5.8 million).

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

**Selling, general, and administrative** The increase in selling, general and administrative expenses for the three months ended September 30, 2004 as compared with the three months ended September 30, 2003 was due to (i) an additional $2.9 million from ongoing sales and marketing programs, (ii) $2.9 million for headcount additions, (iii) $1.1 million due to the movement in the Euro and British pound to U.S. Dollar exchange rate and (iv) other increases of $1.8 million, partially offset by a decline in PowderJect integration costs of $5.3 million and savings of $2.0 million from the second quarter 2004 divestiture of certain PowderJect operations. The increase in selling, general and administrative expenses for the nine months ended September 30, 2004 as

compared with the nine months ended September 30, 2003 was primarily related to additional expenses of $10.1 million attributable to our third quarter 2003 PowderJect acquisition. The remaining increase in selling, general and administrative resulted from $5.1million associated with ongoing sales and marketing programs, $12.8 million for headcount additions and other increases of $2.1 million. These increases were partially offset by savings of $0.6 million from the second quarter 2004 divestiture of certain PowderJect operations.

**Amortization expense** The increase in amortization expense for the nine months ended September 30, 2004 as compared with the nine months ended September 30, 2003 primarily related to the intangible assets acquired following our third quarter 2003 PowderJect acquisition.

***Biopharmaceuticals***

| | Three Months Ended September 30, | | Nine Months Ended September 30, | | $ Change | | % Change | |
|---|---|---|---|---|---|---|---|---|
| | 2004 | 2003 | 2004 | 2003 | Three Months | Nine Months | Three Months | Nine Months |
| | ($ in 000s, except percentages) | | | | | | | |
| Product sales, net: | | | | | | | | |
| Betaseron® | $ 35,171 | $ 29,010 | $ 96,933 | $ 88,788 | $ 6,161 | $ 8,145 | 21.2% | 9.2 |
| TOBI® | 55,734 | 43,022 | 159,600 | 122,740 | 12,712 | 36,860 | 29.5% | 30.0 |
| Proleukin® | 31,739 | 29,859 | 98,664 | 85,223 | 1,880 | 13,441 | 6.3% | 15.8% |
| Other | 8,902 | 8,166 | 29,770 | 22,258 | 736 | 7,512 | 9.0% | 33.7% |
| | 131,546 | 110,057 | 384,967 | 319,009 | 21,489 | 65,958 | 19.5% | 20.7% |
| Collaborative agreement revenues | 278 | 1,364 | 1,052 | 4,645 | (1,086) | (3,593) | (79.6)% | (77.4)% |
| Royalty and license fee revenues | 15,412 | 23,523 | 47,892 | 62,098 | (8,111) | (14,206) | (34.5)% | (22.9)% |
| Other revenues | 1,201 | 5,009 | 9,127 | 23,794 | (3,808) | (14,667) | (76.0)% | (61.6)% |
| Total Biopharmaceutical revenues | $ 148,437 | $ 139,953 | $ 443,038 | $ 409,546 | $ 8,484 | $ 33,492 | 6.1% | 8.2% |
| Gross profit margin | 67% | 74% | 72% | 75% | | | | |
| Research and development | $ 63,252 | $ 56,089 | $ 183,627 | $ 169,827 | $ 7,163 | $ 13,800 | 12.8% | 8.1% |
| Selling, general and administrative | $ 33,322 | $ 29,818 | $ 98,496 | $ 84,723 | $ 3,504 | $ 13,773 | 11.8% | 16.3% |
| Amortization expense | $ 6,240 | $ 6,217 | $ 18,725 | $ 18,638 | $ 23 | $ 87 | 0.4 | 0.5% |

**Product sales** Biopharmaceutical product sales in 2004 and 2003 consisted principally of Betaseron®, TOBI® and Proleukin®.

*Betaseron® interferon beta-1b* We manufacture interferon beta-1b which is marketed by Schering AG and its affiliates, including Berlex Laboratories, Inc. (collectively Schering ), under the trade names Betaseron® (in the U.S and other non-European markets) and Betaferon® (in Europe). Boehringer Ingelheim also supplies Betaferon® to Schering for sale in Europe. For product manufactured by us, we recognize a portion of revenue for product sales upon shipment to Schering and the remainder based on a contractual percentage of sales by Schering, both of which we record as product sales. For product manufactured by Boehringer Ingelheim and marketed by Schering in Europe under the trade name Betaferon®, we receive royalties calculated at the same percentage of sales less the amount paid or incurred by Schering for supply costs, which we record in royalty and license fee revenues. Starting in the fourth quarter 2003, the amount we record as product sales, based on a percentage of sales by Schering, and Betaferon®

royalties, declined by five percentage points pursuant to our contractual agreement with Schering. As a result, we estimate that the percentage of sales per unit on which our payments are based will decrease, reducing our per unit revenue by approximately 18% (for sales of Chiron product) and approximately 34% (for royalties from sales of Boehringer Ingelheim product) from that received prior to the decline. However, there are a number of mitigating considerations, including (i) the transitional supply agreement, (ii) the volume mix of Chiron product and Boehringer Ingelheim product and (iii) the launch of product upgrades with ease-of-use features. We believe these considerations will partially offset this contractual change. In order to supply Betaferon® to Schering, we continue to make capital improvements to our existing manufacturing facilities to increase capacity.

In October 2003, the U.S. Food and Drug Administration approved a new pre-filled diluent syringe for Betaseron®. The pre-filled diluent syringe was launched in January 2004 and enhances the delivery mode and shortens preparation, helping to simplify injections of Betaseron®.

The increase in Betaseron® product sales for the three months ended September 30, 2004 as compared with the three months ended September 30, 2003 primarily related to an additional (i) $9.5 million from inventory ordering patterns and (ii) $1.8 million from patient demand attributed to key marketing programs. These increases were partially offset by a $6.3 million reduction due to a decline in the royalty rate by five percentage points pursuant to our contractual agreement with Schering. The increase in Betaseron® product sales for the nine months ended September 30, 2004 as compared to the nine months ended September 30, 2003 primarily related to an additional (i) $7.5 million from inventory ordering patterns, (ii) $6.4 million from price increases, (iii) $6.3 million from increased patient demand attributed to key marketing programs, (iv) $2.7 million from increased sales of clinical materials and

(iv) $2.3 million from the benefit of foreign exchange rates. These increases were partially offset by a $17.1 million reduction due to a decline in the royalty rate by five percentage points pursuant to our contractual agreement with Schering.

*TOBI® tobramycin* We sell TOBI® directly in the U.S. and certain international markets. The increase in sales for the three months ended September 30, 2004 as compared to the three months ended September 30, 2003 was primarily due to an additional (i) $4.7 million due to increased patient demand in the U.S., (ii) $4.3 million due to wholesaler ordering patterns, (iii) $2.1 million due to price increases and (iv) $1.3 million due to the benefit of the movement in the Euro to U.S. Dollar exchange rate. The increase in sales for the nine months ended September 30, 2004 as compared to the nine months ended September 30, 2003 was primarily due to an additional (i) $11.9 million due to wholesaler ordering patterns, (ii) $8.8 million due to increased patient demand in the U.S, (iii) $6.4 million due to price increases and (iv) $4.9 million due to favorable movement in the Euro to U.S. Dollar exchange rate.

*Proleukin® (aldesleukin)* The increase in sales for Proleukin (aldesleukin) for the three months ended September 30, 2004 as compared with the three months ended September 30, 2003 was primarily due to price increases. The increase in sales for Proleukin (aldesleukin) for the nine months ended September 30, 2004 as compared with the nine months ended September 30, 2003 was primarily due to an additional (i) $6.3 million due to wholesaler ordering patterns, (ii) $3.7 million from price increases and (iii) $2.3 million due to favorable movement in the Euro to U.S. Dollar exchange rate, partially offset by a $1.2 million reduction due to a decline in patient demand.

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.

**Collaborative agreement revenues** We recognize collaborative agreement revenues for fees received as we perform research services and achieve specified milestones.

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

**Royalty and license fee revenues** Our biopharmaceuticals segment earns royalties on third party sales of several products, including Betaferon® and recombinant insulin and glucagon products. Our biopharmaceuticals segment also earns

license fees for technologies, such as hepatitis C virus-related patents, used by third parties to develop therapeutic products.

*Betaferon® interferon beta-1b* We manufacture interferon beta-1b which is marketed by Schering AG and its affiliates, including Berlex Laboratories, Inc. (collectively Schering ), under the trade names Betaseron® (in the U.S and other non-European markets) and Betaferon® (in Europe). Boehringer Ingelheim also supplies Betaferon® to Schering for sale in Europe. For product manufactured by Boehringer Ingelheim, we receive royalties calculated as a percentage of sales less the amount paid or incurred by Schering for supply costs, including Schering s cost to purchase product from Boehringer Ingelheim.

The decrease in Betaferon® royalties for the three months ended September 30, 2004 as compared with the three months ended September 30, 2003 was primarily due to the reduction in the royalty rate of five percentage points ($5.1 million), pursuant to our contractual agreement with Schering, partially offset by (i) $1.6 million due to an increase in demand and (ii) $1.0 million due to favorable movement in the Euro to U.S. Dollar exchange rate.

The decrease for the nine months ended September 30, 2004 as compared with the nine months ended September 30, 2003 was primarily due to the reduction in the royalty rate of five percentage points ($15.5 million), pursuant to our contractual agreement with Schering, partially offset by (i) $4.5 million due to an increase in demand and (ii) $3.9 million due to favorable movement in the Euro to U.S. Dollar exchange rate.

We began supplying Betaferon®, which was previously supplied by Boehringer Ingelheim, to Schering in the fourth quarter 2002 for certain additional European markets. This resulted in a shift of revenue recognized under this agreement to product sales, with a decrease in royalty revenues, beginning in the fourth quarter 2002. In 2003, Schering extended its supply agreement with Boehringer Ingelheim through 2008. The magnitude of the shift of revenue in the future will be contingent on our production capacity, Schering s minimum purchase commitment under the extended supply agreement with Boehringer Ingelheim and market demand. The shift to product sales is expected to increase over the next three years. Future Betaferon® royalties will be influenced by demand, price changes and foreign currency exchange rates.

*Novo Nordisk* We earn royalty revenues on insulin and glucagon product sales by Novo Nordisk AS. Royalties were $1.0 million for the three months ended September 30, 2004 as compared with $2.3 million for the three months ended September 30, 2003 and $3.4 million for the nine months ended September 30, 2004 as compared with $6.2 million for the nine months ended September 30, 2003. The decreases were due to the expiration of patents beginning in late 2003 related to the production of insulin and glucagons.

The balance of royalty and license fee revenues recognized in our biopharmaceuticals segment consisted of various other

agreements, which individually were not material.

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

**Other revenues**

*Contract manufacturing revenues* Our biopharmaceuticals segment recognized contract manufacturing revenues of $1.1 million and $4.7 million for the three months ended September 30, 2004 and 2003, respectively, and $8.6 million and $7.8 million for the nine months ended September 30, 2004 and 2003, respectively. The fluctuation resulted from the level of activity and the timing of contract manufacturing activities.

*Biogen and Serono settlements* As a result of a favorable federal court decision and prior agreements between Chiron and AG s U.S. subsidiary, Berlex Laboratories, and Berlex and Biogen, Biogen was required to make a settlement payment to Schering. In accordance with an earlier contract between Chiron and Berlex, we recognized approximately $13.0 million as revenue during the nine months ended September 30, 2003, which represented our share of this settlement payment. In addition, there was a similar settlement between Berlex and Serono, S.A. of which we recognized approximately $1.4 million during the nine months ended September 30, 2003.

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

Other revenues recognized in our biopharmaceuticals segment may fluctuate due to the nature of the revenues recognized and the timing of events giving rise to these revenues. We cannot guarantee that we will be successful in obtaining additional revenues or that these revenues will not decline.

**Gross profit margin** The decreases in gross profit margin for the three and nine months ended September 30, 2004 as compared to the three and nine months ended September 30, 2003 were primarily due to the contractual change in the royalty rate related to the sale of Betaseron® and the increased costs associated with the pre-filled diluent syringe for Betaseron®.

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

Biopharmaceutical gross profit margin may fluctuate significantly in future periods due to production yields, increased cost to produce the Betaseron® pre-filled diluent syringe, the decline in Betaseron® product sales, based on a percentage of sales by Schering, which decreased by five percentage points pursuant to our contractual agreement with Schering and as the biopharmaceutical product and customer mix changes.

**Research and development** The increase in research and development costs for the three months ended September 30, 2004 as compared with the three months ended September 30, 2003 was primarily the result of activities related to the development of tifacogin, as discussed below.

The increase in research and development costs for the nine months ended September 30, 2004 as compared with the nine months ended September 30, 2003 was primarily the result of activities related to the development of tifacogin, as discussed below, (an additional $28.1 million). These increases were partially offset by (i) a reduction of $9.0 million due to the discontinuance of development of tezacitabine in the first quarter of 2004 based on an analysis of the data from a Phase II trial in patients with gastroesophageal cancer and a decline of $8.4 million in spending due to discontinuance of development of PA-2794.

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. Our research and development expenses related to the SILCAAT trial have decreased for the three and nine months ended September 30, 2004 as a result of the transfer. 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 $12.0 million has been paid through September 30, 2004.

In October 2003, we acquired all of Pfizer, Inc. s, formerly Pharmacia Corporation s, interest in tifacogin, in return for which Pfizer will receive royalties on future sales of tifacogin. In the second quarter 2004, we began enrolling patients in our Phase III trial for tifacogin as a treatment for patients with severe community-acquired pneumonia.

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

**Selling, general, and administrative** The increase in selling, general and administrative expenses for the three months ended September 30, 2004 as compared with the three months ended September 30, 2003 was primarily due to $1.5 million for programs and headcount in support of TOBI® and $ 1.0 million for the Euro to U.S. Dollar exchange rate fluctuation. The increase for

the nine months ended September 30, 2004 as compared with the nine months ended September 30, 2003 was primarily due to (i) $3.3 million for the Euro to U.S. Dollar exchange rate fluctuation, (ii) $2.3 million for increased expenses for programs and headcount in support of TOBI and (iii) $2.3 million for expenses to enhance business processes.

***Other***

| | Three Months Ended September 30, | | Nine Months Ended September 30, | | $ Change | | % Change | |
|---|---|---|---|---|---|---|---|---|
| | 2004 | 2003 | 2004 | 2003 | Three Months | Nine Months | Three Months | Nine Months |
| | ($ in 000 s, except percentages) | | | | | | | |
| Royalty and license fee revenues | $ 60,656 | $ 19,115 | $ 102,787 | $ 55,517 | $ 41,541 | $ 47,270 | 217.3% | 85.1% |
| Selling, general and administrative | 25,326 | 22,920 | 77,279 | 56,906 | 2,406 | 20,373 | 10.5% | 35.8% |
| Interest expense | 7,063 | 6,222 | 19,440 | 12,523 | 841 | 6,917 | 13.5% | 55.2% |
| Interest and other income, net | 5,369 | 5,239 | 41,252 | 31,170 | 130 | 10,082 | 2.5% | 32.3% |

**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 related to the use of our hepatitis C virus 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 hepatitis C virus and HIV nucleic acid testing intellectual property. Two agreements relate to *in vitro* diagnostics products. The third agreement relates to blood screening. See Blood Testing Royalty and license fee revenues above for more information on these agreements.

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 hepatitis C virus-related patent in its *in vitro* diagnostic products. The agreement also provides for royalties on future sales related to Roche s use of our hepatitis C virus-related patent in its *in vitro* diagnostic products, which commenced in the first quarter 2001. Royalty revenues increased for the nine months ended September 30, 2004 as compared with the nine months ended September 30, 2003, by $4.6 million and 13.3%.

The HIV agreement also 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 increased by $37.4 million for the three months ended September 30, 2004 as compared with the three months ended September 30, 2003, and $37.8 million for the nine months ended September 30, 2004 as compared with the nine months ended September 30, 2003. These increases are mainly due to a settlement agreement with Roche, described in more detail below, in which we recognized revenues for a license fee, deferred royalties and a portion of a nonrefundable royalty payment.

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, for the three months ended September 30, 2004, we have 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. We also recognized $0.8 million in interest on the license fee. Also under the settlement agreement, in the first quarter of 2005, we are entitled to receive 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 decreases in equal quarterly increments over the eight quarters of 2005 and 2006. As such, Chiron expects to recognize $64.0 million of the payment as revenue over those eight quarters. The remaining $14.0 million is nonrefundable and was recognized as revenue for the three months ended September 30, 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.

The one time impact on revenues for the three and nine months ended September 30, 2004 from these items 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 one time royalty and license fee revenue | $ 35,646 | $ 10,120 | $ 45,766 |

Currently, the applicable issued hepatitis C virus-related patents expire in 2015 for the U.S. and in 2010 for Europe. Currently, the applicable issued HIV-related patent in Europe expires in 2005.

*Roche PCR agreement* For the three and nine months ended September 30, 2004, we recognized a $3.0 million settlement with Roche regarding a July 1991 agreement between Roche and Cetus Corporation (a company acquired by us) under which we received royalties on sales of polymerase chain reaction products and services sold by Roche and its licensees. Roche s royalty obligations, with certain limited exceptions for future products, expired in the fourth quarter of 2000.

*Bayer* A cross-license agreement provides for royalties to us on HIV and hepatitis C virus products sold by Bayer Corporation. Royalties were consistent for the three months ended September 30, 2004 as compared with the three months ended September 30, 2003. Royalties increased $1.2 million for the nine months ended September 30, 2004 as compared with the nine months ended September 30, 2003.

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

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

**Selling, general, and administrative** The increase in selling, general and administrative expenses for the three months ended September 30, 2004 as compared with the three months ended September 30, 2003 was primarily due to an increase in litigation costs of $4.1 million related to the defense of our patents and technology and an increase in information systems costs of $1.8 million, offset by a $3.5 million reduction in employee related expenses. The increase in selling, general and administrative expenses for the nine months ended September 30, 2004 as compared with the nine months ended September 30, 2003 was primarily due to an increase in litigation costs of $8.4 million related to the defense of our patents and technology, an increase in facility related costs of $7.1 million, an increase in information systems costs of $3.5 million, and an increase in corporate governance costs of $1.7 million, partially offset by lower employee related expenses of $1.8 million.

**Interest expense** The increase in interest expense for the nine months ended September 30, 2004 as compared to the nine months ended September 30, 2003 primarily related to the effect of nine months versus two months of interest

expense recognized on the $500.0 million convertible debentures that were issued on July 30, 2003. The interest expense on the LYONs decreased significantly when the majority of the LYONs were put to us in June 2004. However, interest expense increased due to interest on the $385.0 million convertible debentures that were issued on June 22, 2004.

**Interest and other income, net** Interest and other income, net, primarily consisted of interest income on our cash and investment balances and other non-operating gains and losses. We recognized interest income of $6.6 million and $5.4 million for the three months ended September 30, 2004 and 2003, respectively, and $17.5 million and $18.7 million for the nine months ended September 30, 2004 and 2003, respectively. Interest income varied due to the fluctuating cash balances from the acquisition of PowderJect and the retirement and issuance of long-term debt.

We recognized gains of $1.0 million and $0.0 million for the three months ended September 30, 2004 and 2003, respectively, and $25.0 million and $9.4 million for the nine months ended September 30, 2004 and 2003, respectively, related to the sale of certain equity securities.

On December 31, 1998, we completed the sale of our 30% interest in General Injectibles & Vaccines, Inc., a distribution business, to Henry Schein, Inc. and received payment in full of certain advances we made to General Injectibles & Vaccines. The agreement also provided for us to receive additional payments, calculated as a pre-determined percentage of Henry Schein s gross profit, through 2003. We received $3.5 million for 2003 and $2.0 million for 2002 during the nine months ended September 30, 2004 and 2003, respectively.

There were no losses attributable to impairment of equity securities for the three and nine months ended September 30, 2003. 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.

**Income taxes** The effective tax rate for the three and nine months ended September 30, 2004 was 31.0% and 27.3% respectively, of pretax income from continuing operations, including the charge for purchased in-process research and development related to the Sagres acquisition. The effective tax rate for the three and nine months ended September 30, 2003 was 243.6% and 42.3% respectively, of pretax income from continuing operations, including the charge for purchased in-process research and development related to the PowderJect acquisition. The charges for the purchased in-process research and development in 2003 and

2004 are not tax deductible. The effective tax rate for the three and nine months ended September 30, 2004 and 2003 was 25% of pretax income from continuing operations, after excluding the impact of the purchased in-process research and development charges. The effective tax rate may be affected in future periods by changes in management s estimates with respect to our deferred tax assets and other items affecting the overall tax rate.

Management believes the acquisition of PowderJect may cause an increase in the future effective tax rate and is in the process of evaluating certain options that may mitigate any potential increase. Specifically, most of PowderJect s profits are earned in the United Kingdom subject to a 30% marginal 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 and Chiron Vision in 1998 and 1997, respectively.

Chiron and Bayer Corporation, or 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 excess following this settlement. This settlement resulted in a net gain of $12.8 million, which was included in Gain (loss) from discontinued operations 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.

In the second quarter 2004, Chiron and the IRS entered into a settlement agreement closing the open tax years 1996 to 1998. Pursuant to this settlement agreement we recognized a tax benefit of approximately $12.5 million, which was included in Gain (loss) from discontinued operations for the nine months ended September 30, 2004.

In the third quarter 2003, we reversed approximately $1.2 million, net of tax, related to unutilized reserves for Chiron Diagnostics, which was included in Gain (loss) from discontinued operations for the three and nine months ended September 30, 2003.

In the first quarter 2003, Chiron and Bayer reached a settlement agreement relating to certain claims raised by Bayer under the Stock Purchase Agreement dated September 17, 1998, between Chiron and Bayer for Chiron Diagnostics. Under this settlement agreement, we were required to make a payment to Bayer during the first quarter 2003. Pursuant to this settlement, we recorded a charge, net of adjustment to our previously provided reserve for indemnity obligations, of $7.6 million, offset by an income tax benefit of $9.0 million, resulting in a net gain of $1.4 million which was included in Gain (loss) from discontinued operations for the nine months ended September 30, 2003.

**New Accounting Pronouncements**

In October 2004, the Emerging Issues Task Force (EITF) reached a consensus on EITF Issue No. 04-8 The Effect of Contingently Convertible Instruments on Diluted Earnings per Share, that the dilutive effect of contingent convertible debt instruments ( CoCo s ) must be included in diluted earnings per share regardless of whether the triggering contingency has been satisfied, if dilutive. Adoption of Issue No. 04-8 would be on a retroactive basis and would require restatement of prior period diluted earnings per share, subject to certain transition provisions. It is effective for all periods ending after December 15, 2004. Accounting pursuant to this Issue would not result in additional dilution to our diluted

earnings per share for the three and nine months ended September 30, 2004 from our $500.0 million convertible debentures due 2033 ( 2033 Debentures ) nor from our $385.0 million convertible debentures due 2034 ( 2034 Debentures ).

Financial Accounting Standards Board (or FASB) Interpretation No. 46 (or FIN 46), Consolidation of Variable Interest Entities, an interpretation of Accounting Research Bulletin No. 51 as revised, requires a variable interest entity (or VIE) to be consolidated by a company if that company absorbs a majority of the VIE s expected losses, receives a majority of the entity s expected residual returns, or both, as a result of ownership, contractual or other financial interest in the VIE. Prior to the adoption of FIN 46, VIEs were generally consolidated by companies owning a majority voting interest in the VIE. The consolidation requirements of FIN 46 applied immediately to VIEs created after January 31, 2003; however, the FASB deferred the effective date for VIEs created before February 1, 2003 to the quarter ended March 31, 2004 for calendar year companies. Adoption of the provisions of FIN 46 prior to the deferred effective date was permitted.

We adopted the remaining provisions of FIN 46 in the first quarter of 2004. The adoption of these provisions did not have a material effect on our condensed consolidated financial statements.

On March 31, 2004, the FASB issued an Exposure Draft (ED), Share-Based Payment An Amendment of FASB Statements No. 123 and 95. The proposed Statement addresses the accounting for transactions in which an enterprise receives employee services in exchange for (a) equity instruments of the enterprise or (b) liabilities that are based on the fair value of the enterprise s equity instruments or that may be settled by the issuance of such equity instruments. The proposed Statement would eliminate the ability to account for share-based compensation transactions using APB 25, and generally would require instead that such transactions be accounted for using a fair-value based method. As proposed, companies would be required to recognize an expense for compensation cost related to share-based payment arrangements including stock options and employee stock purchase plans. As proposed, the new rules would be applied on a modified prospective basis as defined in the ED, and would be effective for us beginning July 1, 2005. We are currently evaluating option valuation methodologies and assumptions in light of the evolving accounting standards related to employee stock options. Current estimates of option values using the Black-Scholes method may not

be indicative of results from valuation methodologies ultimately adopted in the final rules.

**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 $1,012.3 million at September 30, 2004, are invested in a diversified portfolio of financial instruments, including money market funds and instruments, corporate notes and bonds, government or government agency securities and other debt securities issued by financial institutions and other issuers with strong credit ratings. By policy, the amount of credit exposure to any one institution is limited. Investments are generally not collateralized and primarily mature within three years.

Subsequent to the third quarter of 2004, the UK regulatory body, the Medicines and Healthcare products Regulatory Agency, or MHRA, sent us a letter prohibiting us from releasing any Fluvirin doses manufactured at our Liverpool facility since March 2, 2004. In that letter, the MHRA asserted that our manufacturing process did not comply with U.K. good manufacturing practices (GMP) regulations. In addition to prohibiting release of existing Fluvirin doses, the MHRA letter also suspended our license to manufacture influenza virus vaccine in our Liverpool facility for three months. Following the MHRA s decision, the FDA conducted its own inspection of our Liverpool facility and provided a written report citing FDA observations concerning GMP compliance and other matters relating to the manufacturing of Fluvirin. The FDA also announced that it would not permit release of any Fluvirin from our Liverpool facility into the United States. We cannot predict if or when we will be able to resume production of Fluvirin at our Liverpool facility. Any significant extension of the suspension could result in our being unable to release Fluvirin for the 2005-2006 season, which would diminish or eliminate any cash flows we receive from the sale of Fluvirin. Sales of Fluvirin influenza vaccine were $219.2 million in 2003. In addition, while we are still in the process of assessing the appropriate corrective steps for our Liverpool plant, our remediation efforts could entail cash payments for additional capital and other expenditures, which could be material. If we suffer a permanent loss of Fluvirin influenza vaccine sales, it would have a material adverse effect on our cash flow.

We are subject to investigations and litigation in connection with this matter. We have received a grand jury subpoena issued by the U.S. Attorney s Office for the Southern District of New York requesting production of certain documents and materials relating to our influenza virus vaccine and the suspension by the MHRA of our license. The Securities and Exchange Commission is also conducting an informal inquiry into whether we have violated any federal securities laws. Additional investigations regarding these matters may arise, including Congressional investigations. We and certain of our officers and directors have also been named as defendants in several putative class action and shareholder derivative lawsuits arising out of these developments. We are in the process of addressing these investigations and litigation, which may entail substantial expense, and the results of which could have a material adverse effect on our consolidated financial position and results of operations or cash flows. It is not known when or on what basis these matters will be concluded.

For additional information concerning the risks we face as a result of these Fluvirin developments, see Factors That May Affect Future Results The recent developments with respect to Fluvirin will harm our business and results of operations. For additional information on the U.S. Attorney s investigation, SEC inquiry and private lawsuits, see Part II, Item 1 of this report on Form 10-Q.

On June 12, 2004, certain holders of our Liquid Yield Option Notes (LYONs), at their option, tendered LYONs with $649.9 million in aggregate principal amount at maturity, which we were required to purchase. The purchase price for the tendered LYONs was $584.31 in cash per $1,000 in principal amount at maturity. The aggregate purchase price for all the LYONs validly surrendered for purchase was $379.7 million. At September 30, 2004, there remains $80.1 million outstanding in aggregate principal amount at maturity with a current accreted balance of $47.1 million.

On June 22, 2004, we issued $385.0 million aggregate principal amount of new convertible debentures, which mature on June 30, 2034. The convertible debentures accrue interest at a rate of 2.75% per year with interest payable each June 30 and December 30 commencing December 30, 2004. The debentures are senior, unsecured obligations and rank equal in right of payment with all of our existing and future unsecured and unsubordinated indebtedness.

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, 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 influenza vaccine sales, it would have a material adverse effect on our cash flow.

**Sources and uses of cash** We had cash and cash equivalents of $201.0 million and $499.9 million at September 30, 2004 and 2003, respectively.

*Operating activities* For the nine months ended September 30, 2004, net cash provided by operating activities was $132.6 million as compared with $253.9 million for the nine months ended September 30, 2003. The decrease in cash provided by operating activities was primarily due to lower income from continuing operations before depreciation, amortization and other non-cash charges as a result of the suspension of our license to manufacture Fluvirin® influenza virus vaccine in our Liverpool facility which prevented the release of any of the product during the 2004-2005 influenza season. Cash provided by operating activities also decreased due to (i) lower royalty payments received under the Roche royalty arrangements for the nine months ended September 30, 2004 as opposed to the nine months ended September 30, 2003, (ii) increased research and development costs and increased selling,

general and administrative expenses for the nine months ended September 30, 2004 and (iii) $14.4 million of cash received as a result of the Biogen and Serono settlements in connection with the McCormick patents in the nine months ended September 30, 2003. These decreases were offset by lower tax payments for the nine months ended September 30, 2004 as compared to the nine months ended September 30, 2003 and a payment to Bayer Corporation during the nine months ended September 30, 2003 from a settlement agreement relating to certain claims raised by Bayer in connection with the Stock Purchase Agreement dated September 17, 1998.

*Investing activities* 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 $3.7 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.

In 2003, our Board of Directors approved $50.7 million in expenditures for a 25-year building lease and $42.2 million for capital improvements, both of which are part of a $97.0 million project for expansion and replacement of our flu vaccines manufacturing facility in Liverpool, England. The new manufacturing facility will replace a portion of the existing flu vaccines manufacturing facilities in Liverpool, England and is anticipated to be available in late 2007 for the manufacture of flu vaccines, subject to regulatory approval. In December 2003, we entered into a 25-year lease for the building; as of September 30, 2004, we have incurred $6.8 million for the capital improvements portion of the project. Management does not currently expect the recent Fluvirin developments to impact the timing of this project.

For the nine months ended September 30, 2003, net cash used in investing activities consisted of cash paid for acquisitions, net of cash acquired of $804.7 million, purchases of investments in marketable debt securities of $622.7 million, capital expenditures of $81.4 million, purchases of equity securities and interests in affiliated companies of $4.3 million and other uses of cash of $12.2 million. For the nine months ended September 30, 2003, cash paid for acquisitions, net of cash acquired, primarily consisted of cash paid to acquire PowderJect Pharmaceuticals, net of cash acquired, of $803.5 million. Cash used in investing activities was offset by proceeds from sales of investments in marketable debt securities of $748.0 million, proceeds from the maturities of investments in marketable debt securities of $364.7 million and proceeds from the sale of equity securities and interests in affiliated companies of $12.5 million.

*Financing activities* 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 reissuance of treasury stock and $5.0 million of proceeds from the issuance debt.

Our Board of Directors has authorized the repurchase of our common stock on the open market. On December 5, 2003, the Board of Directors granted authority to buy 5.0 million shares and authorized the repurchases through December 31, 2004. From January 1, 2004 through September 30, 2004, 2.9 million shares were repurchased.

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

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

**Borrowing arrangements** Under a revolving, committed, uncollateralized credit agreement with a major financial institution, we can borrow up to $100.0 million in the U.S. This credit facility is guaranteed by Novartis AG under a November 1994 Investment Agreement, provides various interest rate options and matures in February 2006. There were no borrowings outstanding under this credit facility at September 30, 2004 and December 31, 2003. In December 1999, Chiron and Novartis amended the November 1994 Investment Agreement to reduce the maximum amount of our obligations that Novartis would guarantee from $725.0 million to $702.5 million. The Novartis loan guarantee will expire on December 31, 2007 unless certain debt ratings are triggered which would extend the guarantee on a declining basis ratably over the subsequent three year period.

As of September 30, 2004, Novartis had also guaranteed $173.3 million of Chiron s lease commitments for a six-year lease to rent a research facility in Emeryville, California.

**Factors That May Affect Future Results**

As a global pharmaceutical company, we are engaged in a rapidly evolving and often unpredictable business. The forward-looking statements contained in this 10-Q and in other periodic reports, press releases and other statements issued by us from time to

time reflect our current beliefs and expectations concerning objectives, plans, strategies, future performance and other future events. The following discussion highlights some of the factors, many of which are beyond our control, which could cause actual results to differ.

*The recent developments with respect to Fluvirin will harm our business and results of operations.*

During the third quarter of 2004, in conducting final internal release procedures for our Fluvirin influenza virus vaccine, our quality systems identified lots that did not meet product sterility specifications. As a result, we determined at the time to delay releasing any Fluvirin doses pending completion of internal investigations. Subsequent to the third quarter, the U.K. regulatory body, the Medicines and Healthcare products Regulatory Agency, or MHRA, sent us a letter prohibiting us from releasing any Fluvirin doses manufactured at our Liverpool facility since March 2, 2004. In that letter, the MHRA asserted that our manufacturing process did not comply with U.K. good manufacturing practices regulations. Following the MHRA s decision, the Food and Drug Administration, or FDA, conducted its own inspection of our Liverpool facility and provided a written report, known as an FDA Form 483 or simply a 483 citing FDA observations concerning GMP compliance and other matters relating to the manufacture of Fluvirin. If the nature of any noted issues requires it or if Chiron fails to respond adequately to the Form 483 observations, the FDA may modify our license in an adverse manner, issue a warning letter against us and impose fines, require temporary or permanent cessation of future manufacturing or selling of Fluvirin or take other action that could reduce our ability to produce or market Fluvirin. The FDA also announced that it would not permit release of any Fluvirin from our Liverpool facility into the United States. We do not expect to release any Fluvirin product during the 2004-2005 influenza season.

In addition to prohibiting release of existing Fluvirin doses, the MHRA letter suspended our license to manufacture influenza virus vaccine in our Liverpool facility for three months. The MHRA could extend the license suspension or even make it permanent. We estimate that Fluvirin production must begin by March 2005 in order for us to be able to release the product in September 2005, so any significant extension of the suspension could result in our being unable to release Fluvirin for the 2005-2006 season, which would harm our business and results of operations. We cannot predict with any certainty if or when we will be able to resume production of Fluvirin at our Liverpool facility. In addition, while we are still in the process of assessing the appropriate corrective steps, our remediation efforts could entail additional capital and other expenditures, which could be material. There can be no assurances that we will be able to make changes to adequately address the issues identified by the FDA and MHRA, or that these regulatory agencies will be satisfied with our remediation efforts. If the license suspension is extended beyond three months, certain assets related to Fluvirin, such as goodwill, certain other intangible assets, the existing Liverpool plant and the new flu vaccines manufacturing facility under construction in Liverpool, with a total carrying value of $913.6 million at September 30, 2004, could be impaired. This could result in our recording impairment losses that could have a material adverse effect on our results of operations. In addition, if we suffer a permanent loss of Fluvirin influenza vaccine sales, it would have a material adverse effect on our cash flow.

Our inability to supply Fluvirin may also lead to loss of market share. As a result of the license suspension, competitors have announced plans to introduce influenza vaccine products in the United States and are seeking expedited regulatory approval to do so. Even if the license suspension expires, some of our customers may choose to purchase flu vaccine from other providers as their products become available in the United States. Loss of market share could have a material adverse effect on our business and results of operations.

We are subject to investigations and litigation in connection with the events described above. We have received a grand jury subpoena issued by the U.S. Attorney s Office for the Southern District of New York requesting production of certain documents and materials relating to our influenza virus vaccine and the suspension by the MHRA of our license. The Securities and Exchange Commission is also conducting an informal inquiry into whether Chiron has violated any federal securities laws. Additional investigations regarding these matters may arise, including Congressional investigations. In addition, we and certain of our officers and directors have also been named as defendants in several putative class action and shareholder derivative lawsuits relating to these developments. Investigations and litigation could cause us to incur substantial expense, require significant time and attention from our management and result in civil and/or criminal penalties against Chiron. The results of any such investigations or proceedings could have a material adverse effect on our business and results of operations.

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

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

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

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

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

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

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

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

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

suppliers, distributors, couriers, collaborative partners, licensees and clinical trial sites.

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

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

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

We use raw materials and other supplies that generally are available from multiple commercial sources. Certain manufacturing processes, however, use materials that are available from sole sources, or that are in short supply, or are difficult for the supplier to produce and certify in accordance with our specifications. From time to time, concerns are raised with respect to potential contamination of biological materials that are supplied to us. These concerns can further tighten market conditions for materials that may be in short supply or available from limited sources. Moreover, regulatory approvals to market our products may be conditioned upon obtaining certain materials from specified sources. Our ability to substitute material from an alternate source may be delayed

pending regulatory approval of such alternate source. Although we work to mitigate the risks associated with relying on sole suppliers, there is a possibility that material shortages could impact production.

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

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

We have entered into contracts with third parties for the packaging of the pre-filled diluent syringe for Betaseron®. 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® due to work stoppages or other factors, our operations could be disrupted until alternative sources are secured.

In connection with the production of our flu vaccine products, we must purchase large quantities of chicken eggs. For Fluvirin® vaccine, we purchase those eggs and incubation services from a single supplier in the United Kingdom and, pursuant to the contract with that supplier, we are required to make specified minimum purchases from that supplier through 2007. If our supplier were to fail to supply eggs in sufficient quantities or quality, including as a result of any health or other issues related to the chickens, our business would be materially adversely affected.

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

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

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

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

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

The possibility that the competitor may have launched its product first;

The competitor may have greater access to certain raw materials;

The competitor may have more efficient manufacturing processes;

The competitor may adapt more quickly to technological change;

The competitor may have greater marketing capabilities;

The competitive product may have therapeutic or other advantages; or

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

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

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

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

*Sales of our products may be adversely affected by the availability and amount of reimbursement to the user of our products from third parties, such as the government and insurance companies.*

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

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

As part of our business strategy, we expect to continue to grow our business through in-licensing, collaborations or acquisitions of products or companies. 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; and

Amortization expenses related to other intangible assets.

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

Challenges associated with managing an increasingly diversified business;

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

Diversion of management s attention from other business concerns;

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

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

Subsequent loss of key personnel.

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

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

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

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

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

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

*Our 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, 2004, our total debt was $940.3 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 indentures 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 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 indentures governing the debentures.

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

We have an alliance with Novartis AG, a life sciences company headquartered in Basel, Switzerland. Under a series of agreements between Chiron and Novartis, and as a result of subsequent stock issuances by Chiron, Novartis ownership interest in Chiron was approximately 42% as of September 30, 2004. The governance agreement between Chiron and Novartis contains provisions that require the approval of Novartis before we enter into certain corporate transactions. These transactions generally include significant debt or equity issuances, debt or equity repurchases, most mergers and acquisitions, the payment of cash dividends, amendments to Chiron s certificate of incorporation or by-laws, and other transactions that would adversely impact the rights of Novartis, or discriminate against Novartis, as a Chiron stockholder. In addition, a majority of the independent directors must approve any material transactions between Chiron and Novartis. These provisions may limit our ability to enter into transactions with third parties otherwise viewed as beneficial to Chiron. All of our shares owned by Novartis are eligible for sale in the public market subject to compliance with the applicable securities laws. We have agreed that, upon Novartis request, we will file one or more registration statements under the Securities Act in order to permit Novartis to offer and sell shares of our common stock. Sales of a substantial number of shares of our common stock by Novartis in the public market could adversely affect the market price of our common stock.

*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 Fluvirin 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;

The sale of a substantial number of shares held by our existing stockholders;

Licensing activities by us; and

The acquisition or sale by us of products, products in development or businesses.

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

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

We pay taxes principally in the U.S., Germany, Italy, The Netherlands and, with the acquisition of PowderJect, the United Kingdom. All of these jurisdictions have in the past and may in the future make changes to their corporate tax rates and other tax laws, which could increase our future tax provision. We have negotiated a number of rulings regarding income and other taxes that are subject to periodic review and renewal. If such rulings are not renewed or are substantially modified, income taxes payable in particular jurisdictions could increase. While we believe that all material tax liabilities are reflected properly in our balance sheet, we are presently under audit in several jurisdictions and may be subject to further audits in the future, and we have no assurance that we will prevail in all cases in the event the taxing authorities disagree with our interpretations of the tax law. In addition, we have assumed liabilities for all income taxes incurred prior to the sales of our former subsidiaries, PowderJect Vaccines, Inc., SBL Vaccin AB, Chiron Vision (subject to certain limitations) and Chiron Diagnostics. Future levels of research and development spending, capital investment and export sales will impact our entitlement to related tax credits and benefits which have the effect of lowering our effective tax rate.

*Volatility of earnings could negatively impact our business.*

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

Inventory management practices, including wholesale ordering patterns;

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

Seasonality of certain vaccine products, including Fluvirin;

The tender driven nature of certain vaccine products;

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

Foreign currency exchange rate fluctuations; and

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

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

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

We must follow accounting standards, financial reporting and corporate governance requirements and tax laws set by the governing bodies and lawmakers in the U.S. and other countries where we do business. From time to time, these governing bodies and lawmakers implement new and revised rules and laws. These new and revised accounting standards, financial reporting and corporate governance requirements and tax laws may require changes to our financial statements, the composition of our board of directors, the composition, the responsibility and manner of operation of various board-level committees, the information filed by us with the governing bodies and enforcement of tax laws against us.

Implementing changes required by such new standards, requirements or laws likely will require a significant expenditure of time, attention and resources, especially by our senior management. It is impossible to predict the impact, if any, on Chiron of future changes to accounting standards, financial reporting and corporate governance requirements and tax laws. In addition, it is possible that the application of certain current accounting standards may change due to environmental factors, which may necessitate a change in our standard practice related to these accounting standards.

**Item 4. Controls and Procedures**

**(a) Evaluation of disclosure controls and procedures** As of the end of the period covered by our Annual Report on Form 10-K for the year ended December 31, 2004, Chiron carried out an evaluation under the supervision and with the participation of Chiron s management, including Chiron s CEO and CFO, of the effectiveness of the design and operation of Chiron s disclosure controls and procedures. Based on that evaluation, Chiron s management, including the CEO and CFO, concluded that as of September 30, 2004, Chiron s disclosure controls and procedures were ineffective to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms. The following paragraphs discuss the reasons and matters on which this conclusion was based.

The management of Chiron Corporation is responsible for establishing and maintaining adequate internal control over financial reporting. Chiron s internal control system was designed to provide reasonable assurance to the Company s management and board of directors regarding the preparation and fair presentation of published financial statements.

The management of Chiron assessed the effectiveness of the Company s internal control over financial reporting as of December 31, 2004. In making its assessment of internal control over financial reporting management used the criteria issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control Integrated Framework.*

In performing the assessment management has identified three material weaknesses in internal control over financial reporting as of December 31, 2004.

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 that may affect 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.

Management has concluded that each of the above control deficiencies represents a material weakness in internal control over financial reporting. A material weakness is a control deficiency, or combination of control deficiencies, that results in a more than remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected. As a result of the material weaknesses described above, management believes 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*.

**(b)** **Remediation steps to address material weakness** We have an ongoing process of analyzing and attempting to improve our internal controls, including those related to the matters identified above. With regard to the revenue recognition material weakness, the Company is taking steps designed to provide its sales force with the necessary training with respect to applicable accounting principles so that the sales force understands the impact of its activities on the Company s financial reporting. In addition, we intend to take steps to implement processes to provide that changes to our standard terms of sale will need specified levels of approval prior to being made, such as approval from finance and legal departments or personnel. Additionally, the Company is in the process of establishing a remediation plan to address the ineffective controls related to the annual tax provision process. The remediation plan is expected to include consideration and identification of additional controls and reconciliations and the consideration and implementation of different analytical tools in order to enhance the analysis and calculation of the tax provision. With regard to the legal services accrual material weakness, we are taking steps to increase awareness and understanding of the accruals process by providing training to the legal department and redesigning the processes related to estimating the accrual and the timely recording of legal invoices, and we are also working to improve communication between the finance and legal departments.

**(c)** **Changes in internal controls** 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 fiscal quarter ended September 30, 2004. Refer to Item 4(b) for a discussion of remediation activities in connection with the material weaknesses in internal control over financial reporting referred to above.

**PART II**

**Item 6. Exhibits**

*(a)* Exhibits

| Exhibit Number | Exhibit |
|---|---|
| 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. |

**CHIRON CORPORATION**

**September 30, 2004**

**SIGNATURES**

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

CHIRON CORPORATION

DATE: April 6, 2005

BY: /s/ HOWARD H. PIEN

Howard H. Pien
*Chief Executive Officer*

DATE: April 6, 2005

BY: /s/ DAVID V. SMITH

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