MEDIMMUNE INC /DE
Form 10-Q
May 06, 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 March 31, 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 May 2, 2005, 247,766,473 shares of Common Stock, par value $0.01 per share, were outstanding.

MEDIMMUNE, INC.

Index to Form 10-Q

Unless otherwise indicated, this quarterly report is as of March 31, 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)

	March 31, 2005 (Unaudited)	December 31, 2004
ASSETS:		
Cash and cash equivalents	$ 318.1	$ 171.3
Marketable securities	226.7	172.6
Trade receivables, net	216.7	203.3
Inventory, net	72.5	64.1
Deferred tax assets, net	60.7	50.6
Other current assets	29.5	31.9
Total Current Assets	924.2	693.8
Marketable securities	1,338.9	1,362.2
Property and equipment, net	318.8	310.9
Deferred tax assets, net	67.6	127.3
Intangible assets, net	10.9	13.1
Goodwill	24.8	24.8
Other assets	32.6	32.3
Total Assets	$ 2,717.8	$ 2,564.4
LIABILITIES AND SHAREHOLDERS EQUITY:		
Accounts payable	$ 13.5	$ 15.1
Accrued expenses	320.5	251.4
Product royalties payable	87.8	85.9
Other current liabilities	32.1	11.4
Total Current Liabilities	453.9	363.8
Long-term debt	506.0	506.2
Other liabilities	1.3	19.8
Total Liabilities	961.2	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 255.5 at March 31, 2005 and 255.4 at December 31, 2004	2.6	2.6
Paid-in capital	2,691.6	2,690.0
Deferred compensation		(0.1)
Accumulated deficit	(683.7)	(788.5)
Accumulated other comprehensive income	(7.2)	11.1
	2,003.3	1,915.1
Less: Treasury stock at cost; 7.3 shares at March 31, 2005 and 6.9 shares at December 31, 2004	(246.7)	(240.5)
Total Shareholders Equity	1,756.6	1,674.6
Total Liabilities and Shareholders Equity	$ 2,717.8	$ 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)

	For the three months ended March 31,	
	2005	**2004**
Revenues:		
Product sales	$ 508.7	$ 483.2
Other revenue	1.1	5.8
Total revenues	509.8	489.0
Costs and expenses:		
Cost of sales	119.8	158.2
Research and development	69.3	49.8
Selling, general and administrative	157.5	123.7
Other operating expenses	2.6	1.8
Total expenses	349.2	333.5
Operating income	160.6	155.5
Interest income	16.7	16.2
Interest expense	(2.0)	(2.2)
Gain on investment activities, net	0.3	6.7
Earnings before income taxes	175.6	176.2
Provision for income taxes	61.5	65.2
Net earnings	$ 114.1	$ 111.0
Basic earnings per share	$ 0.46	$ 0.45
Shares used in calculation of basic earnings per share	248.1	248.2
Diluted earnings per share	$ 0.45	$ 0.43
Shares used in calculation of diluted earnings per share	257.2	258.2

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

MEDIMMUNE, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(in millions)

	For the three months ended March 31,	
	2005	**2004**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net earnings	$ 114.1	$ 111.0
Adjustment to reconcile net earnings to net cash provided by operating activities:		
Deferred taxes	61.4	45.4
Advances from Wyeth		(27.5)
Depreciation and amortization	8.2	10.6
Amortization of premium on marketable securities	3.9	3.5
Realized gains on investments	(0.3)	(6.7)
Losses on write downs of inventory	4.6	18.6
Increase in sales allowances	37.1	18.1
Other	1.0	(0.4)
Other changes in assets and liabilities	10.0	62.7
Net cash provided by operating activities	240.0	235.3
CASH FLOWS FROM INVESTING ACTIVITIES:		
Increase in marketable securities, net	(61.7)	(251.9)
Capital expenditures	(14.5)	(14.5)
Investments in strategic alliances	(1.3)	(12.5)
Net cash used in investing activities	(77.5)	(278.9)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuances of common stock	1.9	1.4
Share repurchases	(17.4)	
Debt prepayments		(172.7)
Repayments of long-term obligations	(0.2)	(0.2)
Net cash used in financing activities	(15.7)	(171.5)
Effect of exchange rate changes on cash		
Net increase (decrease) in cash and cash equivalents	146.8	(215.1)
Cash and cash equivalents at beginning of period	171.3	515.5
Cash and cash equivalents at end of period	$ 318.1	$ 300.4

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 months ended March 31, 2005 (Q1 2005) and March 31, 2004 (Q1 2004) 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 annual report on Form 10-K for the year ended December 31, 2004.

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):

		Q1 2005	Q1 2004(1)
Net earnings, as reported		$ 114.1	$ 111.0
Add:	stock-based employee compensation expense included in historical results for the vesting of stock options assumed in conjunction with the Acquisition, calculated in accordance with FIN 44, Accounting for Certain Transactions Involving Stock Compensation-an Interpretation of APB 25, net of related tax effect	0.1	0.2
Deduct:	stock-based employee compensation expense determined under the fair value based method for all awards, net of related tax effect	(12.7)	(14.9)
Pro forma net earnings		$ 101.5	$ 96.3
Basic earnings per share, as reported		$ 0.46	$ 0.45
Basic earnings per share, pro forma		$ 0.41	$ 0.39
Diluted earnings per share, as reported		$ 0.45	$ 0.43
Diluted earnings per share, pro forma		$ 0.40	$ 0.38

(1) The pro forma net earnings for Q1 2004 of $96.3 million has been recomputed from the amount previously disclosed of $95.0 million 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 March 31, 2005, there was $55.6 million of total unrecognized pro forma compensation cost, net of tax, related to nonvested stock option awards. Approximately 53% and 32% 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 Q1 2005 was 32%, reflecting the implied volatility determined from the market prices of traded call options on the Company s stock. During Q1 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 Q1 2005 and Q1 2004 to estimate the fair value of the Company s employee stock option awards.

Q1 2005 - The fair value of employee stock options granted during Q1 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
Option pricing model	Binomial
Expected stock price volatility	32%
Expected dividend yield	0%
Expected life of option years	4.6 to 5.1
Risk-free interest rate	4.3%
Weighted average fair value of options granted	$ 8.27

Q1 2004 - The fair value of employee stock options granted during Q1 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
Option pricing model	Black-Scholes
Expected stock price volatility	50%
Expected dividend yield	0%
Expected life of option years	5.0
Risk-free interest rate	4.2%
Weighted average fair value of options granted	$ 11.07

Reclassifications

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

3. 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):

	March 31, 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	(28.5)	(26.3)
	$ 10.9	$ 13.1

Amortization of intangible assets is computed on the straight-line method based on the estimated useful lives of the assets. Amortization for Q1 2005 and Q1 2004 was $2.2 million and $4.1 million,

respectively. The estimated aggregate amortization for the remaining life of the Evans agreement is as follows: remainder of 2005, $6.5 million; and 2006, $4.4 million.

4. Inventory

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

	March 31, 2005	December 31, 2004
Raw Materials	15.5	16.5
Work in Process	52.9	38.3
Finished Goods	4.1	9.3
	$ 72.5	$ 64.1

The Company recorded permanent inventory write downs totaling $4.6 million and $13.5 million in cost of goods sold to reflect total FluMist inventories at net realizable value as of March 31, 2005 and 2004, respectively.

5. Earnings per Share

The following is a reconciliation of the numerators and denominators of the diluted EPS computation (in millions):

	Q1 2005	Q1 2004(1)
Numerator (in millions):		
Net income for basic EPS	$ 114.1	$ 111.0
Adjustments for interest expense on 1% Convertible Senior Notes, net of tax	0.6	1.2
Income for diluted EPS	$ 114.7	$ 112.2

	Q1 2005	Q1 2004(1)
Denominator (in millions):		
Weighted average shares for basic EPS	248.1	248.2
Effect of dilutive securities:		
Stock options and warrants	1.8	2.7
1% Convertible Senior Notes	7.3	7.3
Weighted average shares for diluted EPS	257.2	258.2
Basic earnings per share	$ 0.46	$ 0.45
Diluted earnings per share	$ 0.45	$ 0.43

(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. In accordance with EITF No. 04-8, the Company has restated Q1 2004 diluted earnings per share to include the 1% Convertible Senior Notes as they were dilutive under the if-converted method.

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 21.3 million and 21.5 million shares of common stock, respectively, at prices ranging from $24.20 to $83.25 per share and $23.84 to $83.25 per share, respectively, were outstanding at March 31, 2005 and March 31, 2004 but were not included in the computation of diluted earnings per share because the exercise price of the options exceeded the average market price.

6. Income Taxes

The Company s effective tax rate for Q1 2005 and Q1 2004 was 35% and 37%, respectively. The effective tax rate for Q1 2005 was favorably impacted by the increase in credits available for research and development activities, including credits earned for orphan drug status of certain research and experimentation activities.

7. Comprehensive Income

	Q1 2005	Q1 2004
Net earnings	114.1	111.0
Change in foreign currency translation adjustment	(0.4)	(0.2)
Change in unrealized (loss) gain on investments, net of tax	(17.9)	4.3
Change in unrealized gain on cash flow hedges, net of tax		2.6
Comprehensive income	$ 95.8	$ 117.7

During Q1 2004, reclassification adjustments for realized gains on available-for-sales securities, net of tax, were $4.1 million. Reclassification adjustments during Q1 2005 were immaterial.

8. Shareholders Equity

During Q1 2005, the Company repurchased approximately 0.7 million shares of common stock under the stock repurchase program at a cost of $17.4 million, or an average cost of $24.53 per share. Through May 2, 2005, the Company has repurchased an additional 0.5 million shares at an average cost of $24.95 per share. The Company is holding repurchased shares as treasury shares and is using them for general corporate purposes, including but not limited to acquisition-related transactions and for issuance upon exercise of outstanding stock options.

9. 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. 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 since that time. With respect to the other legal proceedings described therein, other than the AWP litigation matters (which are described in greater detail below), the following material developments have occurred:

With respect to the appeal filed by Celltech R&D Ltd. against the Company in the U.K. Court of Appeal, the Company was notified on April 20, 2005 that Celltech has withdrawn its appeal of the German Adair matter, which means a final decision in the Company s favor has been reached with respect to this matter. The other pending matter with Celltech related to the Adair 927 Patent is not

affected by this development. With respect to the Adair 927 Patent matter, as of March 31, 2005, the Company estimates the range of possible pre-tax loss from $0 to $33 million, exclusive of any potential offsets and royalty obligations going forward relating to Celltech s litigation against the Company in the U.K. on the Adair 927 Patent. To date, the Company has not made any royalty payments to Celltech under the January 19, 1998 license agreement.

In the Company s suit against Centocor, Inc., oral argument occurred before the United States Court of Appeals for the Federal Circuit in April 2005, and the Company is awaiting a decision.

With respect to the AWP litigation matters, the following is intended to update and replace the corresponding disclosure 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: The Company, together with a number of other pharmaceutical manufacturers, is a defendant in several actions brought by the Alabama Attorney General, the City of New York and 44 New York State Counties that are pending in federal and state courts as of March 31, 2005, relating to the pricing of Synagis. The federal cases brought against the Company by various New York State Counties have been consolidated for pre-trial purposes under the caption In re Pharmaceutical Industry Average Wholesale Price Litigation, MDL No. 1456, Civ. Action No. 01-CV-12257-PBS, before the United States District Court Judge Patti B. Saris in the United States District Court for the District of Massachusetts (AWP Multidistrict litigation). The Counties, and New York City, allege that the defendants, including the Company, manipulated the average wholesale price (AWP), a price listed by price reporting agencies and used as a Medicaid reimbursement benchmark, causing the Counties and New York City to pay artificially inflated prices for covered drugs. In addition, (with the exception of Erie County, which has sued the Company in state court and alleges only improper AWP reporting) the Counties and New York City argue that the defendants (including the Company) did not accurately report best price, a statutorily defined term that must be reported by manufacturers in order to qualify for Medicaid reimbursement. The plaintiffs seek declaratory and injunctive relief, disgorgement of profits, and treble and punitive damages suffered as a result of defendants alleged unlawful practices related to prescription medication paid for by Medicaid. Likewise, in January 2005 a complaint was filed by the State of Alabama against more than 70 companies, including the Company, accusing all defendants of improper AWP and AMP submissions and further alleging fraudulent misrepresentation, unjust enrichment and wantonness. As of March 31, 2005, the Company estimates the range of possible pre-tax loss from the Alabama, New York City and New York State County actions to be from $0 to $10 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 Q1 2005

Product sales increased 5% in Q1 2005 as compared to Q1 2004, reflecting 12% growth in sales of Synagis, offset by the impact of lower product sales of FluMist in the current quarter, due to the timing of revenue recognition related to sales for the 2003/2004 influenza season. We recorded diluted net earnings of $0.45 per share in Q1 2005 compared to diluted net earnings per share of $0.43 in Q1 2004. The growth in net income was primarily attributable to a 20% increase in gross profit, partially offset by increased selling, general and administrative expenses, and research and development spending.

During Q1 2005, we amended our agreement with GlaxoSmithKline (GSK) for the development of the 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.

The Company s cash and marketable securities at March 31, 2005 totaled $1.9 billion as compared to $1.7 billion at December 31, 2004, reflecting the impact of operating cash flows generated in Q1 2005.

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 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 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 of three months to nine months.

For all FluMist inventory components on hand as of March 31, 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 March 31, 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 March 31, 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 Q1 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. 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 March 31, 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	(0.4)	0.5	0.1
Cost of goods sold recognized on 2004/2005 inventory	(3.2)	3.1	(0.1)
Production, net	14.6	(4.3)	10.3
Disposals and scrap	(2.8)	2.3	(0.5)
As of March 31, 2005	$ 58.9	$ (34.1)	$ 24.8

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 delays 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 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. For Q1 2005, the expected life of an option, as derived from the output of the binomial model, ranged from 4.6 years to 5.1 years. For Q1 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 Q1 2005 was 32%, reflecting the implied volatility determined from the market prices of traded call options on our stock. During Q1 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

Q1 2005 compared to Q1 2004

Revenues Product Sales

(in millions)	Q1 2005	Q1 2004	Growth
Synagis	$ 471.6	$ 421.7	12 %
Ethyol	22.7	24.4	(7)%
FluMist	2.8	25.9	(89)%
Other Products	11.6	11.2	4%
	$ 508.7	$ 483.2	5%

Product sales grew 5% in Q1 2005 to $508.7 million as compared to $483.2 million in Q1 2004, reflecting a 12% increase in sales of Synagis, offset by a decline in revenue from sales of FluMist due to the timing of revenue recognition for product sold during the 2003/2004 season. Of the overall 5% increase in product sales, domestic sales volume of Synagis, Ethyol and CytoGam accounted for eight growth points and an additional six percentage points were due to domestic price increases of Synagis, Ethyol and CytoGam. These increases were partly negated by higher sales allowances that reduced sales by three percentage points and a decrease in FluMist product sales that reduced sales by five percentage points. The decrease in sales of FluMist reflects the fact that FluMist shipped to our former partner, Wyeth, in 2003 could not be recognized as revenue until Q1 2004 when returns and discounts could be reliably estimated. International sales were relatively consistent period over period.

Synagis - Synagis accounted for approximately 93% and 87% of our product sales in Q1 2005 and Q1 2004, respectively. In Q1 2005, domestic sales of Synagis increased 13% to $439.5 million from Q1 2004 sales of $390.1 million. Of the overall 13% increase, approximately ten percentage points resulted from higher sales volumes and another seven percentage points are due to price increases, partially offset by higher sales allowances that caused a reduction of four percentage points.

We record Synagis international product sales based on AI s sales price to customers, as defined in our distribution agreement. Our reported international sales of Synagis increased 1% to $32.1 million for Q1 2005 as compared to $31.6 million in Q1 2004. The increase is attributable to an increase in the sales price caused by a change in the mix of countries to which we sell Synagis internationally that favorably impacted the average sales price and the favorable currency translation impact of a weakened U.S. dollar, partially offset by a 29% decrease in sales volume which we believe is due to the early stocking of inventories by AI for the 2004/2005 RSV season. We currently expect that in 2005, stocking of inventories for the 2005/2006 RSV season will resume a more normal pattern this year.

Ethyol - Ethyol accounted for approximately 4% and 5% of our product sales in Q1 2005 and Q1 2004, respectively. Worldwide sales of Ethyol declined 7% to $22.7 million in Q1 2005, compared to $24.4 million in Q1 2004. Of the overall decline, approximately ten percentage points resulted from increases in sales allowances, offset by an increase in domestic sales prices that contributed three percentage points. International sales of Ethyol were consistent for Q1 2005 and Q1 2004.

FluMist FluMist accounted for 1% and 5% of our product sales in Q1 2005 and Q1 2004, respectively. Sales of FluMist were $2.8 million in Q1 2005, as compared to $25.9 million in Q1 2004, a decrease primarily due to the timing of revenue recognition for product shipped during 2003. During Q1 2005, we shipped estimated net doses of approximately 0.3 million resulting in product sales of $2.8 million. Our Q1 2004 product sales of FluMist amounted to $25.9 million, representing transfer price revenues for 4.1 million doses shipped to Wyeth, our former partner, during 2003 related to the 2003/2004 season. At December 31, 2003, we concluded that the variables associated with FluMist product revenues were not determinable, largely due to low sales volume and the lack of returns history and comparable rebate redemption rates for the new product. As a result, product revenues associated with the doses that were shipped to Wyeth in 2003 were not recognized until Q1 2004.

Other Products - Sales of other products in Q1 2005, which include sales of CytoGam, NeuTrexin, and

by-products that result from the CytoGam manufacturing process, increased 4% to $11.6 million in Q1 2005 from $11.2 million in Q1 2004, driven by a 17% increase in CytoGam sales.

Revenues Other Revenues

Other revenues decreased to $1.1 million for Q1 2005 compared to $5.8 million in Q1 2004. Other revenues in Q1 2004 are largely comprised of contractual payments received from Wyeth prior to dissolution of our collaboration, including royalties related to the 2003/2004 influenza season, supply goal payments and corporate funding for clinical development and sales and marketing programs.

Cost of Sales

Cost of sales was $119.8 million for Q1 2005 compared to $158.2 million in Q1 2004. Gross margins on product sales for Q1 2005 were 76%, up nine percentage points from Q1 2004. Gross margins for all products, excluding FluMist, were 77% and 75% in Q1 2005 and Q1 2004, respectively. Gross margins for FluMist did not materially impact overall gross margins for Q1 2005, but reduced gross margins in Q1 2004 by eight percentage points. The lower impact of FluMist on gross margins for Q1 2005 was due to improved sales volume estimates and lower manufacturing cost estimates for the 2005/2006 influenza season (see Critical Accounting Estimates Inventory).

Research and Development Expenses

Research and development expenses increased 39% to $69.3 million in Q1 2005, compared to $49.8 million in Q1 2004. The increase in our drug discovery and development expenses is related to a large number of ongoing clinical and preclinical studies, particularly for Numax and CAIV-T which we advanced into Phase 3 in late 2004, as well as costs associated with the expansion of infrastructure to support these studies. During Q1 2005, research and development expenses also include approximately $0.9 million in connection with the technology transfer and transition activities associated with reacquisition of the influenza vaccines franchise from Wyeth.

During Q1 2005, we continued to advance our pipeline, completing a Phase 3 study to bridge refrigerator-stable CAIV-T to frozen FluMist; initiating patient enrollment in the Southern Hemisphere for our pivotal Phase 3 study for Numax; completing patient enrollment in our Phase 2 prostate cancer study with Vitaxin; and filing an investigational new drug (IND) application to begin clinical studies of our RSV/PIV-3 candidate vaccine.

Selling, General and Administrative Expenses

Selling, general and administrative (SG&A) expenses increased 27% to $157.5 million in Q1 2005 compared to $123.7 million in Q1 2004. The increase is largely attributable to increased co-promotion expense, corresponding to the increase in Synagis sales, the impact of ongoing costs associated with the 2004 expansion of the pediatric commercial organization and increased marketing activities. SG&A expense as a percentage of product sales was 31% and 26% in Q1 2005 and Q1 2004, respectively.

Other Operating Expenses

Other operating expenses were $2.6 million in Q1 2005 compared to $1.8 million in Q1 2004. Other operating expenses primarily include excess capacity charges associated with the plasma production section of the Frederick Manufacturing Center located in Frederick, Maryland.

Interest Income and Expense

We earned interest income of $16.7 million and $16.2 million for Q1 2005 and Q1 2004, respectively, primarily due to higher average rates. Interest expense for Q1 2005, net of amounts capitalized, was $2.0 million, down from $2.2 million in Q1 2004. This decrease is largely due to the retirement of the 5¼% Convertible Subordinated Notes in March 2004, partially offset by a decrease in capitalized interest, as the new R&D facility and corporate headquarters were completed in March 2004.

Gain on Investment Activities

We recorded a net gain on investment activities of $0.3 million during Q1 2005, compared to a net gain of $6.7 million during Q1 2004. The Q1 2004 gain principally consists of realized gains on the sale of certain of our publicly traded equity investments.

Taxes

We recorded income tax expense of $61.5 million for Q1 2005, resulting in an effective rate of 35%. We recorded income tax expense of $65.2 million for Q1 2004 resulting in an effective rate of 37%. The effective tax rate for Q1 2005 was favorably impacted by the increase in credits available for research and development activities, including credits earned for orphan drug status of certain research and experimentation activities.

Net Earnings

The reported net income for Q1 2005 was $114.1 million, or $0.46 per share basic and $0.45 per share diluted, compared to net income for Q1 2004 of $111.0 million or $0.45 per share basic and $0.43 per share diluted. Shares used in computing basic and diluted earnings per share in Q1 2005 were 248.1 million and 257.2 million, respectively, while shares used in computing basic and diluted earnings per share for Q1 2004 were 248.2 million and 258.2 million, respectively.

We do not believe inflation had a material effect on our financial statements.

LIQUIDITY AND CAPITAL RESOURCES

Sources and uses of cash - Cash and marketable securities were $1.9 billion at March 31, 2005 as compared to $1.7 billion at December 31, 2004, an increase of 10%. The increase in cash is primarily due to operating cash flows generated during Q1 2005. Working capital increased to $470.3 million at March 31, 2005 from $330.0 million at December 31, 2004, also due to cash generated by our operations.

Operating Activities

Net cash provided by operating activities was $240.0 million in Q1 2005 as compared to $235.3 million in Q1 2004. The change versus prior period is primarily the result of the increase in net earnings in Q1 2005.

Investing Activities

Cash used for investing activities during Q1 2005 amounted to $77.5 million, as compared to $278.9 million during Q1 2004. Cash used for investing activities in Q1 2005 included net additions to our investment portfolio of $61.7 million; capital expenditures totaling $14.5 million, primarily for the construction of our new pilot plant in Gaithersburg, Maryland and the expansion of our FluMist manufacturing facilities in Speke, England; and minority interest investments in strategic partners totaling $1.3 million through our venture capital subsidiary.

Financing Activities

Financing activities used $15.7 million in cash for Q1 2005, as compared to $171.5 million used in the comparable period of 2004. The decrease is principally due to the use of $172.7 million in cash during Q1 2004 to repurchase and retire the balance of the 5 ¼% Convertible Subordinated Notes. During Q1 2005, we used $17.4 million in cash to repurchase shares of our common stock as authorized under our share repurchase program. Approximately $1.9 million was received upon the exercise of employee stock options in Q1 2005, as compared to $1.4 million received in Q1 2004.

Our primary source of liquidity is operating cash flow. Management continues to believe that such internally generated cash flow as well as its existing funds will be adequate to service its existing debt and other cash requirements. We expend cash to finance our research and development and clinical trial programs; to obtain access to new technologies through collaborative research and development agreements with strategic partners, through our venture capital subsidiary, or through other means; to fund capital projects; and to finance the production of inventories. In February 2005, our Board of Directors approved an additional $100 million in funding for our venture capital subsidiary to $200 million. Also, the BBB rating on our outstanding indebtedness, considered to be investment grade, will contribute to our ability to access capital markets, should we desire or need to do so. We may raise additional capital in the future to take advantage of favorable conditions in the market or in connection with our development activities.

Our Board of Directors has authorized the repurchase of up to $500 million of the Company s common stock during the period from July 2003 through June 2006 in the open market or in privately negotiated transactions, pursuant to terms management deems appropriate and at such times it may designate. During Q1 2005, we repurchased approximately 0.7 million shares of our common stock under the stock repurchase program at a total cost of $17.4 million, or an average cost of $24.53 per share. Through May 2, 2005, we have repurchased an additional 0.5 million shares at an average cost of $24.95 per share. As of May 2, 2005, approximately $210 million was available under the authorization for additional repurchases of stock. We are holding repurchased shares as treasury shares and are using them for general corporate purposes, including but not limited to acquisition-related transactions and for issuance upon exercise of outstanding stock options.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We believe our primary market risks as of March 31, 2005 continue to be the exposures to loss resulting from changes in interest rates, foreign currency exchange rates, and equity prices. Our market risks at March 31, 2005 have not changed significantly from those discussed in our Form 10-K for the year ended December 31, 2004. For other information regarding the Company s market risk exposure, please refer to Part II, Item 7A, Quantitative and Qualitative Disclosures About Market Risk of the Company s Annual Report on Form 10-K for the year ended December 31, 2004.

ITEM 4. CONTROLS AND PROCEDURES

The Company maintains disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act)) that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission s rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer, President and Vice Chairman, and Senior Vice President and Chief Financial Officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable, and not absolute, assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Accordingly, no evaluation or implementation of a control system can provide complete assurance that all control issues and all possible instances of fraud have been or will be detected.

As of the end of the period covered by this report, the Company carried out an evaluation, under the supervision and with the participation of the Company s management, including the Company s Chief Executive Officer, President and Vice Chairman and its Senior Vice President and Chief Financial Officer, of the effectiveness of the Company s disclosure controls and procedures, as required by Rule 13a-15(b) promulgated under the Exchange Act. Based upon that evaluation, the Company s Chief Executive Officer, President and Vice Chairman and its Senior Vice President and Chief Financial Officer concluded that the Company s disclosure controls and procedures were effective at the reasonable assurance level.

In addition, the management of the Company, with the participation of the Company s Chief Executive Officer, President and Vice Chairman and its Senior Vice President and Chief Financial Officer, have determined that there was no change in the Company s internal control over financial reporting that occurred during Q1 2005 that has materially affected, or is reasonably likely to materially affect, the Company s internal control over financial reporting.

PART II - OTHER INFORMATION

ITEM 1. **LEGAL PROCEEDINGS**

Information with respect to legal proceedings is included in Note 9 of Part I, Item 1 Financial Statements, and is incorporated herein by reference and should be read in conjunction with the related disclosure previously reported in the Company s Annual Report on Form 10-K for the year ended December 31, 2004.

ITEM 2. **UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

(c) Issuer purchases of equity securities(1)

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Approximate Dollar Value that May Yet Be Purchased Under the Plans or Programs
January 1, 2005 through January 31, 2005	609,800	$ 24.63	609,800	$ 225,149,000
February 1, 2005 through February 28, 2005		$		$ 225,149,000
March 1, 2005 through March 31, 2005	100,000	$ 23.94	100,000	$ 222,756,000

(1) The Company s Board of Directors has authorized the repurchase of up to $500 million of the Company s common stock on the open market or in privately negotiated transactions during the period from July 2003 through June 2006.

ITEM 3. **DEFAULTS UPON SENIOR SECURITIES NONE**

ITEM 4. **SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS NONE**

ITEM 5. **OTHER INFORMATION NONE**

ITEM 6. **EXHIBITS**

(a) Exhibits:

10.1	Letter Agreement with Mr. Melvin D. Booth, dated March 31, 2005, for part-time employment.
31.1	Certification pursuant to 18 USC Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification pursuant to 18 USC Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification pursuant to 18 USC Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, furnished as permitted by Item 601(b)(32)(ii) of Regulation S-K. This Exhibit 32 is not filed for purposes of Section 18 of the Securities Exchange Act of 1934, and is not and should not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934.

SIGNATURES

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

MEDIMMUNE, INC.
(Registrant)

/s/ David M. Mott
Date: May 6, 2005 David M. Mott
Chief Executive Officer, President and Vice Chairman
Principal Executive Officer

/s/ Lota S. Zoth
Date: May 6, 2005 Lota S. Zoth
Senior Vice President and Chief Financial Officer
Principal Financial Officer

/s/ Mark E. Spring
Date: May 6, 2005 Mark E. Spring
Vice President, Finance and Controller
Principal Accounting Officer