

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

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D. C. 20549**

**FORM 10-Q**



**¼ 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**

**(State or other jurisdiction of  
incorporation or organization)**

**52-1555759**

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

**One MedImmune Way, Gaithersburg, MD 20878**

Edgar Filing: MEDIMMUNE INC /DE - Form 10-Q

(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  No

Indicate by check mark whether the registrant is an accelerated filer (as defined by Rule 12b-2 of the Exchange Act). Yes  No

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

---

**MEDIMMUNE, INC.**

**Index to Form 10-Q**

**Part I Financial Information**

<u>Item 1.</u>	<u>Financial Statements</u> <u>Consolidated Balance Sheets</u> <u>Consolidated Statements of Operations</u> <u>Condensed Consolidated Statements of Cash Flows</u> <u>Notes to Consolidated Financial Statements</u>
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>
<u>Item 4.</u>	<u>Controls and Procedures</u>

**Part II Other Information**

<u>Item 1.</u>	<u>Legal Proceedings</u>
<u>Item 2.</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>
<u>Item 3.</u>	<u>Defaults upon Senior Securities</u>
<u>Item 4.</u>	<u>Submission of Matters to a Vote of Security Holders</u>
<u>Item 5.</u>	<u>Other Information</u>
<u>Item 6.</u>	<u>Exhibits</u>

MedImmune, Synagis, CytoGam, Ethyol, FluMist, NeuTrexin, RespiGam and Vitaxin are registered trademarks of the Company. Numax is a trademark of the Company.

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
<b>ASSETS:</b>		
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
<b>Total Current Assets</b>	<b>862.3</b>	<b>693.8</b>
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
<b>Total Assets</b>	<b>\$ 2,445.7</b>	<b>\$ 2,564.4</b>
<b>LIABILITIES AND SHAREHOLDERS EQUITY:</b>		
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
<b>Total Current Liabilities</b>	<b>258.7</b>	<b>363.8</b>
Long-term debt	505.7	506.2
Other liabilities	1.0	19.8
<b>Total Liabilities</b>	<b>765.4</b>	<b>889.8</b>
<b>Commitments and Contingencies</b>		
<b>SHAREHOLDERS EQUITY:</b>		
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)
<b>Total Shareholders Equity</b>	<b>1,680.3</b>	<b>1,674.6</b>
<b>Total Liabilities and Shareholders Equity</b>	<b>\$ 2,445.7</b>	<b>\$ 2,564.4</b>

Edgar Filing: MEDIMMUNE INC /DE - Form 10-Q

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
<b>Revenues:</b>				
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
<b>Costs and expenses:</b>				
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
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
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
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
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)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
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**



## Edgar Filing: MEDIMMUNE INC /DE - Form 10-Q

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*

## Edgar Filing: MEDIMMUNE INC /DE - Form 10-Q

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*

## Edgar Filing: MEDIMMUNE INC /DE - Form 10-Q

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

## Edgar Filing: MEDIMMUNE INC /DE - Form 10-Q

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.



Edgar Filing: MEDIMMUNE INC /DE - Form 10-Q

	Q1 2004		Q2 2004	
	Black-Scholes		Black-Scholes	
Option pricing model				
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):

	<b>June 30, 2005</b>	<b>December 31, 2004</b>
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**



## Edgar Filing: MEDIMMUNE INC /DE - Form 10-Q

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



Edgar Filing: MEDIMMUNE INC /DE - Form 10-Q

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

	Q2 2005		Q2 2004		YTD 2005		YTD 2004
<b>Numerator (in millions):</b>							
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

Edgar Filing: MEDIMMUNE INC /DE - Form 10-Q

	Q2 2005	Q2 2004	YTD 2005	YTD 2004
<b>Denominator (in millions):</b>				
Weighted average shares for basic EPS	247.4	248.7	247.7	248.5
<b>Effect of dilutive securities:</b>				
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**





## Edgar Filing: MEDIMMUNE INC /DE - Form 10-Q

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

## Edgar Filing: MEDIMMUNE INC /DE - Form 10-Q

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

## Edgar Filing: MEDIMMUNE INC /DE - Form 10-Q

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
<b>FluMist Details</b>					
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

## Edgar Filing: MEDIMMUNE INC /DE - Form 10-Q

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
<b>Synagis</b>			
Domestic	\$ 43.5	\$ 39.7	10%
International	7.4	16.4	(55)%
	50.9	56.1	(9)%
<b>Ethyol</b>			
Domestic	21.0	24.1	(13)%
International	1.6	0.9	81%
	22.6	25.0	(9)%
<b>FluMist</b>		1.2	N/A
<b>Other Products</b>	11.2	8.4	33%
<b>Total Product Sales</b>	\$ 84.7	\$ 90.7	(7)%

*Synagis* - *Synagis* accounted for approximately 60% and 62% of our product sales in Q2 2005 and Q2 2004, respectively. Due to the seasonal nature of *Synagis* sales, only five to six percent of the respective overall seasonal sales (July 1 through June 30) typically occur in the second quarter. In Q2 2005, domestic sales of *Synagis* increased 10% to \$43.5 million from Q2 2004 sales of \$39.7 million. The growth over Q2 2004 primarily resulted from higher sales volumes, with higher sales allowances offsetting the impact of price increases.

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* decreased 55% to \$7.4 million for Q2 2005 as compared to \$16.4 million in Q2 2004. The decrease is primarily attributable to the early stocking of inventories by AI for the 2004/2005 RSV season during Q2 2004. We currently expect that stocking of inventories by AI for the 2005/2006 RSV season will resume a more normal pattern.

*Ethyol* - *Ethyol* accounted for approximately 27% and 28% of our product sales in Q2 2005 and Q2 2004, respectively. Domestic sales of *Ethyol* declined 13% to \$21.0 million in Q2 2005, compared to \$24.1 million in Q2 2004. Of the overall decline, approximately 19 percentage points resulted from a decrease in domestic sales volume. We believe that the lower domestic sales volumes are primarily due to the depletion of wholesaler inventories to accommodate end-user demand that was 2% stronger than in the first quarter of 2005. End-user demand in Q2 2005 declined from

Q2 2004 levels due partially to a temporary surge in demand in the prior year quarter, and in part to the on-going impact of the adoption of a relatively new form of radiation treatment in the head and neck cancer market. The decrease in domestic sales volume was partially offset by an increase in domestic sales prices that contributed five growth points, and the remaining increase was due to lower sales allowances that added one growth point. We recorded growth in international sales of Ethyol of \$0.7 million to \$1.6 million in Q2 2005.

**FluMist** Our Q2 2004 product sales of FluMist amounted to \$1.2 million, representing the final agreed-upon reconciliation of sales discounts and returns with Wyeth as part of the dissolution of our collaboration, relating to the 2003/2004 influenza season. Due to the seasonal nature of influenza, the majority of FluMist sales are expected to occur between October and January. Our results for Q2 2005 reflect that seasonality, and we expect that our results will reflect that seasonality going forward.

**Other Products** - Sales of other products in Q2 2005, which include sales of CytoGam, NeuTrexin, and by-products that result from the CytoGam manufacturing process, increased 33% to \$11.2 million in Q2 2005 from \$8.4 million in Q2 2004, driven by a 35% increase in CytoGam sales.

#### **Cost of Sales**

Cost of sales was \$28.0 million for Q2 2005 compared to \$37.3 million in Q2 2004. Gross margins on product sales for Q2 2005 were 67%, up eight percentage points from Q2 2004. Gross margins for all products, excluding FluMist, were 71% and 76% in Q2 2005

and Q2 2004, respectively, primarily reflecting the favorable impact of higher international Synagis sales during Q2 2004 on margins. Gross margins for FluMist did not materially impact overall gross margins for Q2 2005, but reduced gross margins in Q2 2004 by 17 percentage points. The lower impact of FluMist on gross margins for Q2 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**



## Edgar Filing: MEDIMMUNE INC /DE - Form 10-Q

Research and development expenses increased 17% to \$79.3 million in Q2 2005, compared to \$67.8 million in Q2 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 Q2 2005 and Q2 2004, research and development expenses also include approximately \$0.5 million and \$10.8 million, respectively, in connection with the technology transfer and transition activities associated with reacquisition of the influenza vaccines franchise from Wyeth.

During Q2 2005, we completed 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. In our pivotal Phase 3 trial for Numax in which we are comparing it to Synagis, we enrolled 605 additional patients in the Southern Hemisphere component of the trial during Q2 2005. Also during Q2 2005, we initiated and completed enrollment for a Phase 2 study for Numax in the southern hemisphere to evaluate the safety of re-dosing children for a second season, and we completed enrollment in the Vitaxin Phase 2 study in prostate cancer.

During Q2 2005, we entered into a collaboration agreement with Avalon Pharmaceuticals, Inc. to discover and develop small molecule therapeutic compounds in the area of inflammatory disease. In addition, we entered into a collaboration with Seattle Genetics to utilize their proprietary technology to develop antibody-based therapeutics to treat cancer. Under the terms of these agreements, we made upfront payments (that are reflected as Research and Development expenses) and are contingently obligated to provide research and development support, milestone payments and royalties on potential future product sales related to these collaborations.

### **Selling, General and Administrative Expenses**



Selling, general and administrative ( SG&A ) expenses increased 3% to \$60.9 million in Q2 2005 compared to \$58.9 million in Q2 2004. The increase is largely attributable to the expansion of the pediatric commercial organization, increased marketing activities, and increased co-promotion expense, corresponding to the increase in domestic Synagis sales.

#### **Impairment of Intangible Asset**

As a result of entering into agreements to dissolve the collaboration with Wyeth during April 2004, we recorded a permanent impairment charge of \$73.0 million that represented the remaining unamortized cost originally recorded for the original collaboration with Wyeth.

#### **Acquired IPR&D**

We recorded a charge of \$24.7 million for acquired IPR&D during Q2 2004 in conjunction with our reacquisition of the influenza vaccines franchise from Wyeth. The charge represented the relative fair value of purchased in-process technologies at the acquisition date, calculated utilizing the income approach, of certain IPR&D projects, primarily CAIV-T.

#### **Taxes**

We recorded an income tax benefit of \$23.9 million for Q2 2005, resulting in an effective tax rate of 35%. We recorded an income tax benefit of \$54.9 million for Q2 2004, resulting in an effective rate of 37% for the period, excluding the impact of \$6.9 million of IPR&D charges incurred during Q2 2004 that are not deductible for tax purposes. The decline in the effective tax rate reflects additional tax credits available for certain research and development activities, including credits earned for orphan drug status of certain research and experimentation activities.

#### **Net Loss**

The reported net loss for Q2 2005 was \$44.2 million, or \$0.18 per share, compared to net loss for Q2 2004 of \$100.3 million or \$0.40 per share. Shares used in computing net loss per share in Q2 2005 were 247.4, while shares used in computing net loss per share for Q2 2004 were 248.7 million.

## YTD 2005 compared to YTD 2004

## Revenues Product Sales

(in millions)	YTD 2005	YTD 2004	Change
<b>Synagis</b>			
Domestic	\$ 483.0	\$ 429.8	12%
International	39.5	48.0	(18)%
	522.5	477.8	9%
<b>Ethyol</b>			
Domestic	42.6	47.4	(10)%
International	2.7	2.0	39%
	45.3	49.4	(8)%
<b>FluMist</b>	2.8	27.1	(90)%
<b>Other Products</b>	22.8	19.6	16%
<b>Total Product Sales</b>	\$ 593.4	\$ 573.9	3%

*Synagis* - Synagis accounted for approximately 88% and 83% of our product sales for YTD 2005 and YTD 2004, respectively. We achieved a 12% increase in domestic Synagis sales to \$483.0 million for YTD 2005, up from \$429.8 million in YTD 2004. The growth over the prior year period resulted from higher unit sales volumes, as the impact of price increases was largely offset by higher sales allowances during Q2 2005. Our reported international sales of Synagis decreased to \$39.5 million in YTD 2005 compared to \$48.0 million in YTD 2004, primarily due to the early stocking of inventories for 2004/2005 Synagis season by AI during YTD 2004.

*FluMist* FluMist accounted for approximately 0.5% and 4.7% of our product sales for YTD 2005 and YTD 2004, respectively. Sales of FluMist were \$2.8 million in YTD 2005, as compared to \$27.1 million in YTD 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 YTD 2004 sales of FluMist amounted to \$27.1 million and include transfer price for product shipped to Wyeth for the entire 2003/2004 season. During 2003, we shipped 4.1 million doses of FluMist to Wyeth, our former collaboration partner, who was contractually responsible for distributing the product to third parties. 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 the first quarter of 2004. Our Q2 2004 product sales of FluMist amounted to \$1.2 million, representing the final agreed-upon reconciliation of sales discounts and returns with Wyeth as part of the dissolution of our collaboration.

*Ethyol* - Ethyol accounted for approximately 8% and 9% of our product sales for YTD 2005 and YTD 2004, respectively. Worldwide Ethyol sales declined 8% to \$45.3 million in YTD 2005, as compared to \$49.4 million in YTD 2004, primarily driven by a 10% decline in domestic sales due to lower unit sales volumes for YTD 2005. We



believe that the lower domestic unit volumes for YTD 2005 as compared to YTD 2004 are partially due to the depletion of wholesaler inventories from December 31, 2004 levels to accommodate end-user demand. In contrast, we experienced an increase in wholesaler inventories from December 31, 2003 levels. Domestic end-user demand in the YTD 2005 period declined approximately 3% over YTD 2004, due to the ongoing impact of the adoption of a relatively new form of radiation treatment in the head and neck cancer market. International sales grew from \$2.0 million in YTD 2004 to \$2.7 million in YTD 2005.

*Other Products* - Sales of other products include sales of CytoGam, RespiGam, NeuTrexin, and by-products that result from the CytoGam manufacturing process and amounted to \$22.8 million in YTD 2005 as compared to \$19.6 million for YTD 2004. The increase is primarily due to a 25% increase in sales of CytoGam.

**Revenues   Other Revenues**



## Edgar Filing: MEDIMMUNE INC /DE - Form 10-Q

Other revenues of \$4.9 million for YTD 2005 are lower than YTD 2004 other revenues of \$8.7 million largely due to decreased revenues under collaborative agreements. Other revenues in YTD 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 and corporate funding for clinical development and sales and marketing programs.

**Cost of Sales**

Cost of sales for YTD 2005 decreased 24% to \$147.8 million from \$195.5 million for YTD 2004. Gross margins on product sales were 75% for YTD 2005, up nine percentage points from gross margins of 66% for YTD 2004. Gross margins for all products, excluding FluMist, were 76% and 75% in YTD 2005 and YTD 2004, respectively. Gross margins for FluMist did not materially impact overall gross margins for YTD 2005, but reduced gross margins in YTD 2004 by nine percentage points. The lower impact of FluMist on gross margins for YTD 2005 was due to improved sales volume estimates and lower manufacturing cost estimates for the 2005/2006 influenza season (see Critical Accounting Estimates).

**Research and Development Expenses**



## Edgar Filing: MEDIMMUNE INC /DE - Form 10-Q

Research and development expenses of \$148.6 million in YTD 2005 increased 26% from \$117.6 million in YTD 2004. The increase is due largely to direct costs associated with ongoing and additional clinical and preclinical trials for product candidates, as well as increases in headcount and related expenses in support of increased research and development activities. Also included in research and development expenses in YTD 2005 and 2004 are \$1.4 million and \$10.8 million, respectively, in costs for technology transfer and transition activities associated with our assumption of research and development activities related to the influenza vaccines franchise.

### **Selling, General, and Administrative Expenses**

Selling, general and administrative ( SG&A ) expenses increased 20% to \$218.4 million in YTD 2005 compared to \$182.6 million in YTD 2004. The increase is largely attributable to increased co-promotion expense, corresponding to the increase in domestic Synagis sales, and the expansion of the pediatric commercial organization. Also included in SG&A expense in YTD 2004 is \$0.8 million for other Wyeth-related transition activities. As a percentage of product sales, SG&A expense increased to 37% of product sales for YTD 2005 compared to 32% of products sales in YTD 2004.

### **Impairment of Intangible Asset**

As a result of entering into agreements to dissolve the collaboration with Wyeth during April 2004, we recorded a permanent impairment loss of \$73.0 million that represented the remaining unamortized cost originally recorded for the original collaboration with Wyeth.

### **Acquired IPR&D**

We recorded a charge of \$24.7 million for acquired IPR&D for YTD 2004 in conjunction with our reacquisition of the influenza vaccines franchise from Wyeth. The charge represented the relative fair value of purchased in-process technologies at the acquisition date, calculated utilizing the income approach, of certain IPR&D projects, primarily CAIV-T.

### **(Loss) Gain on Investment Activities**

We recorded a net loss on investment activities of \$0.9 million during YTD 2005, compared to a net gain of \$7.3 million during YTD 2004. The YTD 2004 net gain principally consists of realized gains on the sale of certain of our publicly traded equity investments.

### **Taxes**

We recorded income tax expense of \$37.6 million for YTD 2005, resulting in an effective tax rate of 35%. Comparatively, we recorded income tax expense of \$10.3 million for YTD 2004, which resulted in an effective tax rate of 37%, excluding the impact of approximately \$6.9 million of non-deductible charges for IPR&D incurred during the second quarter of 2004. Our effective tax rate in both years is impacted by the availability of the estimated credits available for research and development activities, including credits earned for orphan drug status of certain research and development activities, relative to our earnings growth. These credits will vary from year to year depending on the activities of the

Company.

**Net Earnings**

We reported net earnings for YTD 2005 of \$69.9 million, or \$0.28 per share compared to net earnings for YTD 2004 of \$10.7 million, or \$0.04 per share.

Shares used in computing basic and diluted earnings per share for YTD 2005 were 247.7 million and 257.0 million, while shares used for computing basic and diluted earnings per share for YTD 2004 were 248.5 million and 249.8 million, respectively.

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

**LIQUIDITY AND CAPITAL RESOURCES**





## Edgar Filing: MEDIMMUNE INC /DE - Form 10-Q

**Sources and uses of cash** - Cash and marketable securities were \$1.8 billion as of June 30, 2005 as compared to \$1.7 billion as of December 31, 2004, an increase of 4%. The increase in cash is primarily due to operating cash flows generated during YTD 2005. Working capital increased to \$603.6 million at June 30, 2005 from \$330.0 million as of December 31, 2004, also due to cash generated by our operations.

### *Operating Activities*

Net cash provided by operating activities was \$188.6 million in YTD 2005 as compared to \$103.9 million in YTD 2004. The change compared to prior period is primarily the result of the increase in net earnings in YTD 2005.

### *Investing Activities*

Cash used for investing activities during YTD 2005 amounted to \$74.7 million, as compared to \$262.8 million during YTD 2004. Cash used for investing activities in YTD 2005 included net additions to our investment portfolio of \$29.8 million; capital expenditures totaling \$37.0 million, primarily for the construction of our new pilot lab in Gaithersburg, Maryland and the expansion of our FluMist manufacturing facilities in Speke, England; and minority interest investments in strategic partners totaling \$7.9 million through our venture capital subsidiary. We expect our capital expenditures for the full year to range from \$100 million to \$150 million.

### *Financing Activities*

Financing activities used \$57.2 million in cash for YTD 2005, as compared to \$163.2 million used in YTD 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 YTD 2005, we used \$67.5 million in cash to repurchase shares of our common stock as authorized under our share repurchase program. Approximately \$10.8 million was received upon the exercise of employee stock options and through the employee stock purchase plan in YTD 2005, as compared to \$9.9 million received in YTD 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.

During Q2 2005, we 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.

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 YTD 2005, we 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, we have repurchased an additional 0.4 million shares at an average cost of \$27.33 per share. As of July 18, 2005, approximately \$163 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 June 30, 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 June 30, 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 ( CEO ), and Senior Vice President and Chief Financial Officer ( CFO ), 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 CEO and CFO, 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 CEO and its CFO 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 CEO and its CFO, have determined that there was no change in the Company's internal control over financial reporting that occurred during Q2 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 10 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 as updated in the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2005.

**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
April 1, 2005 through April 30, 2005	445,000	\$ 24.86	445,000	\$ 211,693,000
May 1, 2005 through May 31, 2005	751,300	\$ 26.23	751,300	\$ 191,985,000
June 1, 2005 through June 30, 2005	733,680	\$ 26.30	733,680	\$ 172,690,000

(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**

On May 19, 2005 the Company held its Annual Meeting of Stockholders. Nine director nominees were re-elected to one year terms by vote of the Company's stockholders at such meeting, as follows:

	For	Against	Withheld	Abstain/ Non-vote
Wayne T. Hockmeyer, Ph.D.	208,767,900		4,843,949	
David M. Mott	208,801,485		4,810,364	
David Baltimore, Ph.D.	210,405,902		3,205,947	
M. James Barrett, Ph.D.	194,158,922		19,452,927	
James H. Cavanaugh, Ph.D.	193,595,545		20,016,304	
Barbara H. Franklin	195,714,100		17,897,749	
Gordon S. Macklin	181,281,042		32,330,807	
George M. Milne, Jr., Ph.D.	210,026,074		3,585,775	
Elizabeth H. S. Wyatt	210,469,621		3,142,228	

## Edgar Filing: MEDIMMUNE INC /DE - Form 10-Q

The following proposals were also approved by vote of the Company's stockholders at such meeting, as follows:

To approve the amendment to the 2004 Stock Incentive Plan	119,614,057	61,236,149	1,470,061
To approve and ratify PricewaterhouseCoopers LLP as the Company's independent auditors for 2005	209,283,917	3,084,296	1,243,636



**ITEM 5. OTHER INFORMATION NONE**



**ITEM 6. EXHIBITS**

(a) Exhibits:

- 3.1 Company By-laws, currently in effect (as last amended as of May 19, 2005).
- 10.1(1) Patent License Agreement (Adair Patent Rights) (MedI-493), dated as of January 19, 1998, by and between Celltech Therapeutics Limited and the Company.
- 10.2(1) Patent License Agreement (Adair Patent Rights) (MedI-493), dated as of June 24, 2005, by and among Celltech R&D Limited, UCB S.A. and the Company.
- 31.1 Rule 13-14(a)/15d-14(a) Certification of CEO.
- 31.2 Rule 13-14(a)/15d-14(a) Certification of CFO.
- 32.1 Section 1350 Certifications 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.

---

(1) Confidential treatment has been requested. The copy filed as an exhibit omits the information subject to the confidentiality request.

**SIGNATURES**



Edgar Filing: MEDIMMUNE INC /DE - Form 10-Q

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)

Date: July 21, 2005

/s/ David M. Mott  
David M. Mott  
Chief Executive Officer, President and Vice Chairman  
Principal Executive Officer

Date: July 21, 2005

/s/ Lota S. Zoth  
Lota S. Zoth  
Senior Vice President and Chief Financial Officer  
Principal Financial Officer

Date: July 21, 2005

/s/ Mark E. Spring  
Mark E. Spring  
Vice President, Finance and Controller  
Principal Accounting Officer