CELGENE CORP /DE/ Form 10-Q October 29, 2008

UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549 FORM 10-Q

(Mark one)

DESCRIPTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2008 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 0-16132
CELGENE CORPORATION

(Exact name of registrant as specified in its charter)

Delaware 22-2711928

(State or other jurisdiction of incorporation or organization)

(I.R.S. Employer Identification Number)

86 Morris Avenue, Summit, NJ

07901

(Address of principal executive offices)

(Zip Code)

(908) 673-9000

(Registrant s telephone number, including area code)

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 b No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer b Accelerated filer o

Non-accelerated filer o

Smaller reporting company o

(Do not check if a smaller reporting company)

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

Yes o No b

At October 23, 2008, 458,188,433 shares of Common Stock, par value \$.01 per share, were outstanding.

CELGENE CORPORATION FORM 10-Q TABLE OF CONTENTS

PART I FINANCIAL INFORMATION	Page No.
Item 1 Unaudited Consolidated Financial Statements	
Consolidated Statements of Operations Three- and Nine-Month Periods Ended September 30, 2008 and 2007	3
Consolidated Balance Sheets As of September 30, 2008 and December 31, 2007	4
Consolidated Statements of Cash Flows Nine-Month Periods Ended September 30, 2008 and 2007	5
Notes to Unaudited Consolidated Financial Statements	7
Item 2 Management s Discussion and Analysis of Financial Condition and Results of Operations	25
Item 3 Quantitative and Qualitative Disclosures About Market Risk	42
Item 4 Controls and Procedures	44
PART II OTHER INFORMATION	
Item 1 Legal Proceedings	44
Item 1A Risk Factors	44
Item 2 Unregistered Sales of Equity Securities and Use of Proceeds	44
Item 3 Defaults Upon Senior Securities	44
Item 4 Submission of Matters to a Vote of Security Holders	44
Item 5 Other Information	44
Item 6 Exhibits	45
<u>Signatures</u>	46
Exhibit 31.1 Exhibit 31.2 Exhibit 32.1 Exhibit 32.2 Exhibit 99.1	

CELGENE CORPORATION AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

(Dollars in thousands, except per share amounts)

		Three-Mo En Septen 2008	ded		Ni	ne-Month P Septem 2008		
Revenue: Net product sales Collaborative agreements and other revenue Royalty revenue	\$	567,017 2,402 23,046	\$	331,169 4,616 14,123	\$	1,541,556 9,960 75,011	\$	919,910 14,520 56,800
Total revenue		592,465		349,908		1,626,527		991,230
Expenses: Cost of goods sold (excluding amortization expense) Research and development Selling, general and administrative Amortization of acquired intangible assets Acquired in-process research and development Total expenses		70,534 160,911 168,607 32,833		34,066 130,841 94,736 2,290 261,933		190,452 462,650 485,345 77,842 1,740,000 2,956,289		84,840 301,341 310,669 6,755 703,605
Total expenses		432,003		201,933		2,930,289		703,003
Operating income (loss)		159,580		87,975	(1,329,762)		287,625
Other income and expense: Interest and investment income, net Equity in losses of affiliated companies Interest expense Other income (expense), net		19,678 2,338 512 2,464		28,296 1,106 2,614 732		69,281 8,761 3,968 4,957		79,447 3,338 7,913 (3,345)
Income (loss) before income taxes		178,872		113,283	(1,268,253)		352,476
Income tax provision		42,058		74,450		116,138		201,364
Net income (loss)	\$	136,814	\$	38,833	\$ (1,384,391)	\$	151,112
Net income (loss) per common share: Basic Diluted	\$ \$	0.30 0.29	\$ \$	0.10 0.09	\$ \$	(3.17) (3.17)	\$ \$	0.40 0.36

Weighted average shares:

Basic 456,509 383,774 437,206 380,841

Diluted 468,891 432,817 437,206 431,208

See accompanying Notes to Unaudited Consolidated Financial Statements

3

CELGENE CORPORATION AND SUBSIDIARIES CONSOLIDATED BALANCE SHEETS (Unaudited)

(Dollars in thousands, except per share amounts)

	Sep	tember 30, 2008	De	cember 31, 2007
Assets				
Current assets:				
Cash and cash equivalents	\$	1,517,120	\$	1,218,273
Marketable securities available for sale		937,050		1,520,645
Accounts receivable, net of allowances of \$7,927 and \$4,213 at September 30, 2008 and December 31, 2007, respectively		275,409		167,252
Inventory		90,344		49,076
Deferred income taxes		59,808		20,506
Other current assets		144,483		108,669
Total current assets		3,024,214		3,084,421
Property, plant and equipment, net		234,414		197,428
Investment in affiliated companies		18,245		14,422
Intangible assets, net		462,235		92,658
Goodwill		523,617		39,033
Other assets		94,699		183,322
Total assets	\$	4,357,424	\$	3,611,284
Liabilities and Stockholders Equity				
Current liabilities:				
Accounts payable	\$	54,938	\$	37,876
Accrued expenses		329,678		159,220
Income taxes payable		15,541		4,989
Convertible notes		1.265		196,555
Current portion of deferred revenue		1,365		7,666
Other current liabilities		47,488		26,625
Total current liabilities		449,010		432,931
Deferred revenue, net of current portion		3,095		60,303
Non-current income taxes payable		257,068		211,307
Other non-current liabilities		59,890		62,799
Total liabilities		769,063		767,340

Commitments and Contingencies

Stockholders Equity:

Preferred stock, \$.01 par value per share, 5,000,000 shares authorized; none		
outstanding at September 30, 2008 and December 31, 2007, respectively		
Common stock, \$.01 par value per share, 575,000,000 shares authorized;		
issued 462,213,553 and 407,150,694 shares at September 30, 2008 and		
December 31, 2007, respectively	4,622	4,072
Common stock in treasury, at cost; 4,092,612 and 4,026,116 shares at		
September 30, 2008 and December 31, 2007, respectively	(153,769)	(149,519)
Additional paid-in capital	5,035,170	2,780,849
(Accumulated deficit) retained earnings	(1,259,731)	124,660
Accumulated other comprehensive (loss) income	(37,931)	83,882
Total stockholders equity	3,588,361	2,843,944
Total liabilities and stockholders equity	\$ 4,357,424	\$ 3,611,284

See accompanying Notes to Unaudited Consolidated Financial Statements

4

CELGENE CORPORATION AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited) (Dollars in thousands)

	Nine-Month Periods Ender September 30,		
	2008	2007	
Cash flows from operating activities:			
Net (loss) income	\$ (1,384,391)	\$ 151,112	
Adjustments to reconcile net (loss) income to net cash provided by operating activities:			
Depreciation of long-term assets	25,470	15,455	
Amortization of intangible assets	78,138	7,047	
Provision for accounts receivable allowances	6,642	6,353	
Deferred income taxes	(9,770)	(4,334)	
Acquired in-process research and development	1,740,000		
Share-based compensation expense	75,650	41,630	
Equity in losses of affiliated companies	8,362	2,910	
Share-based employee benefit plan expense	7,358	6,436	
Other, net	12,434	1,526	
Change in current assets and liabilities, excluding the effect of acquisition:			
Accounts receivable	(70,740)	(23,148)	
Inventory	(5,799)	(34,480)	
Other operating assets	(12,359)	(11,088)	
Accounts payable and other operating liabilities	(20,708)	61,162	
Income tax payable	26,088	93,085	
Deferred revenue	(31)	(2,733)	
Net cash provided by operating activities	476,344	310,933	
Cash flows from investing activities:			
Proceeds from sales of marketable securities available for sale	981,502	1,462,836	
Purchases of marketable securities available for sale	(471,699)	(2,362,302)	
Payments for acquisition of business, net of cash acquired	(746,779)		
Capital expenditures	(53,635)	(38,447)	
Investment in affiliated companies	(12,185)	(1,621)	
Purchases of investment securities	(8,236)	(23,356)	
Other	11,528		
Net cash used in investing activities	(299,504)	(962,890)	
Cash flows from financing activities:			
Net proceeds from exercise of common stock options and warrants	106,932	136,033	

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Excess tax benefit from share-based compensation arrangements	59,459	112,614
Net cash provided by financing activities	166,391	248,647
Effect of currency rate changes on cash and cash equivalents	(44,384)	4,630
Net increase (decrease) in cash and cash equivalents	\$ 298,847	\$ (398,680)
Cash and cash equivalents at beginning of period	\$ 1,218,273	\$ 1,439,415
Cash and cash equivalents at end of period	\$ 1,517,120	\$ 1,040,735
See accompanying Notes to Unaudited Consolidated Financial Statements		

Table of Contents

CELGENE CORPORATION AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF CASH FLOWS (Continued) (Unaudited) (Dollars in thousands)

	Nine-Month Periods Ended September 30,			
		2008		2007
Supplemental schedule of non-cash investing and financing activity: Change in net unrealized loss on marketable securities available for sale and cash flow hedges	\$	100,527	\$	43,988
Matured shares tendered in connection with stock option exercises	\$	(4,250)	\$	(6,457)
Conversion of convertible notes	\$	196,543	\$	130
Supplemental disclosure of cash flow information: Interest paid	\$	1,640	\$	5,250
Income taxes paid	\$	28,084	\$	
See accompanying Notes to Unaudited Consolidated Financial Statements				

6

Table of Contents

1. Nature of Business and Summary of Significant Accounting Policies

Nature of Business and Basis of Presentation: Celgene Corporation and its subsidiaries (collectively Celgene or the Company) is a global biopharmaceutical company primarily engaged in the discovery, development and commercialization of innovative therapies designed to treat cancer and immune-inflammatory diseases. On March 7, 2008, the Company acquired all of the outstanding common stock and stock options of Pharmion Corporation, or Pharmion, which prior to the acquisition was a global biopharmaceutical company that acquired, developed and commercialized innovative products for the treatment of hematology and oncology patients, for \$2.67 billion in a combination of cash and Celgene common stock. The Company s commercial stage products include REVLIMI®, THALOMID® / Thalidomide, VIDAZA®, ALKERAN® and FOCALIN®. FOCALIN® is sold exclusively to Novartis Pharma AG, or Novartis. The Company also derives revenues from a licensing agreement with Novartis, which entitles it to royalties on FOCALIN XR® and the entire RITALIN® family of drugs, and sales of bio-therapeutic products and services through the Company s Cellular Therapeutics subsidiary.

The accompanying unaudited consolidated financial statements have been prepared from the books and records of the Company pursuant to U.S. generally accepted accounting principles for interim information and the rules and regulations of the Securities and Exchange Commission for reporting on Form 10-Q. Pursuant to such rules and regulations, certain information and footnote disclosures normally included in complete annual financial statements have been condensed or omitted. The consolidated financial statements include the accounts of Celgene Corporation and its subsidiaries. All intercompany transactions and balances have been eliminated. Investments in limited partnerships and interests in which the Company has an equity interest of 50% or less and does not otherwise have a controlling financial interest are accounted for by either the equity or cost method. Certain immaterial reclassifications have been made to the prior period consolidated financial statements in order to conform to the current period presentation. The interim consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto included in the Company s Annual Report on Form 10-K for the year ended December 31, 2007.

The preparation of the consolidated financial statements requires management to make estimates and assumptions that affect reported amounts and disclosures. Actual results could differ from those estimates. The Company is subject to certain risks and uncertainties related to product development, regulatory approval, market acceptance, scope of patent and proprietary rights, intense competition, rapid technological change and product liability.

Interim results may not be indicative of the results that may be expected for the full year. In the opinion of management, these financial statements include all normal and recurring adjustments considered necessary for a fair presentation of these interim consolidated financial statements.

Recent Accounting Principles: In September 2006, the Financial Accounting Standards Board, or FASB, issued Statement of Financial Accounting Standards, or SFAS, No. 157, Fair Value Measurements, or SFAS 157, which establishes a framework for measuring fair value and expands disclosures about fair value measurements. The FASB partially deferred the effective date of SFAS 157 for non-financial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a nonrecurring basis to fiscal years beginning after November 15, 2008. The effective date for financial assets and liabilities that are recognized on a recurring basis was January 1, 2008. The Company has determined that its adoption of SFAS 157 on January 1, 2008 for financial assets and liabilities did not have a material impact on its consolidated financial statements. See Note 6 for expanded disclosures required by SFAS 157. The Company is currently evaluating the impact that the adoption of SFAS 157 related to non-financial assets will have, if any, on its consolidated financial statements.

7

Table of Contents

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities, or SFAS 159, which provides companies with an option to report selected financial assets and liabilities at fair value. SFAS 159 establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities and highlights the effect of a company s choice to use fair value on its earnings. It also requires a company to display the fair value of those assets and liabilities for which it has chosen to use fair value on the face of the balance sheet. SFAS 159 was effective for the Company beginning January 1, 2008 and did not have a material impact on its consolidated financial statements.

In June 2007, the FASB ratified Emerging Issues Task Force, or EITF, Issue No. 07-3, Accounting for Non-Refundable Advance Payments for Goods or Services to be Used in Future Research and Development Activities, or EITF 07-3, which provides that non-refundable advance payments for future research and development activities should be deferred and capitalized until the related goods are delivered or the related services are performed. EITF 07-3 was effective for the Company on a prospective basis beginning January 1, 2008 and did not have a material impact on its consolidated financial statements.

In December 2007, the FASB ratified EITF Issue No. 07-1, Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property, or EITF 07-1, which provides guidance on how the parties to a collaborative agreement should account for costs incurred and revenue generated on sales to third parties, how sharing payments pursuant to a collaboration agreement should be presented in the income statement and certain related disclosure requirements. EITF 07-1 will be effective for the Company beginning January 1, 2009 on a retrospective basis. The Company is currently evaluating the impact that the adoption of EITF 07-1 will have, if any, on its consolidated financial statements.

In December 2007, the FASB issued SFAS No. 141R, Business Combinations, or SFAS 141R, which replaces FASB Statement No. 141, Business Combinations, and requires an acquirer to recognize the assets acquired, the liabilities assumed and any noncontrolling interest in the acquiree at the acquisition date, measured at their fair values as of that date, with limited exceptions specified in the Statement. It is effective prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008.

In December 2007, the FASB issued SFAS No. 160, Noncontrolling Interests in Consolidated Financial Statements, an Amendment of ARB No. 51, or SFAS 160, which changes the accounting for and reporting of noncontrolling interests (formerly known as minority interests) in consolidated financial statements. SFAS 160 is effective January 1, 2009. Upon implementation, prior periods will be recast for the changes required by SFAS 160. The Company is currently evaluating the impact that the adoption of SFAS 160 will have, if any, on its consolidated financial statements.

In March 2008, the FASB issued SFAS No. 161, Disclosures about Derivative Instruments and Hedging Activities, or SFAS 161, which is intended to improve financial reporting about derivative instruments and hedging activities by requiring enhanced disclosures to enable investors to better understand their effects on an entity s financial position, financial performance and cash flows. It is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008, with early adoption encouraged. The Company is currently evaluating the impact that the adoption of SFAS 161 will have, if any, on its consolidated financial statements.

In May 2008, the FASB issued FASB Staff Position, or FSP, No. APB 14-1, Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement), or FSP APB 14-1, which requires separate accounting for the debt and equity components of convertible debt issuances that have a cash settlement feature permitting settlement partially or fully in cash upon conversion.

8

Table of Contents

A component of such debt issuances representative of the approximate fair value of the conversion feature at inception should be bifurcated and recorded to equity, with the resulting debt discount amortized to interest expense in a manner that reflects the issuer s nonconvertible, unsecured debt borrowing rate. The requirements for separate accounting must be applied retrospectively to previously issued convertible debt issuances as well as prospectively to newly issued convertible debt issuances, negatively affecting both net income and earnings per share, in financial statements issued for fiscal years beginning after December 15, 2008. Since the Company s past convertible debt issuance did not include a cash settlement feature, it does not expect the adoption of FSP APB 14-1 will have any impact on its consolidated financial statements.

In June 2008, the FASB issued FSP EITF No. 03-6-1, Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities, or FSP EITF 03-6-1. The FSP addresses whether instruments granted in share-based payment transactions are participating securities prior to vesting and therefore need to be included in the earnings allocation in calculating earnings per share under the two-class method described in SFAS No. 128, Earnings per Share. The FSP requires companies to treat unvested share-based payment awards that have non-forfeitable rights to dividends or dividend equivalents as a separate class of securities in calculating earnings per share. The FSP is effective for fiscal years beginning after December 15, 2008; earlier application is not permitted. Since the Company s past share-based payment awards did not include non-forfeitable rights to dividends or dividend equivalents, it does not expect the adoption of FSP EITF 03-6-1 will have any impact on its consolidated financial statements.

Significant Accounting Policies: The Company s significant accounting policies are described in Note 1 of the Notes to the Consolidated Financial Statements included in its Annual Report on Form 10-K for the year ended December 31, 2007. In addition, the following additional significant accounting policy is now applicable: Derivatives and Hedging Activities: SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities, or SFAS 133, as amended, requires that all derivative instruments be recognized on the balance sheet at their fair value. Changes in the fair value of derivative instruments are recorded each period in current earnings or other comprehensive income (loss), depending on whether a derivative instrument is designated as part of a hedging transaction and, if it is, the type of hedging transaction. For a derivative to qualify as a hedge at inception and throughout the hedged period, the Company formally documents the nature and relationships between the hedging instruments and hedged item. The Company assesses, both at inception and on an on-going basis, whether the derivative instruments that are used in cash flow hedging transactions are highly effective in offsetting the changes in cash flows of hedged items. The Company assesses hedge ineffectiveness on a quarterly basis and records the gain or loss related to the ineffective portion of derivative instruments, if any, to current earnings. If the Company determines that a forecasted transaction is no longer probable of occurring, it discontinues hedge accounting and any related unrealized gain or loss on the derivative instrument is recognized in current earnings. The Company uses derivative instruments, including those not designated as part of a hedging transaction, to manage its exposure to movements in foreign exchange rates. The use of these derivative instruments modifies the exposure of these risks with the intent to reduce the risk or cost to the Company. The Company does not use derivative instruments for speculative trading purposes and is not a party to leveraged derivatives.

2. Acquisition of Pharmion Corporation

On March 7, 2008, Celgene acquired all of the outstanding common stock and stock options of Pharmion in a transaction accounted for under the purchase method of accounting for business combinations. Under the purchase method of accounting, the assets acquired and liabilities assumed of Pharmion are recorded as of the acquisition date, at their respective fair values, and consolidated with those of Celgene. The reported consolidated financial condition and results of operations of Celgene after completion of the acquisition reflect these fair values. The operating results of Pharmion are included in the Company s consolidated financial statements from the date of acquisition.

9

Table of Contents

Celgene paid a total purchase price of \$2.761 billion to acquire all of the outstanding Pharmion common shares and stock options. Each Pharmion share of common stock (other than shares owned by Celgene or its wholly owned subsidiaries, held in Pharmion s treasury or to which appraisal rights were perfected) were converted into the right to receive (i) 0.8367 shares of common stock of Celgene and (ii) \$25.00 in cash. The combination of cash and Celgene stock paid to Pharmion stockholders consisted of \$921.0 million in cash and approximately 30.8 million shares of Celgene common stock valued at \$1.749 billion. The purchase price included acquisition-related costs of \$26.2 million, the fair value of vested Celgene stock options issued of \$44.9 million and the cost of Celgene s investment in Pharmion common shares prior to the acquisition.

Prior to the acquisition, Pharmion was a global biopharmaceutical company that acquired, developed and commercialized innovative products for the treatment of hematology and oncology patients. Celgene acquired Pharmion to enhance its portfolio of therapies for patients with life-threatening illnesses worldwide with the addition of Pharmion s marketed products, and several products in development for the treatment of hematological and solid tumor cancers. By combining this new product portfolio with Celgene s existing operational and financial capabilities, Celgene expects to enlarge its global market share through increased product offerings and expanded clinical, regulatory and commercial capabilities.

(Amounts in thousands)

Purchase Price Summary:

Stock issued at fair value	\$ 1,749,222
Cash paid	920,805
Acquisition-related costs	26,187
Fully vested stock options issued	44,924
Pharmion shares previously owned	20,212
Total purchase price paid	\$ 2,761,350

The acquisition was accounted for using the purchase method of accounting for business combinations and the preliminary purchase price allocation resulted in the following amounts being allocated to the assets acquired and liabilities assumed at the acquisition date based upon their respective fair values.

(Amounts in thousands)	March 7, 2008	
Current assets	\$	340,415
Property, plant and equipment		8,404
Developed product rights		510,986
In-process research and development		1,740,000
Other noncurrent assets		304
A scate acquired		2 600 100
Assets acquired		2,600,109
Restructuring		(69,000)
Net deferred taxes		(128,352)
Liabilities assumed		(141,748)
Net assets acquired		2,261,009
Goodwill		500,341
Acquisition cost	\$	2,761,350

Table of Contents

The fair value of the acquired identifiable intangible assets consists primarily of developed product rights for the following marketed products at date of acquisition: VIDAZA® IV in the U.S. market, Thalidomide Pharmion in certain foreign markets and other minor commercialized products. The weighted average amortization period for these assets, in total, is 6.5 years. The weighted average amortization period for compassionate use rights is 1.2 years, while the weighted average amortization period for the developed product rights is 7.1 years.

In-process research and development, or IPR&D, represents compounds under development by Pharmion at the date of acquisition that had not yet achieved regulatory approval for marketing in certain markets or had not yet been completed and have no alternative future use. The \$1.74 billion estimated fair value of these intangibles was derived using the multi-period excess-earnings method, a form of the income approach. The IPR&D primarily related to development and approval initiatives for VIDAZA® IV in the E.U. market, the oral form of azacitidine in the U.S. and E.U. markets and Thalidomide Pharmion® in the E.U. market. The projected cash flows for valuation purposes were based on key assumptions such as estimates of revenues and operating profits related to the programs considering their stages of development; the time and resources needed to complete the regulatory approval process for the products; and the life of the potential commercialized products and associated risks, including the inherent difficulties and uncertainties in obtaining regulatory approvals.

For VIDAZA® IV in the E.U. market, the related future net cash flows were estimated using a risk-adjusted discount rate of 10.0% and an anticipated regulatory approval date in late 2008 with market exclusivity rights expected to continue through 2019. For the oral form of azacitidine in the United States and European Union, the future net cash flows were estimated using a risk-adjusted discount rate of 11.0% for each market. The anticipated regulatory approval in the European Union was assumed for 2013 with exclusivity continuing through 2023, and the anticipated regulatory approval in the United States was assumed for 2013 with exclusivity continuing through 2018. For Thalidomide Pharmion® in the E.U. market, the future net cash flows were estimated using a risk-adjusted discount rate of 9.5% and an anticipated regulatory approval date in 2008 with exclusivity continuing through 2018. In accordance with FASB Interpretation No. 4, Applicability of FASB Statement No. 2 to Business Combinations Accounted for by the Purchase Method, the purchase price allocated to IPR&D intangible assets has been expensed to income immediately subsequent to the acquisition because the compounds do not have any alternative future use. This charge is not deductible for tax purposes.

The excess of purchase price over the fair value amounts assigned to the assets acquired and liabilities assumed represents the goodwill amount resulting from the acquisition. The amount allocated to goodwill is preliminary and subject to change, depending on the results of the final purchase price allocation. The Company does not expect any portion of this goodwill to be deductible for tax purposes. The goodwill attributable to the Company s acquisition of Pharmion has been recorded as a noncurrent asset in the Company s Consolidated Balance Sheet and will not be amortized, but is subject to