MEDIMMUNE INC /DE
Form 10-Q
July 21, 2005

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D. C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2005

0-19131

(Commission File No.)

MedImmune, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**52-1555759**
(State or other jurisdiction of incorporation or organization)	(I. R. S. Employer Identification No.)

One MedImmune Way, Gaithersburg, MD 20878

(Address of principal executive offices) (Zip Code)

Registrant s telephone number, including area code **(301) 398-0000**

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 by Rule 12b-2 of the Exchange Act). Yes ý No o

As of July 18, 2005, 246,331,970 shares of Common Stock, par value $0.01 per share, were outstanding.

MEDIMMUNE, INC.

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Unless otherwise indicated, this quarterly report is as of June 30, 2005. This quarterly report will not be updated as a result of new information or future events.

PART I FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

MEDIMMUNE, INC.

CONSOLIDATED BALANCE SHEETS

(in millions)

	June 30, 2005 (Unaudited)	December 31, 2004
ASSETS:		
Cash and cash equivalents	$ 228.0	$ 171.3
Marketable securities	454.5	172.6
Trade receivables, net	13.6	203.3
Inventory, net	87.5	64.1
Deferred tax assets, net	55.6	50.6
Other current assets	23.1	31.9
Total Current Assets	862.3	693.8
Marketable securities	1,088.7	1,362.2
Property and equipment, net	332.3	310.9
Deferred tax assets, net	91.8	127.3
Intangible assets, net	8.7	13.1
Goodwill	24.8	24.8
Other assets	37.1	32.3
Total Assets	$ 2,445.7	$ 2,564.4
LIABILITIES AND SHAREHOLDERS EQUITY:		
Accounts payable	$ 17.3	$ 15.1
Accrued expenses	144.2	251.4
Product royalties payable	53.2	85.9
Other current liabilities	44.0	11.4
Total Current Liabilities	258.7	363.8
Long-term debt	505.7	506.2
Other liabilities	1.0	19.8
Total Liabilities	765.4	889.8
Commitments and Contingencies		
SHAREHOLDERS EQUITY:		
Preferred stock, $.01 par value; authorized 5.5 shares; none issued or outstanding		
Common stock, $.01 par value; authorized 420.0 shares; issued 255.4 at June 30, 2005 and 255.4 at December 31, 2004	2.6	2.6
Paid-in capital	2,692.3	2,690.0
Deferred compensation		(0.1)
Accumulated deficit	(733.2)	(788.5)
Accumulated other comprehensive income	1.3	11.1
	1,963.0	1,915.1
Less: Treasury stock at cost; 8.8 shares at June 30, 2005 and 6.9 shares at December 31, 2004	(282.7)	(240.5)
Total Shareholders Equity	1,680.3	1,674.6
Total Liabilities and Shareholders Equity	$ 2,445.7	$ 2,564.4

The accompanying notes are an integral part of these financial statements.

MEDIMMUNE, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

(in millions, except per share data)

	Three months ended June 30,		Six months ended June 30,	
	2005	**2004**	**2005**	**2004**
Revenues:				
Product sales	$ 84.7	$ 90.7	$ 593.4	$ 573.9
Other revenue	3.8	2.9	4.9	8.7
Total revenues	88.5	93.6	598.3	582.6
Costs and expenses:				
Cost of sales	28.0	37.3	147.8	195.5
Research and development	79.3	67.8	148.6	117.6
Selling, general and administrative	60.9	58.9	218.4	182.6
Other operating expenses	2.9	2.1	5.5	3.9
Impairment of intangible asset		73.0		73.0
Acquired in-process research and development		24.7		24.7
Total expenses	171.1	263.8	520.3	597.3
Operating (loss) income	(82.6)	(170.2)	78.0	(14.7)
Interest income	17.6	16.5	34.3	32.7
Interest expense	(1.9)	(2.1)	(3.9)	(4.3)
(Loss) gain on investment activities	(1.2)	0.6	(0.9)	7.3
(Loss) earnings before income taxes	(68.1)	(155.2)	107.5	21.0
(Benefit) provision for income taxes	(23.9)	(54.9)	37.6	10.3
Net (loss) earnings	$ (44.2)	$ (100.3)	$ 69.9	$ 10.7
Basic (loss) earnings per share	$ (0.18)	$ (0.40)	$ 0.28	$ 0.04
Shares used in calculation of basic (loss) earnings per share	247.4	248.7	247.7	248.5
Diluted (loss) earnings per share	$ (0.18)	$ (0.40)	$ 0.28	$ 0.04
Shares used in calculation of diluted (loss) earnings per share	247.4	248.7	257.0	249.8

The accompanying notes are an integral part of these financial statements.

MEDIMMUNE, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(in millions)

	Six months ended June 30,	
	2005	**2004**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net earnings	$ 69.9	$ 10.7
Adjustment to reconcile net earnings to net cash provided by operating activities:		
Impairment of intangible asset		73.0
Deferred taxes	37.8	10.7
Advances from Wyeth		(51.9)
Depreciation and amortization	16.3	19.8
Amortization of premium on marketable securities	7.8	7.6
Realized losses (gains) on investments	0.9	(7.3)
Losses on write downs of inventory	7.6	26.2
Decrease in sales allowances	(12.3)	(20.4)
Other	2.3	0.6
Other changes in assets and liabilities	58.3	34.9
Net cash provided by operating activities	188.6	103.9
CASH FLOWS FROM INVESTING ACTIVITIES:		
Increase in marketable securities, net	(29.8)	(210.8)
Capital expenditures	(37.0)	(34.5)
Investments in strategic alliances	(7.9)	(17.5)
Net cash used in investing activities	(74.7)	(262.8)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuances of common stock	10.8	9.9
Share repurchases	(67.5)	
Debt prepayments		(172.7)
Repayments of long-term obligations	(0.5)	(0.4)
Net cash used in financing activities	(57.2)	(163.2)
Effect of exchange rate changes on cash		
Net increase (decrease) in cash and cash equivalents	56.7	(322.1)
Cash and cash equivalents at beginning of period	171.3	515.5
Cash and cash equivalents at end of period	$ 228.0	$ 193.4

The accompanying notes are an integral part of these financial statements.

MEDIMMUNE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

1. Organization

MedImmune, Inc., a Delaware corporation (together with its subsidiaries, the Company), is a biotechnology company headquartered in Gaithersburg, Maryland. The Company is committed to advancing science to develop better medicines that help people live healthier, longer and more satisfying lives. The Company currently focuses its efforts on using biotechnology to produce innovative products for prevention and treatment in the therapeutic areas of infectious disease, oncology and immunology. The Company s scientific expertise is largely in the areas of monoclonal antibodies and vaccines. The Company markets four products, Synagis, FluMist, Ethyol and CytoGam and has a diverse pipeline of development-stage products.

2. Summary of Significant Accounting Policies

General

The financial information presented as of and for the three and six months ended June 30, 2005 (Q2 2005 and YTD 2005, respectively) and as of and for the three and six months ended June 30, 2004 (Q2 2004 and YTD 2004, respectively) is unaudited. In the opinion of the Company s management, the financial information presented herein contains all adjustments, which consist only of normal recurring adjustments, necessary for a fair presentation of results for the interim periods presented. Interim results are not necessarily indicative of results for an entire year or for any subsequent interim period. These consolidated financial statements should be read in conjunction with the Company s 2004 Annual Report on Form 10-K and the Company s March 31, 2005 Quarterly Report on Form 10-Q.

New Accounting Pronouncements

In December 2004, the FASB issued SFAS 123R, a revision of SFAS 123, Accounting for Stock-based Compensation. SFAS 123R requires public companies to recognize expense associated with share-based compensation arrangements, including employee stock options, using a fair value-based option pricing model, and eliminates the alternative to use the intrinsic value method of accounting for share-based payments under Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees (APB 25). SFAS 123R was to be effective for the Company s interim quarter beginning on July 1, 2005, but in April 2005 the Securities and Exchange Commission (SEC) issued a rule that delays the date for compliance with SFAS 123R to the Company s fiscal year beginning January 1, 2006. Adoption of the expense provisions of the statement is expected to have a material impact on the Company s results of operations. SFAS 123R allows three alternative transition methods for public companies; the Company has not determined which transition method it will adopt. Upon adoption, the Company will select an expense attribution method to use for new share-based awards that have graded-vesting features and service conditions. Currently, the Company anticipates implementing the straight-line expense attribution method, whereas the Company s current expense attribution method is the graded-vesting method, an accelerated method, described by FASB Interpretation No. 28 (FIN 28), Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plans.

Stock-based Compensation

Compensation costs attributable to stock option and similar plans are currently recognized based on any excess of the quoted market price of the stock on the date of grant over the amount the employee is required to pay to acquire the stock, in accordance with the intrinsic-value method under APB 25. Such amount, if any, is accrued over the related vesting period.

The following table illustrates the effect on net earnings and earnings per share if the Company had applied the fair value recognition provisions to stock-based employee compensation (in millions, except per share data):

		Q2 2005	Q2 2004(1)	YTD 2005	YTD 2004(1)
Net (loss) earnings, as reported		$ (44.2)	$ (100.3)	$ 69.9	$ 10.7
Add:	Stock-based employee compensation expense included in historical results for the vesting of stock options assumed in conjunction with the Aviron acquisition, calculated in accordance with FIN 44, Accounting for Certain Transactions Involving Stock Compensation-an Interpretation of APB 25, net of related tax effect		0.2	0.1	0.4
Deduct:	Stock-based employee compensation expense determined under the fair value based method for all awards, net of related tax effect	(14.2)	(16.0)	(28.8)	(31.4)
Pro forma net (loss) earnings		$ (58.4)	$ (116.1)	$ 41.2	$ (20.3)
Basic (loss) earnings per share, as reported		$ (0.18)	$ (0.40)	$ 0.28	$ 0.04
Basic (loss) earnings per share, pro forma		$ (0.24)	$ (0.47)	$ 0.17	$ (0.08)
Diluted (loss) earnings per share, as reported		$ (0.18)	$ (0.40)	$ 0.28	$ 0.04
Diluted (loss) earnings per share, pro forma		$ (0.24)	$ (0.47)	$ 0.16	$ (0.08)

(1) The pro forma net losses for Q2 2004 and YTD 2004 of $116.1 million and $20.3 million, respectively, have been recomputed from the pro forma net losses previously disclosed of $115.6 million and $14.3 million, respectively, in order to reflect a revised estimated tax effect and to properly reflect the Company s accounting policy for amortization of compensation costs using the graded-vesting method described by FIN 28.

As of June 30, 2005, there was approximately $62 million of total unrecognized pro forma compensation cost, net of tax, related to nonvested stock option awards. Approximately 41% and 41% of this unrecognized compensation cost will be amortized during the remainder of 2005 (for disclosure purposes) and in 2006, respectively.

Effective January 1, 2005, the Company has estimated the fair value of stock compensation expense associated with employee stock options using the binomial model approach. The Company believes that the binomial approach provides a better measure of fair value of employee stock options because it incorporates assumptions about patterns of employee exercises in relation to such considerations as stock price appreciation, post-vesting employment termination behavior, the contractual term of the option and other factors. Historically, the Company estimated the fair value of employee stock options using the Black-Scholes option pricing model, which does not incorporate such correlation assumptions.

Based on an analysis of economic data that marketplace participants would likely use in determining an exchange price for an option, the Company s weighted-average estimate of expected volatility for YTD 2005 ranged from 31% to 32%, reflecting the implied volatility determined from the market prices of traded call options on the Company s stock. During YTD 2004, the weighted-average estimate of expected volatility using monthly observations was 50%, based on the historical volatility over the expected term.

The following disclosure provides a description of the significant assumptions used during 2005 and 2004 to estimate the fair value of the Company s employee stock option awards.

2005 - The fair value of employee stock options granted during 2005 was estimated using a binomial model that uses the weighted-average assumptions shown in the table below. The Company uses historical data to estimate option exercise and employee termination within the binomial model; separate groups of employees that have similar historical exercise behavior are considered separately for valuation purposes. The expected life of an option is derived from the output of the binomial model and represents the period of time that options granted are expected to be outstanding; the range given below results from certain groups of employees exhibiting different exercise patterns. The risk-free interest rate is based on the rate currently available for zero-coupon U.S. government issues with a term equal to the contractual life of the option.

	Q1 2005	Q2 2005
Option pricing model	Binomial	Binomial
Expected stock price volatility	32%	31%
Expected dividend yield	0%	0%
Expected life of option years	4.6 to 5.1	4.5 to 5.4

Risk-free interest rate		4.3%		4.2%
Weighted average fair value of options granted	$	8.27	$	9.41

2004 - The fair value of employee stock options granted during 2004 was estimated using a Black-Scholes model that uses the weighted-average assumptions shown in the table below. The expected life of an option was derived from historical stock option exercise experience. The risk-free interest rate was based on the rate currently available for zero-coupon U.S. government issues with a term equal to the expected life of the option.

	Q1 2004	Q2 2004
Option pricing model	Black-Scholes	Black-Scholes
Expected stock price volatility	50%	50%
Expected dividend yield	0%	0%
Expected life of option years	5.0	5.0
Risk-free interest rate	2.8%	3.9%
Weighted average fair value of options granted	$ 11.07	$ 11.49

Product Royalties

During Q2 2005, the Company recouped approximately $12 million from licensors related to overpayments under various royalty agreements. This amount has been deferred until fully realizable and recorded in Other Current Liabilities.

3. Dissolution of the Collaboration with Wyeth

During Q2 2004, the Company entered into agreements to dissolve the collaboration with Wyeth for FluMist, CAIV-T and all related technology. As a result of the dissolution, MedImmune reacquired the influenza vaccines franchise, and assumed full responsibility for the manufacturing, marketing, and sale of FluMist and any subsequent related product. Wyeth provided bulk manufacturing materials and transferred clinical trial data, as well as provided manufacturing services, during a transition that was completed in large part by the end of 2004. In connection with the dissolution of the collaboration, during Q2 2004 the Company recorded a charge to in-process research and development of $24.7 million and a permanent impairment charge of $73.0 million to write off the remaining unamortized cost of the intangible asset recorded for the worldwide collaboration with Wyeth.

4. Intangible Assets

The Company s intangible assets are definite-lived assets stated at amortized cost. The Company reviews its intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Intangible assets are comprised of the following (in millions):

	June 30, 2005	December 31, 2004
Agreement with Evans	$ 39.0	$ 39.0
Other intangible assets	0.4	0.4
	39.4	39.4
Less accumulated amortization	(30.7)	(26.3)
	$ 8.7	$ 13.1

Amortization of intangible assets is computed on the straight-line method based on the estimated useful lives of the assets. Amortization for Q2 2005 and Q2 2004 was $2.2 million and $2.2 million, respectively. Amortization for YTD 2005 and YTD 2004 was $4.4 million and $6.3 million, respectively. The estimated aggregate amortization for the remaining life of the Evans agreement is as follows: remainder of 2005, $4.3 million; and 2006, $4.4 million.

5. Inventory

Inventory, net of valuation reserves, is comprised of the following (in millions):

	June 30, 2005	December 31, 2004
Raw Materials	$ 14.7	$ 16.5
Work in Process	65.3	38.3
Finished Goods	7.5	9.3
	$ 87.5	$ 64.1

The Company recorded permanent inventory write downs totaling $3.0 million and $12.9 million during Q2 2005 and Q2 2004, respectively, and $7.6 million and $26.2 million during YTD 2005 and YTD 2004, respectively, in cost of goods sold to reflect total FluMist inventories at net realizable value.

6. Earnings per Share

The following is a reconciliation of the numerators and denominators of the diluted EPS computation:

	Q2 2005	Q2 2004	YTD 2005	YTD 2004
Numerator (in millions):				
Net (loss) earnings for basic EPS	$ (44.2)	$ (100.3)	$ 69.9	$ 10.7
Adjustments for interest expense on 1% Convertible Senior Notes, net of tax (1)			1.1	
(Loss) earnings for diluted EPS	$ (44.2)	$ (100.3)	$ 71.0	$ 10.7

	Q2 2005	Q2 2004	YTD 2005	YTD 2004
Denominator (in millions):				
Weighted average shares for basic EPS	247.4	248.7	247.7	248.5
Effect of dilutive securities:				
Stock options and warrants			2.0	1.3
1% Convertible Senior Notes (1)			7.3	
Weighted average shares for diluted EPS	247.4	248.7	257.0	249.8
Basic (loss) earnings per share	$ (0.18)	$ (0.40)	$ 0.28	$ 0.04
Diluted (loss) earnings per share	$ (0.18)	$ (0.40)	$ 0.28	$ 0.04

(1) EITF Issue No. 04-8, The Effect of Contingently Convertible Debt on Diluted Earnings per Share, which became effective during the fourth quarter of 2004, requires that all contingently convertible debt instruments be included in diluted earnings per share using the if-converted method, regardless if the market price trigger (or other contingent feature) has been met. Under the provisions of EITF 04-8, the Company s 1% Convertible Senior Notes, which represent 7.3 million potential shares of common stock, will be included in the calculation of diluted earnings per share using the if-converted method whether or not the contingent requirements have been met for conversion to common stock, unless the effect is anti-dilutive.

The Company incurred a net loss for Q2 2005 and Q2 2004 and, accordingly, did not assume exercise or conversion of any of the Company s outstanding stock options, warrants, or convertible notes during the periods because to do so would be anti-dilutive. As a result, options and warrants to purchase 34.0 million and 31.0 million shares of common stock were outstanding at June 30, 2005 and 2004, respectively, but were excluded from the calculation of diluted earnings per share.

If option exercise prices are greater than the average market price of the Company s common stock for the period presented, the effect of including such options in the earnings per share calculation is anti-dilutive. Options to purchase 20.9 million and 21.1 million shares of common stock, respectively, at prices ranging from $25.15 to $83.25 per share and $24.05 to $83.25 per share, were outstanding as of June 30, 2005 and 2004, respectively, but were not included in the computation of diluted earnings per share for YTD 2005 and YTD 2004 because the exercise price of the options exceeded the average market price.

7. Income Taxes

The Company s effective tax rate was 35% for both Q2 2005 and Q2 2004. The Company s effective tax rate for YTD 2005 was 35%, compared to an effective tax rate of 49% for YTD 2004. The effective tax rate for QTD 2004 and YTD 2004 was impacted by approximately $6.9 million of non-deductible charges for in-process research and development incurred during the second quarter of 2004.

8. Comprehensive Income

	Q2 2005	Q2 2004	YTD 2005	YTD 2004
Net (loss) earnings	$ (44.2)	$ (100.3)	$ 69.9	$ 10.7
Change in foreign currency translation adjustment	(0.4)	(0.1)	(0.8)	(0.3)
Change in unrealized (loss) gain on investments, net of tax	8.9	(25.8)	(9.0)	(21.5)
Change in unrealized gain on cash flow hedges, net of tax				2.6
Comprehensive income (loss)	$ (35.7)	$ (126.2)	$ 60.1	$ (8.5)

Reclassification adjustments, net of tax, during YTD 2004 were $4.4 million. Reclassification adjustments for Q2 2005, YTD 2005 and Q2 2004 were immaterial.

9. Shareholders Equity

During Q2 2005, the Company repurchased approximately 1.9 million shares of common stock under the stock repurchase program at a cost of $50.1 million, or an average cost of $25.94 per share. During YTD 2005, the Company repurchased approximately 2.6 million shares of common stock under the stock repurchase program at a cost of $67.5 million, or an average cost of $25.56 per share. Through July 18, 2005, the Company has repurchased an additional 0.4 million shares at an average cost of $27.33 per share. The Company is holding repurchased shares as treasury shares and is using them for general corporate purposes, including but not limited to for issuance upon exercise of outstanding stock options and acquisition-related transactions.

10. Legal Proceedings

The Company s material legal proceedings are described in Note 17 to the consolidated financial statements included with the

Company s Annual Report on Form 10-K for the year ended December 31, 2004, as updated in the Company s Quarterly Report on Form 10-Q for the quarter ended March 31, 2005. There have not been any material developments in the proceedings between the Company and Genentech, Inc. or between the Company and Sun Pharmaceutical Industries Limited other than those previously disclosed. With respect to the other legal proceedings described therein, the following material developments have occurred:

On June 24, 2005 the Company settled its dispute with Celltech R&D Ltd. related to the Adair 927 Patent, resulting in the dismissal of all pending litigation related to the patent. Under the terms of the settlement, the Company has no royalty obligation for sales of Synagis before July 1, 2005, which was estimated to range up to $35 million under the original license terms. The Company agreed to pay Celltech a royalty (which is lower than the royalty rate called for in the original license agreement) based on Synagis sold or manufactured in the United States after July 1, 2005, but the Company does not expect its overall royalty obligation with respect to sales of Synagis to materially change as a result of the settlement.

In the Company s suit against Centocor, Inc., the United States Court of Appeals for the Federal Circuit issued a decision on June 1, 2005 denying the Company s appeal. The Company has filed a Petition for Rehearing en banc and is awaiting a decision on that petition.

With respect to the AWP litigation matters, there have been no material developments in the Alabama case, or the New York Counties that were not consolidated in federal court subsequent to the disclosure provided in the Company s Quarterly Report on Form 10-Q for the quarter ended March 31, 2005, although the Alabama case and the case brought by the Counties of New York have been removed from state court to federal court upon the motion of the defendant. With respect to the federal consolidated County case brought by New York Counties in Federal Court, the majority of the causes of action against the Company had been dismissed, but approximately 30 New York Counties have filed an amended and consolidated complaint asserting similar claims to those raised in the original complaint as well as new claims directed to RespiGam and CytoGam and new allegations related to the alleged improper reporting of the Wholesaler Acquisition Cost of various products, including Synagis, RespiGam and CytoGam, and how this alleged improper reporting affects the AWP for these products. As of June 30, 2005, the Company estimates the range of possible pre-tax loss from the Alabama action, the New York City action and the New York State County actions (both consolidated and unconsolidated) to be between $0 to $11 million**,** exclusive of alleged treble damages, best price related claims and other asserted state law causes of action. The Company intends to vigorously defend the claims asserted in such complaints.

ITEM 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Management s Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements regarding future events and future results that are based on current expectations, estimates, forecasts, and the beliefs, assumptions and judgments of our management. Readers are cautioned that these forward-looking statements are only predictions and are subject to risks and uncertainties that are difficult to predict. Readers are referred to the Forward-Looking Statements and Risk Factors sections in Part I, Item 1 of our Form 10-K for the year ended December 31, 2004.

INTRODUCTION

MedImmune is committed to advancing science to develop better medicines that help people live healthier, longer and more satisfying lives. MedImmune currently focuses its efforts on using biotechnology to produce innovative products for prevention and treatment in the therapeutic areas of infectious disease, autoimmune disease and cancer. MedImmune s scientific expertise is largely in the areas of monoclonal antibodies and vaccines. MedImmune markets four products, Synagis, FluMist, Ethyol and CytoGam and has a diverse pipeline of development-stage products.

OVERVIEW OF YTD 2005

Total revenues increased 3% in YTD 2005 as compared to YTD 2004, reflecting 9% growth in sales of Synagis, offset by the impact of lower product sales of FluMist, due to the timing of revenue recognition related to sales for the 2003/2004 influenza season. We recorded diluted net earnings of $0.28 per share in YTD 2005 compared to diluted net earnings per share of $0.04 in YTD 2004. YTD 2004 results reflect the impact of the in-process research and development and impairment charges totaling $97.7 million incurred for the reacquisition of the influenza vaccines franchise from Wyeth. The growth in net income in YTD 2005 is also attributable to an 18% increase in gross profit, partially offset by increased selling, general and administrative expenses, and research and development spending.

Our clinical development efforts in the first half of 2005 included completion of the Phase 3 study to bridge refrigerator-stable CAIV-T to frozen FluMist, with preliminary data showing comparable immunogenicity. In addition, we continued the preparatory steps required for unblinding the Phase 3 efficacy trial results with CAIV-T in the fall. We also completed dosing patients in the first Northern Hemisphere portion for our pivotal Phase 3 study for Numax and initiated patient enrollment for the Southern Hemisphere component of the study, and completed patient enrollment in our Phase 2 prostate cancer study with Vitaxin.

During the first half of 2005, we amended our agreement with GlaxoSmithKline for the development of an HPV vaccine. Under the amended agreement, we may also receive certain milestone payments and royalties on future development and sales of an investigational HPV vaccine now in Phase 3 development by Merck & Co., Inc. In addition, we amended our international distribution agreement with Abbott International (AI) to include the exclusive distribution of Numax outside of the United States, if and to the extent approved for marketing by the appropriate regulatory authorities.

During June 2005, we settled the dispute with Celltech R&D Ltd. related to the Adair 927 Patent, resulting in the dismissal of all pending litigation related to the patent. Under the terms of the settlement, we have no royalty obligation for sales of Synagis before July 1, 2005, which was estimated to range up to $35 million under the original license terms. We agreed to pay Celltech a royalty (which is lower than the royalty

rate called for in the original license agreement) based on Synagis sold or manufactured in the United States after July 1, 2005, but we do not expect our overall royalty obligation with respect to sales of Synagis to materially change as a result of the settlement.

The Company s cash and marketable securities at June 30, 2005 totaled $1.8 billion as compared to $1.7 billion as of December 31, 2004, reflecting the impact of operating cash flows generated during the first six months of 2005, partially offset by repurchases of approximately 2.6 million shares of our common stock at a total cost of $67.5 million.

CRITICAL ACCOUNTING ESTIMATES

The preparation of consolidated financial statements requires management to make estimates and judgments with respect to the selection and application of accounting policies that affect the reported amounts of assets, liabilities, revenues and expenses, and the disclosures of contingent assets and liabilities. We consider an accounting estimate to be critical if the accounting estimate requires us to make assumptions about matters that were highly uncertain at the time the accounting estimate was made and if changes in the estimate that are reasonably likely to occur from period to period, or use of different estimates that we reasonably could have used in the current period, would have a material impact on our financial condition or results of operations. For additional information regarding our critical accounting estimates, please refer to Part II, Item 7, Management s Discussion and Analysis of Financial Condition and Results of Operations of the Company s Annual Report on Form 10-K for the year ended December 31, 2004. In addition, there are other items within our financial statements that require estimation, but are not deemed critical as defined above. Changes in estimates used in these and other items could have a material impact on our financial statements.

Inventory - We capitalize inventory costs associated with certain products prior to regulatory approval and product launch, based on management s judgment of probable future commercial use and net realizable value. We could be required to permanently write down previously capitalized costs related to pre-approval or pre-launch inventory upon a change in such judgment, due to a denial or delay of approval by regulatory bodies, a delay in commercialization, or other potential factors. Conversely, our gross margins may be favorably impacted if some or all of the inventory previously written down becomes available and is used for commercial sale.

We capitalize inventory costs associated with marketed products based on management s judgment of probable future commercial use and net realizable value. We could be required to permanently write down previously capitalized costs related to commercial inventory due to quality issues or other potential factors. Conversely, our gross margins may be favorably impacted if some or all of the inventory previously written down was recovered through further processing or receipt of a specification waiver from regulatory agencies, and becomes available and is used for commercial sale.

We are required to state all inventory at lower of cost or market. In assessing the ultimate realization of inventories, we are required to make judgments as to multiple factors affecting our inventories and compare these with current or committed inventory levels. In the highly regulated industry in which we operate, raw materials, work-in-process and finished goods inventories have expiration dates that must be factored into our judgments about the recoverability of inventory costs. Additionally, if our estimate of a product s demand and pricing is such that we may not fully recover the cost of inventory, we must consider that in our judgments as well. In the context of reflecting inventory at the lower of cost or market, we will record permanent inventory write-downs as soon as a need for such a write-down is determined. Such write-downs in inventory are permanent in nature, and will not be reversed in future periods.

The valuation of FluMist inventories requires a significant amount of judgment for multiple reasons. Specifically, the manufacturing process is complex, in part due to the required annual update of the formulation for recommended influenza strains, and there can be no guarantee that we will be able to continue to successfully manufacture the product.

The annual FluMist production cycle begins in October of the year prior to the influenza season in which the product will be available for consumption. For example, the production cycle for the 2005/2006 season began in October 2004. The production cycle begins by preparing the master viral working seeds and readying the manufacturing facilities for the bulk monovalent production, blending three monovalent strains into a trivalent vaccine, filling into intranasal sprayers, packaging sprayers into multi-dose packs and distributing the frozen product. Our raw materials have expiration dates (dates by which they must be used in the production process) that range from 24 months to 60 months. Our semi-processed raw materials and work-in-process inventory have multiple components, each having different expiration dates that range from

nine to 24 months. Each season s finished FluMist product has an approved shelf life ranging from three to nine months.

For all FluMist inventory components on hand as of June 30, 2005, we reviewed the following assumptions to determine the amount of any necessary reserves: expected production levels and estimated cost per dose; sales volume projections that are subject to variability; the expected price to be received for the product and anticipated distribution costs; and current information about the influenza strains recommended by the Centers for Disease Control and Prevention for each season s vaccine. The methodology used to calculate adjustments required to value our FluMist inventories as of June 30, 2005 at net realizable value was consistent with the methodology used for our valuations since approval in June 2003.

The valuation of inventory as of June 30, 2005 is based on sales volume and price estimates for the 2005/2006 season that are largely based on our actual experience for the 2004/2005 season. During the first quarter of 2005, we revised our estimate of production costs for the 2005/2006 season based on anticipated reductions in our plant and manufacturing costs, which decreased the per unit cost to produce FluMist. Sales and production estimates for the 2005/2006 season incorporated into the inventory valuations performed as of June 30, 2005 were generally consistent with the first quarter of 2005. Using these assumptions, we compared the amount of expected FluMist sales with the expected production cost to estimate the net realizable value of FluMist inventories as of June 30, 2005.

The table below summarizes the activity within the components of FluMist inventories (in millions):

	Gross Inventory	Reserves	Net Inventory
FluMist Details			
As of December 31, 2004	$ 50.7	$ (35.7)	$ 15.0
Raw materials, net	(1.4)	1.5	0.1
Cost of goods sold recognized on 2004/2005 inventory	(3.2)	3.1	(0.1)
Production, net	30.0	(7.6)	22.4
Disposals and scrap	(19.5)	18.4	(1.1)
As of June 30, 2005	$ 56.6	$ (20.3)	$ 36.3

Because finished FluMist product has an approved shelf life of three to nine months, no finished product produced for a particular flu season may be sold in a subsequent season. Thus, if our actual sales fall below our projections, we will be required to write off any remaining inventory balance at the end of the flu season.

For our other products, we periodically assess our inventory balances to determine whether net realizable value is below recorded cost. Factors we consider include expected sales volume, production capacity and expiration dates.

NEW ACCOUNTING STANDARDS

Issued in December 2004, Statement of Financial Accounting Standards (SFAS) No.123R requires public companies to recognize expense associated with share-based compensation arrangements, including employee stock options, using a fair value-based option pricing model, and eliminates the alternative to use Accounting Principles Board Opinion 25 s intrinsic value method of accounting for share-based payments. SFAS 123R was to be effective for our quarter beginning on July 1, 2005, but in April 2005 the Securities and Exchange Commission (SEC) issued a rule that delayed the date for compliance with SFAS 123R to our quarter beginning January 1, 2006. We expect that adoption of the expense provisions of the Statement will have a material impact on our results of operations. SFAS 123R allows three alternative transition methods for public companies; we have not determined which transition method we will adopt. Upon the adoption of SFAS 123R, we will select an expense attribution method to use for new share-based awards that have graded-vesting features and service conditions. Currently, we anticipate implementing the straight-line expense attribution method, whereas our current expense attribution method is the graded-vesting method, an accelerated method, described by FIN 28.

In anticipation of the adoption of SFAS 123R, we are currently evaluating alternative stock-based compensation programs, including potential changes in the quantity or type of instruments used in share-based payment programs and changes in the terms of share-based payment arrangements. Any potential changes to our compensation strategy would likely affect comparability to our prior period footnote disclosures of pro forma net earnings and earnings per share.

The actual pro forma expense for disclosure purposes in 2005 is dependent on a number of factors that we cannot predict, including the number of stock options granted, our common stock price, expected future volatility, and other variables utilized in estimating the fair value of stock

options at the time of grant. However, we expect that our pro forma after tax expense for disclosure purposes for stock-based compensation for the full twelve months in 2005 will approximate $40 million to $50 million. Prior to adoption of FAS 123R in Q1 2006, the Company s financial statements will not be impacted by the pro forma compensation expense disclosures.

The pro forma stock-based compensation expense disclosure for 2005 is expected to be lower than 2004 due to a lower number of stock options estimated to be granted in 2005, the diminishing impact of accelerated amortization of compensation expense for prior period options (which were assigned higher fair values) under the graded vesting method, and an anticipated reduction in the estimated fair value of new stock option grants.

The estimated fair value of new stock option grants beginning in 2005 is expected to be lower than 2004 for the following reasons:

Binomial Model Effective January 1, 2005, we have estimated the fair value of stock compensation expense associated with employee stock options using the binomial model approach. We believe the binomial approach provides a better measure of fair value of employee stock options because it incorporates assumptions about patterns of employee exercises in relation to such considerations as stock price appreciation, post-vesting employment termination behavior, the contractual term of the option and other factors. Historically, we estimated the fair value of employee stock options using the Black-Scholes option pricing model, which does not incorporate such correlation assumptions.

Shorter Expected Life The expected life of an option represents the period of time that options granted are expected to be outstanding. During YTD 2005, the expected life of an option, as derived from the output of the binomial model, ranged from 4.5 years to 5.4 years. For YTD 2004, the expected life of an option was 5 years, estimated based on historical stock option exercise experience.

Lower Expected Stock Price Volatility Based on an analysis of economic data that marketplace participants would likely use in determining an exchange price for an option, our weighted-average estimate of expected volatility for YTD 2005 ranged from

31% to 32%, reflecting the implied volatility determined from the market prices of traded call options on our stock. During YTD 2004, the weighted-average estimate of expected volatility was 50%, based on the historical volatility over the expected life, using monthly observations.

RESULTS OF OPERATIONS

Q2 2005 compared to Q2 2004

Revenues Product Sales

(in millions)	Q2 2005	Q2 2004	Change
Synagis			
Domestic	$ 43.5	$ 39.7	10%
International	7.4	16.4	(55)%
	50.9	56.1	(9)%
Ethyol			
Domestic	21.0	24.1	(13)%
International	1.6	0.9	81%
	22.6	25.0	(9)%
FluMist		1.2	N/A
Other Products	11.2	8.4	