

MEDIMMUNE INC /DE  
Form 10-Q  
August 08, 2003

**SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D. C. 20549**

**FORM 10-Q**

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

For the quarterly period ended June 30, 2003

**MedImmune, Inc.**  
(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

0-19131  
(Commission File No.)

52-1555759  
(I.R.S. Employer Identification No.)

35 West Watkins Mill Road, Gaithersburg, MD 20878  
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code (301) 417-0770

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 August 5, 2003, 249,836,270 shares of Common Stock, par value \$0.01 per share, were outstanding.

**MEDIMMUNE, INC.**  
Index to Form 10-Q

**Page**

**Part I-- FINANCIAL INFORMATION**

Item 1. Consolidated Financial Statements

Consolidated Balance Sheets	1
Consolidated Statements of Operations	2
Condensed Consolidated Statements of Cash Flows	3
Notes to Consolidated Financial Statements	4-9

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations 10-21

Item 3. Quantitative and Qualitative Disclosures About Market Risk 21

Item 4. Controls and Procedures 22

**Part II-- OTHER INFORMATION**

MedImmune, Inc. (Exact name of registrant as specified in its charter)

	<u>Page</u>
Item 1. Legal Proceedings	23
Item 2. Changes in Securities and Use of Preceeds	23
Item 3. Defaults Upon Senior Securities	23
Item 4. Submission of Matters to a Vote of Security Holders	23
Item 5. Other Information	24
Item 6. Exhibits and Reports on Form 8-K	24

Trademark information: Synagis® (palivizumab), CytoGam® (cytomegalovirus immune globulin intravenous (human)), RespiGam® (respiratory syncytial virus immune globulin intravenous (human)), and Vitaxin® are registered trademarks of MedImmune, Inc. Numax™ is a trademark of MedImmune, Inc. Ethyol® (amifostine) and NeuTrexin® (trimetrexate glucuronate for injection) are registered trademarks of MedImmune Oncology, Inc. FluMist™ (Influenza Virus Vaccine Live, Intranasal) is a trademark of MedImmune Vaccines, Inc.

Unless otherwise indicated, this quarterly report is as of June 30, 2003. This quarterly report will not be updated as a result of new information or future events.

## **PART I FINANCIAL INFORMATION**

### **ITEM 1. CONSOLIDATED FINANCIAL STATEMENTS**

#### **MEDIMMUNE, INC. CONSOLIDATED BALANCE SHEETS**

(in thousands)

	<b>June 30, 2003</b>	<b>December 31, 2002</b>
	<b>(Unaudited)</b>	
<b>ASSETS:</b>		
Cash and cash equivalents	\$ 105,523	\$ 130,056
Marketable securities	286,761	396,882
Trade receivables, net	6,039	113,774
Inventory, net	81,379	59,963
Deferred tax assets	18,555	25,735
Other current assets	37,543	17,023
	<hr/>	<hr/>
Total Current Assets	535,800	743,433
Marketable securities	1,195,689	896,118
Property and equipment, net	215,520	183,992
Deferred tax assets, net	167,213	222,038
Intangible assets, net	104,955	113,275

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

	June 30,	December 31,
Goodwill	15,970	15,970
Other assets	24,878	13,463
	<hr/>	<hr/>
Total Assets	\$ 2,260,025	\$ 2,188,289
	<hr/>	<hr/>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY:</b>		
Accounts payable	\$ 12,300	\$ 19,773
Accrued expenses	101,619	157,359
Product royalties payable	47,633	74,048
Deferred revenue	2,209	6,789
Other current liabilities	9,622	8,684
	<hr/>	<hr/>
Total Current Liabilities	173,383	266,653
	<hr/>	<hr/>
Long-term debt	216,203	217,554
Obligations to Evans	25,135	24,755
Other liabilities	1,985	2,093
	<hr/>	<hr/>
Total Liabilities	416,706	511,055
	<hr/>	<hr/>
Commitments and Contingencies		
<b>SHAREHOLDERS' EQUITY:</b>		
Preferred stock, \$.01 par value; authorized 5,525 shares; none issued or outstanding	--	--
Common stock, \$.01 par value; authorized 420,000 shares; issued and outstanding 252,391 at June 30, 2003 and 251,262 at December 31, 2002	2,524	2,513
Paid-in capital	2,638,189	2,613,075
Deferred compensation	(2,971)	(6,823)
Accumulated deficit	(833,165)	(956,140)
Accumulated other comprehensive income	38,742	24,609
	<hr/>	<hr/>
Total Shareholders' Equity	1,843,319	1,677,234
	<hr/>	<hr/>
Total Liabilities and Shareholders' Equity	\$ 2,260,025	\$ 2,188,289
	<hr/>	<hr/>

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

**MEDIMMUNE, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
**(Unaudited)**  
(in thousands, except per share data)

	For the three months ended June 30,	For the six months ended June 30,	
2003	2002	2003	2002

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

		For the	For the	
Revenues:				
Product sales	\$ 85,864	\$ 57,330	\$ 518,299	\$ 377,998
Other revenue	31,935	6,392	35,446	15,357
	<u>117,799</u>	<u>63,722</u>	<u>553,745</u>	<u>393,355</u>
Costs and expenses:				
Cost of sales	23,197	15,642	126,028	95,519
Research and development	28,904	34,545	59,568	78,614
Selling, general and administrative	55,495	47,354	173,581	142,994
Other operating expenses	1,415	22,152	22,871	43,993
Acquired in-process research and development	--	--	--	1,179,321
	<u>109,011</u>	<u>119,693</u>	<u>382,048</u>	<u>1,540,441</u>
Operating income (loss)	8,788	(55,971)	171,697	(1,147,086)
Interest income	14,310	11,863	27,300	23,797
Interest expense	(1,604)	(1,767)	(3,403)	(4,529)
Loss on investment activities	(139)	(109)	(396)	(109)
	<u>21,355</u>	<u>(45,984)</u>	<u>195,198</u>	<u>(1,127,927)</u>
Earnings (loss) before income taxes	21,355	(45,984)	195,198	(1,127,927)
Provision (benefit) for income taxes	7,901	(16,528)	72,223	18,387
	<u>\$ 13,454</u>	<u>\$ (29,456)</u>	<u>\$ 122,975</u>	<u>\$ (1,146,314)</u>
Net earnings (loss)				
Basic earnings (loss) per share	\$ 0.05	\$ (0.12)	\$ 0.49	\$ (4.62)
Shares used in calculation of basic earnings (loss) per share	252,106	250,161	251,836	248,110
Diluted earnings (loss) per share	\$ 0.05	\$ (0.12)	\$ 0.48	\$ (4.62)
Shares used in calculation of diluted earnings (loss) per share	258,200	250,161	257,390	248,110

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

**MEDIMMUNE, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(Unaudited)  
(in thousands)

For the  
six months ended  
June 30,  
2003 2002

For the

**CASH FLOWS FROM OPERATING ACTIVITIES:**

Net earnings (loss)	\$ 122,975	\$ (1,146,314)
Noncash items:		
Acquired in-process research and development	--	1,179,321
Deferred taxes	67,041	22,383
Deferred revenue	(4,580)	(3,049)
Depreciation and amortization	18,497	16,415
Amortization of premium on marketable securities	7,381	4,480
Amortization of deferred compensation	2,666	11,823
Amortization of premium on convertible subordinated notes	(933)	(886)
Losses on writedowns of inventory	20,519	6,453
Decrease in sales allowances	(27,461)	(937)
Decrease in restructuring liability for cash employee termination costs	(251)	(4,802)
Other	1,438	1,396
Other changes in assets and liabilities, net of effects of acquisition of Aviron	(12,709)	69,014
Net cash provided by operating activities	194,583	155,297

**CASH FLOWS FROM INVESTING ACTIVITIES:**

Increase in marketable securities	(183,567)	(379,863)
Net cash acquired in acquisition of Aviron	--	146,853
Capital expenditures	(43,573)	(37,987)
Investments in strategic alliances	(11,780)	(3,734)
Net cash used in investing activities	(238,920)	(274,731)

**CASH FLOWS FROM FINANCING ACTIVITIES:**

Proceeds from issuance of common stock	20,272	38,146
Repayments on long-term obligations	(415)	(389)
Net cash provided by financing activities	19,857	37,757
Effect of exchange rate changes on cash	(53)	99
Net decrease in cash and cash equivalents	(24,533)	(81,578)
Cash and cash equivalents at beginning of period	130,056	171,255
Cash and cash equivalents at end of period	\$ 105,523	\$ 89,677

**Supplemental schedule of noncash investing and financing activities:**

During January 2002, the Company acquired 100% of the outstanding capital stock of Aviron through an exchange offer and merger transaction. The Company exchanged approximately 34.0 million of its common shares for all of the outstanding shares of Aviron common stock and assumed Aviron's outstanding options and warrants, for which approximately 7.0 million additional shares of the Company's common stock are issuable. The estimated fair value of the net assets acquired was \$1,635.1 million, and included \$1,179.3 million of acquired research and development assets that were charged to our 2002 results at the date of acquisition and \$211.4 million of 5 ¼ % convertible subordinated notes (the Notes) due in 2008.

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. During January 2002, the Company completed its acquisition of Aviron, subsequently renamed MedImmune Vaccines, Inc., a vaccines company headquartered in Mountain View, California, through an exchange offer and merger transaction (the Acquisition). The Acquisition was accounted for as a purchase, and the results of operations of MedImmune Vaccines are included in the results of the Company effective January 10, 2002.

On June 17, 2003, the U.S. Food and Drug Administration (FDA) approved the biologics license application for the commercial sale of FluMist, the first influenza vaccine delivered as a nasal mist available in the United States. FluMist is indicated for active immunization for the prevention of disease caused by influenza A and B viruses in healthy people, 5-49 years of age. MedImmune manufactures FluMist and co-promotes FluMist with a division of Wyeth.

In addition to FluMist, the Company currently actively markets three other products, Synagis, Ethyol and CytoGam, and is developing a diverse pipeline of potential future products. The Company is focused on developing new products, particularly vaccines and antibodies that address significant medical needs in the areas of infectious diseases, immunology and oncology.

**2. Summary of Significant Accounting Policies**

**General**

The financial information presented as of and for the three months and six months ended June 30, 2003 (Q2 2003 and YTD 2003, respectively) and as of and for the three months and six months ended June 30, 2002 (Q2 2002 and YTD 2002, 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 annual report on Form 10-K for the year ended December 31, 2002.

**Stock-based Compensation**

Compensation costs attributable to stock option and similar plans are 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 Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees (APB 25). Such amount, if any, is accrued over the related vesting period.

In December 2002, the FASB issued SFAS No. 148, Accounting for Stock-Based Compensation-Transition and Disclosure (SFAS 148). SFAS 148 amends SFAS No. 123, Accounting for Stock-Based Compensation (SFAS 123), to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, this Statement amends the disclosure requirements of SFAS 123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. The alternative methods of transition and additional disclosure requirements of SFAS 148 are effective January 1, 2003.

The following table illustrates the effect on net earnings and earnings per share if the Company had applied the fair value recognition provisions of SFAS 123 to stock-based employee compensation (in millions, except per share data):

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

	Q2 2003	Q2 2002	YTD 2003	YTD 2002
Net earnings (loss), as reported	\$ 13.5	(\$ 29.5)	\$123.0	(\$1,146.3)
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	0.6	2.1	1.7	7.6
Deduct: stock-based employee compensation expense determined under the fair value based method for all awards, net of related tax effect	(24.8 )	(24.7)	(49.1)	(47.8)
Pro forma net earnings (loss)	(\$ 10.7 )	(\$ 52.1)	\$ 75.6	(\$1,186.5)
Basic earnings (loss) per share, as reported	\$ 0.05	(\$ 0.12)	\$ 0.49	(\$4.62)
Basic earnings (loss) per share, pro forma	(\$ 0.04 )	(\$ 0.21)	\$ 0.30	(\$4.78)
Diluted earnings (loss) per share, as reported	\$ 0.05	(\$ 0.12)	\$ 0.48	(\$4.62)
Diluted earnings (loss) per share, pro forma	(\$ 0.04 )	(\$ 0.21)	\$ 0.30	(\$4.78)

### 3. Intangible Assets

Intangible assets are 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 at June 30, 2003 are comprised of the following (in millions):

Worldwide collaborative agreement with Wyeth	\$ 90.0
Contract manufacturing agreement with Evans	39.0
Other intangible assets	0.4
	<hr/>
	129.4
Less accumulated amortization	(24.4)
	<hr/>
	\$ 105.0
	<hr/>

Amortization of intangible assets is computed on the straight-line method based on the estimated useful lives of the assets. Amortization expense for Q2 2003 and YTD 2003 was \$1.9 million and \$6.1 million, respectively. As of June 30, 2003, capitalized inventory related to FluMist includes approximately \$2.2 million of amortization costs associated with the contract manufacturing agreement with Evans. The estimated aggregate amortization for each of the next five years is as follows: 2003, \$16.6 million; 2004, \$16.4 million; 2005, \$16.4 million; 2006, \$12.0 million; and 2007, \$7.7 million.

### 4. Restructuring Liability

As of June 30, 2003, the remaining balance of the restructuring liability for estimated costs associated with the Company's restructuring plan was \$0.7 million. The restructuring plan was originally formulated and announced to employees in December 2001, to consolidate and restructure certain functions, including the involuntary termination of certain executives and other employees of MedImmune Vaccines from various functions and levels.

The restructuring liability activity through June 30, 2003 is summarized as follows (in millions):

	Balance as of 12/31/02	Restructuring Charges Incurred	Balance at 6/30/03
Employee severance costs	\$ --	\$ --	\$ --

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

		Restructuring		
Acceleration of employee stock options	--	--	--	--
Other facility-related costs	1.0	(0.3)	0.7	
Total	\$ 1.0	\$ (0.3)	\$ 0.7	

## 5. Inventory

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

	June 30, 2003	December 31, 2002
Raw Materials	\$ 19.4	\$ 30.4
Work in Process	40.8	19.4
Finished Goods	21.2	10.2
	\$ 81.4	\$ 60.0

The Company has capitalized inventory costs associated with FluMist manufacturing prior to product launch, based on management's judgment of probable future commercial use. In recognition of management's assessment that certain inventory materials will reach their expiration dates prior to commercial use, the Company recorded reserves for such unmarketable inventory. During the first quarter of 2003, the Company recorded reserves in other operating expenses totaling approximately \$19.6 million for inventoriable costs related to FluMist production that would likely not be recovered. During Q2 2003, the Company disposed of \$10.8 million of fully-reserved finished goods inventory related to the 2002/2003 flu season. As of June 30, 2003, the Company has a FluMist related inventory balance of \$81.2 million against which there is a reserve of \$45.2 million, resulting in a net inventory balance of \$36.0 million.

## 6. Earnings per Share

Basic earnings per share is computed based on the weighted average number of common shares outstanding during the period. Diluted earnings per share is computed based on the weighted average shares outstanding adjusted for all dilutive potential common shares. The dilutive impact, if any, of common stock equivalents outstanding during the period, including outstanding stock options and warrants, is measured by the treasury stock method. The dilutive impact, if any, of the Company's convertible subordinated notes is measured using the if-converted method. Potential common shares are not included in the computation of diluted earnings per share if they are antidilutive. The following is a reconciliation of the denominator of the diluted EPS computation for the periods reported. There are no reconciling items to the numerator for the EPS computation for the periods reported (in millions).

	Q2 2003	Q2 2002	YTD 2003	YTD 2002
Denominator:				
Weighted average shares outstanding	252.1	250.2	251.8	248.1
Effect of dilutive securities:				
Stock options, warrants, and Notes	6.1	--	5.6	--
Denominator for diluted EPS	258.2	250.2	257.4	248.1

The following table shows the number of shares and related price ranges of those shares that were excluded from the EPS computation for the first two quarters of 2003. These options to purchase shares of common stock were outstanding during the period, but were not included in the computation of diluted earnings per share as the exercise prices for these options were greater than the average market price of the common stock during the period, and therefore would be antidilutive (in millions).

Q1 2003	Q2 2003
------------	------------



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

	Q1	Q2
Price range of stock options:		
\$30.16-\$83.25	15.0	
\$35.41 - \$83.25		14.3
The Company incurred a net loss for Q2 2002 and YTD 2002 and, accordingly, did not assume exercise or conversion of any of the Company's outstanding stock options, warrants, or Notes because to do so would be anti-dilutive.		

## 7. Income Taxes

The reported effective tax rate for the first six months of 2003 is 37% of pretax income, based on the current estimate of the annual effective tax rate. The effective tax rate may be affected in future periods by changes in estimates with respect to the deferred tax assets and other items affecting the overall tax rate. Income tax expense for the first six months of 2002 was based on an estimated annual effective tax rate on pretax income of 36%.

## 8. Comprehensive Income

	Q2 2003	Q2 2002	YTD 2003	YTD 2002
Net earnings (loss)	\$13.5	(\$29.5)	\$123.0	(\$1,146.3)
Changes in:				
Foreign currency translation adjustment	0.2	0.5	1.0	0.4
Unrealized gain (loss) on investments, net of tax	9.6	8.3	13.3	(0.9)
Unrealized gain (loss) on hedged inventory purchases, net of tax	--	0.4	(0.2)	0.4
Comprehensive income (loss)	\$23.3	(\$20.3)	\$137.1	(\$1,146.4)

## 9. Recent Accounting Pronouncements

In January 2003, the FASB issued FIN No. 46, Consolidation of Variable Interest Entities, an interpretation of Accounting Research Bulletin No. 51. FIN No. 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. In accordance with the adoption provisions of FIN No. 46, during Q2 2003 the Company adopted the provisions as they relate to the Company's contractual relationships with variable interest entities established subsequent to January 31, 2003, with an immaterial impact to the Company's consolidated financial position, results of operations and cash flows. The Company will apply the consolidation provisions of FIN No. 46 relative to its investments in variable interest entities established prior to February 1, 2003 during the third quarter of 2003, and is currently evaluating the effect on its consolidated financial position, results of operations and cash flows.

## 10. Subsequent Events

During July 2003, the Company's Board of Directors authorized a repurchase, over a two-year period, of up to \$500 million of the Company's common stock in the open market or in privately negotiated transactions, pursuant to terms management deems appropriate. The Company will hold repurchased shares as treasury shares and intends to use them for general corporate purposes, including but not limited to acquisition-related transactions and for issuance upon exercise of outstanding stock options. Through August 5, 2003, the Company had repurchased approximately 2.9 million shares at a cost of \$112.3 million.

During July 2003, the Company issued \$500 million aggregate principal amount of convertible senior notes due 2023. The notes bear interest at one percent per annum payable semi-annually in arrears on January 15 and July 15 of each year. Beginning July 2006, the Company will pay contingent interest on the notes during a six-month interest period if the average trading price of the notes is above a specified level. Under certain circumstances, the notes will be convertible into the Company's common stock at an initial conversion price of approximately \$68.18 per share. On or after July 15, 2006, the Company may at its option redeem all or a portion of the notes for cash at a redemption price equal to 100% of the principal amount of the notes to be redeemed, plus any accrued and unpaid interest; contingent interest, if any; and liquidated damages, if any. In addition, on each of July 15, 2006, July 15, 2009, July 15, 2013, and July 15, 2019, holders may require the Company to purchase all or a

portion of their notes for cash at 100% of the principal amount of the notes to be purchased, plus any accrued and unpaid interest; contingent interest, if any; and liquidated damages, if any.

The Company intends to use the proceeds of the offering to repurchase shares of its common stock under the stock repurchase program, and for general corporate purposes, which may include pre-funding of the retirement of existing debt obligations, and possible acquisitions or other external growth opportunities. The notes were issued in a private placement and were expected to be resold by the initial purchasers to qualified institutional buyers under Rule 144A of the Securities Act of 1933.

## 11. Legal Proceedings

In October 2000, Celltech Chiroscience Limited, now known as Celltech R&D Limited ( Celltech ), commenced a legal proceeding against the Company in the U.K. High Court of Justice, Chancery Division, Patents Court. Celltech alleges that the Company failed to pay royalties with respect to its sales of Synagis as required by a license agreement dated January 19, 1998. Under the agreement, the Company obtained from Celltech a worldwide license to make, use and/or sell product under a patent (and related applications) pertaining to humanized antibodies. In the proceeding, Celltech sought payment of a 2% royalty based on net sales of Synagis sold or manufactured in the United States, with interest, and certain costs, including attorney's fees. On October 28, 2002, the High Court of Justice ruled in favor of the Company and dismissed Celltech's case. This dismissal was upheld on appeal on July 17, 2003.

On September 16, 2002, Celltech commenced a second legal proceeding against the Company in the U.K. High Court of Justice, Chancery Division, Patents Court, based on the license agreement dated January 19, 1998. Celltech seeks payment of a 2% royalty based on net sales of Synagis sold or manufactured in Germany, with interest and certain costs, including attorney fees. To date, the Company has not made the royalty payments that are the subject of this second lawsuit. This matter is scheduled for trial before the High Court of Justice in March 2004.

On April 5, 2002, the Company filed a suit against Centocor, Inc. ( Centocor ) in the United States District Court for the District of Maryland. The Company currently pays Centocor a royalty for sales of Synagis made or sold in the United States pursuant to a patent Sublicense Agreement. In the litigation, the Company seeks a declaratory judgment that it has no obligation to continue paying royalties to Centocor on the basis that the patent is invalid, unenforceable and does not cover Synagis. Additionally, the Company seeks an injunction preventing Centocor from enforcing this patent. In January 2003, the Company amended its complaint to add the Trustees of Columbia University in the City of New York and the Board of Trustees of Leland Stanford Jr. University as defendants. After various motions were filed and decided, a Second Amended Complaint was filed by MedImmune in July 2003. Discovery is ongoing.

On January 14, 2003, a lawsuit was filed by the County of Suffolk New York ( Suffolk ) in the United States District Court, Eastern District of New York, naming the Company along with approximately 25 other pharmaceutical and biotechnology companies as defendants. The complaint asserts claims under the federal RICO statute, as well as various state, statutory and common laws to recover monetary damages, civil penalties, declaratory and injunctive relief, disgorgement of profits, treble and punitive damages suffered as a result of defendants' alleged unlawful practices related to prescription medications paid for by Medicaid. Suffolk alleges that the defendants (including the Company) manipulated the average wholesale price ( AWP ) causing Suffolk to pay artificially inflated prices for covered drugs including, in the case of the Company, Synagis. In addition, Suffolk argues that the defendants (including the Company) did not accurately report the best price under the Medicaid Program. In March 2003, the Suffolk Case was, for pretrial purposes, consolidated with and transferred to the United States District Court for the District of Massachusetts, In re Pharmaceutical Industry Average Wholesale Price Litigation (AWP MultiDistrict Litigation). An Amended Complaint was filed in the Suffolk Case on August 1, 2003.

On April 11, 2003, the Company filed a suit against Genentech, Inc., Celltech R&D Ltd. and City of Hope National Medical Center in the United States District Court for the Central District of California. The Company currently pays Genentech a royalty for sales of Synagis made or sold in the United States pursuant to a patent License Agreement between the parties dated as of June 1997 and covering United States Patent No. 6,331,415B1 (the Cabilly Patent ). In the complaint, the Company alleges that the Cabilly Patent was obtained as a result of a collusive agreement between Genentech and Celltech that violates federal and California antitrust laws as well as California's unfair business practices act. Additionally, the Company alleges that the Cabilly Patent is invalid and unenforceable under federal patent law. The Company thus seeks a declaration that it owes no royalty payments under existing licensing agreements with Genentech.

---

The Company is also involved in other legal proceedings arising in the ordinary course of its business. After consultation with its legal counsel, the Company believes that it has meritorious defenses to the claims against the Company referred to above and is determined to defend its position vigorously. While it is impossible to predict with certainty the eventual outcome of these proceedings, the Company believes they are unlikely to have a material adverse effect on its financial position but might have a material adverse effect on its results of operations for a particular period. There can be no assurance that the Company will be successful in any of the litigation it has initiated.

## 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 our future results that are based on current expectations, estimates, forecasts, and the beliefs and assumptions of our management. Readers are cautioned that these forward-looking statements are only predictions or estimates and are subject to risks, uncertainties, and assumptions 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, 2002.

### OVERVIEW

Since 1988, MedImmune has been focused on using biotechnology to produce innovative products to prevent or treat infectious disease, autoimmune disease and cancer. In January 2002, we acquired Aviron (subsequently renamed MedImmune Vaccines, Inc.), a California-based vaccines company. The operating results of MedImmune Vaccines, Inc. have been included in our consolidated operating results beginning January 10, 2002.

Having made significant advances in the last several years, we are now a fully integrated company with the ability and infrastructure to take products from discovery through development, manufacturing, and into the market. On June 17, 2003, the biologics license application for the commercial sale of FluMist was approved by the FDA. FluMist is the first influenza vaccine delivered as a nasal mist available in the United States. FluMist is indicated for active immunization for the prevention of disease caused by influenza A and B viruses in healthy people, 5-49 years of age. MedImmune manufactures FluMist and co-promotes FluMist with a division of Wyeth.

In addition to FluMist, we currently actively market three other products, Synagis, Ethyol and CytoGam, and are developing a broad and diverse pipeline of potential future products. We are focused on developing important new products, particularly vaccines and antibodies that address significant unmet medical needs in the areas of infectious diseases, immunology and oncology.

### CRITICAL ACCOUNTING ESTIMATES

The preparation of consolidated financial statements requires us 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 base our estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following critical accounting estimates have the greatest impact on the preparation of our consolidated financial statements.

**Inventory Capitalization** We capitalize inventory costs associated with products prior to regulatory approval and product launch, based on management's judgment of probable future commercial use. We could be required to expense 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 necessary regulatory bodies, a delay in commercialization, or other potential factors.

Most of the inventory components for FluMist have expiration dates that range from nine to 24 months. During the last quarter of 2002 and first half of 2003, we incurred inventoriable costs associated with FluMist manufacturing in anticipation of commercial launch for the 2003/2004 flu season. With respect to all FluMist inventory on hand as of June 30, 2003, we reviewed the following assumptions to determine the amount of reserves, if any, required to write down the inventory to net realizable value: the expected sales volume; the concentration of viral material in our vaccine; anticipated changes in the manufacturing process; anticipated delays in obtaining FDA lot release for finished vaccine; and other variables associated with product launch efforts. During the first quarter of 2003, the Company recorded reserves in other operating expenses totaling approximately \$19.6 million for inventoriable costs related to FluMist production that would likely not be recovered. During Q2 2003, the Company disposed of \$10.8 million of fully-reserved finished goods inventory related to the 2002/2003 flu season. As of June 30, 2003, we have \$81.2 million of inventory against which we have a reserve of \$45.2 million, resulting in a net inventory balance of \$36.0 million. If FluMist sales levels are higher than expected, we may be able to utilize more inventory than anticipated and, with licensure now in place, our gross margins would be favorably impacted in the last half of 2003 when most of the inventory is sold. If FluMist sales levels are lower than expected, we may have further reserves or writedowns for obsolete inventory.

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.

**Sales Allowances and Other Sales Related Estimates** We estimate the amount of sales discounts and sales returns, recorded as a reduction of gross product sales, by applying rates determined by our past experience to actual sales for the period. We estimate our co-promotion expense and sales commissions, recorded as selling, general and administrative expense, by applying an estimated rate that is based upon an estimate of projected sales for the season, to our actual sales for the period. We estimate the level of bad debts as a percentage of gross trade accounts receivable balances, based upon our assessment of the concentration of credit risk, the financial condition and environment of our customers and the level of credit insurance we obtain on our customers' balances. We record provisions for bad debts as a reduction of gross product sales. For the first six months of 2003, we decreased our reserves for bad debts by approximately \$6.6 million, based on our current application of this methodology, in large part as a consequence of the overall reduction in accounts receivable balances. We estimate the aggregate amount of rebates due to government purchasers, recorded as a reduction to gross product sales, based upon historical experience and our best estimate of the proportion of the sales that will be subject to this reimbursement, largely comprised of Medicaid payments to state governments. If our historical trends are not indicative of the future, or our actual sales are materially different from projected amounts, or if our assessments prove to be materially different than actual occurrence, our results could be affected. During the first three months of 2003, we adjusted our estimate of rebates due to government purchasers to reflect favorable historical experience. Absent our favorable historical experience and a change in our estimate of the proportion of the sales that are subject to reimbursement, our reserves for rebates due to government purchasers would have been approximately \$15.2 million higher for the first six months of 2003.

**Investments** We regularly enter into collaborative research and development agreements with strategic partners. As part of the agreements, we may obtain common stock, preferred stock, convertible debt or other debt or equity securities in these strategic partners. These companies may be public or privately held companies. At the time the securities are obtained, we determine if the investment should be accounted for under the cost method, equity method, or consolidation method based upon multiple factors including: percentage ownership of the company; representation on board of directors; participation in policy-making processes; technological dependency; veto rights of partners; our role on key technical or product development committees; revenue dependence; other extraordinary voting rights; and a determination regarding the investee company's primary beneficiary. Investments accounted for under the equity method are adjusted quarterly for the Company's proportionate share of the investee's gains or losses, which may fluctuate significantly from quarter to quarter. Each quarter, we evaluate all of our investments, and recognize an impairment charge in the consolidated statements of operations when a decline in the fair value of an investment falls below its cost value and is judged to be other than temporary. We consider various factors in determining whether we should recognize an impairment charge, including: the length of time and extent to which the fair value has been less than our cost basis; the financial condition and near-term prospects of the issuer; fundamental changes to the business prospects of the investee; share prices of subsequent offerings; and our intent and ability to hold the investment for a period of time sufficient to allow for any anticipated recovery in market value. Especially with regards to investments in earlier stage, privately held companies, considerable judgment is required in making assessments of fair value.

## RESULTS OF OPERATIONS

To present our results in the same manner as we view the performance of the business and the resulting underlying trends, we have presented certain expense categories with and without certain Acquisition-related adjustments, including: the acquired in-process research and development charge; amortization of intangible assets, compensation expense associated with the assumption and vesting of unvested stock options, retention and severance payments; and the amortization of the premium on convertible subordinated notes. Inclusion of such Acquisition-related adjustments is consistent with generally accepted accounting principles (GAAP). Where we exclude such adjustments, we use the term "adjusted" to describe the results.

### Q2 2003 compared to Q2 2002

#### Revenues Product Sales (in millions)

	Q2 2003	Q2 2002	Growth
Synagis	\$ 54.9	\$ 32.5	69%
Ethylol	24.8	16.6	49%
Other Products	6.2	8.2	(24%)
	<u>\$ 85.9</u>	<u>\$ 57.3</u>	50%

For Q2 2003, product sales grew 50% to \$85.9 million as compared to \$57.3 million in Q2 2002, primarily due to increased sales of Synagis.

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

**Synagis** Synagis accounted for approximately 64% and 57% of our product sales in Q2 2003 and Q2 2002, respectively. We achieved an 83% increase in domestic Synagis sales to \$49.7 million for 2003, up from \$27.1 million in 2002. This strong growth was driven primarily by an increase in unit sales that contributed 52 of the 83 percentage points, an increase in price that contributed three points and a decrease in sales allowances that contributed 28 points, reflecting a reduction in our estimate of rebates due to government purchasers and reserves for bad debts. We record Synagis international product sales based on Abbott International's (AI's) sales price to customers, as defined in our agreement. AI is our exclusive distributor of Synagis outside of the United States. Our reported international sales of Synagis were \$5.2 million and \$5.4 million in the 2003 and 2002 periods, respectively.

**Ethiol** Ethiol accounted for approximately 29% of our product sales in both Q2 2003 and Q2 2002. Worldwide Ethiol sales grew 49% to \$24.8 million in Q2 2003, as compared to \$16.6 million in Q2 2002. This growth was driven by a number of contributing factors, including: a strong increase in domestic unit sales that contributed 29 of the 49 percentage points; a domestic price increase that contributed 12 points; a decrease in reserves for bad debts that contributed four points; and an increase in sales to our international partner, Schering-Plough Corporation (Schering), that contributed four points. We record Ethiol international product sales based on a percentage of Schering's end-user sales, as defined in our agreement.

**Other Products** Sales of other products in Q2 2003, which include sales of CytoGam, NeuTrexin, RespiGam, and by-products that result from the CytoGam manufacturing process, decreased \$2.0 million, or 24% from Q2 2002. The decrease is driven by a 40% decrease in CytoGam sales. We believe this decrease is the result of a reduction in wholesaler inventory levels during the second quarter of 2003, rather than due to changes in demand for the product.

**Forward-looking commentary** We believe that the growth rate of our product sales, while remaining at double-digit levels, will decelerate during the second half of 2003 relative to the second half of 2002. Additionally due to the significant contribution of Synagis, we believe our revenues and operating results will reflect the seasonality of that product's use to prevent RSV disease, which occurs primarily during the winter months, for the foreseeable future. In addition, this seasonality will be compounded by FluMist, which was recently approved by the FDA, and is expected to be sold primarily during the third and fourth quarters of the year, the most common time for yearly influenza vaccination. The high concentration of product sales in a portion of the year exaggerates the adverse consequences on our sales of any manufacturing or supply delays, any sudden loss of inventory, any inability to satisfy product demand, or of any unsuccessful sales or marketing strategies during the Synagis and FluMist selling seasons. The level of future product sales will depend on several factors, including, but not limited to: potential limitations on pricing and profitability by government or third-party payors; availability of finished product inventory; commercialization of competitive products; and the degree of acceptance of our products in the marketplace.

### Revenues Other Revenues

Other revenues increased \$25.5 million to \$31.9 million for Q2 2003 compared to \$6.4 million in Q2 2002, primarily due to increased revenues under collaborative agreements. During Q2 2003, we recorded \$20.0 million of milestone revenue under our worldwide collaborative agreement with Wyeth, associated with the approval of FluMist. Also during Q2 2003, we recognized \$7.5 million of revenue under our international distribution agreement with Abbott International for achieving in excess of \$100 million in end-user sales of Synagis outside the U.S. during a single RSV season.

**Forward-looking commentary** We anticipate the level of other revenues for the remainder of 2003 will increase over the prior year period, but at a lower rate as compared to our growth for the first half of the year. Year-over-year, we expect significant growth in other revenues, largely due to milestone and royalty payments associated with the commercialization of FluMist. The level of contract revenues in future periods will depend primarily upon the extent to which we enter into other collaborative contractual arrangements, if any, and the extent to which we achieve certain milestones provided for in existing agreements. Future revenues from the sale of excess production capacity will vary depending on the extent to which we enter into these types of arrangements, and are not expected to be significant for 2003 or thereafter.

Based on current estimates of costs to complete, the expected timing of revenues to be recognized in the future as we fulfill certain obligations under our collaborative agreement with Schering-Plough Corporation, for which we have deferred a portion of the up-front and milestone payments received under the contingency adjusted performance model, is as follows: \$0.2 million in the second half of 2003; \$0.4 million in 2004; and \$0.4 million in 2005.

### Cost of Sales

Cost of sales for Q2 2003 increased 48% to \$23.2 million from \$15.6 million in Q2 2002, due largely to an increase in product sales volumes. Gross margins on products sales were 73% in both Q2 2003 and Q2 2002.

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

**Forward-looking commentary** We expect that gross margins may vary significantly from quarter to quarter, based on changes in the product mix due to seasonality. For the remainder of 2003, we anticipate that gross margins on product sales will decline significantly over the prior year period, primarily due to the commencement of FluMist sales, which are expected to have lower margins, during the second half of 2003. We expect that, on an annual basis, our gross margin percentage for 2003 should be slightly lower than 2002, due to the launch of FluMist.

### Research and Development Expenses

(in millions)

Q2 2003			Q2 2002		
Historical	Acquisition-Related Adjustments	Adjusted	Historical	Acquisition-Related Adjustments	Adjusted
\$28.9	(\$ 1.1)	\$27.8	\$34.5	(\$ 1.2)	\$33.3

Research and development expenses of \$28.9 million in Q2 2003 decreased 16% from \$34.5 million in Q2 2002. Excluding Acquisition-related adjustments in both periods, research and development expenses for Q2 2003 were \$27.8 million, down 17% over Q2 2002. The decline is largely due to the completion of several late-stage clinical trials by the end of 2002, including certain Phase 2 studies with siplizumab in psoriasis, and the Phase 3 Synagis clinical trial in congenital heart disease patients, the results of which were submitted to the FDA in November 2002. Our ongoing clinical programs also include several products and product candidates in various stages of development, including trials for Vitaxin, and a pediatric trial of a liquid formulation of Synagis. Additionally, we have multiple programs in the preclinical development stage.

**Forward-looking commentary** For the remainder of 2003, we anticipate that the growth in our research and development expenditures will accelerate significantly, in part due to the recently announced collaboration with Critical Therapeutics, a private biotechnology company. In connection with the alliance, we incurred a licensing fee of \$12.5 million during July 2003 to acquire an exclusive, worldwide license for technology associated with High Mobility Group Box Chromosomal Protein 1 ( HMGB-1 ), and we may be obligated for research funding and milestone payments in the future. On an annualized basis, we expect research and development expenses to be up slightly in 2003 compared to 2002. This is largely due to the anticipation of post-marketing commitments related to FluMist, additional trials associated with Vitaxin, and the continued progress of other pipeline candidates, partially offset by the impact of the conclusion of trials and studies during 2002.

### Selling, General, and Administrative Expenses

(in millions)

Q2 2003			Q2 2002		
Historical	Acquisition-Related Adjustments	Adjusted	Historical	Acquisition-Related Adjustments	Adjusted
\$55.5	(\$2.1)	\$53.4	\$47.4	(\$ 2.7)	\$44.7

Selling, general and administrative ( SG&A ) expenses increased 17% to \$55.5 million in Q2 2003 compared to \$47.4 million in Q2 2002. Excluding Acquisition- related adjustments, adjusted SG&A expenses for Q2 2003 were \$53.4 million, up 19% over \$44.7 million in Q2 2002, due primarily to increased co-promotion expenses for Synagis associated with the product's domestic sales growth and a modest increase in the size of the sales force associated with the marketing launch of FluMist.

### Other Operating Expenses

(in millions)

Q2 2003			Q2 2002		
Historical	Acquisition-Related Adjustments	Adjusted	Historical	Acquisition-Related Adjustments	Adjusted
\$1.4	(\$--)	\$1.4	\$22.2	(\$ 3.5)	\$18.7

Other operating expenses, which reflect manufacturing start-up costs and other manufacturing related costs, were \$1.4 million in Q2 2003 compared to \$22.2 million in Q2 2002. Adjusted other operating expenses were \$1.4 million for Q2 2003, compared to \$18.7 million in Q2 2002. The decrease is due to the shift in the costs of FluMist manufacturing that are capitalized in inventory this year, but were expensed as other operating costs in last year's quarter.

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

**Forward-looking commentary-** For the remainder of 2003, we expect the level of other operating expenses to decline dramatically versus the prior year period, as the costs of FluMist manufacturing are inventoried and subsequently expensed to cost of sales as product is sold to Wyeth.

### Interest Income and Expense

We earned interest income of \$14.3 million for Q2 2003, compared to \$11.9 million in Q2 2002, reflecting higher cash balances available for investment, partially offset by a decrease in short-term interest rates that lowered the overall portfolio yield. Interest expense for Q2 2003, net of amounts capitalized, was \$1.6 million, down from \$1.8 million in Q2 2002. This decrease is largely due to interest expense capitalized in connection with several large construction projects currently undertaken by the Company, including construction of the new corporate headquarters in Maryland, and manufacturing facilities in Pennsylvania and the U.K. that began during 2002.

**Forward-looking commentary-** We expect interest expense to increase during the second half of 2003 and beyond, as a result of the issuance during July 2003 of \$500 million of Convertible Notes due 2023. The notes bear interest at one percent per annum payable semi-annually in arrears, and beginning in 2006, we will pay contingent interest on the notes during a six-month interest period if the average trading price of the notes is above a specified level. The notes are convertible into our common stock at \$68.18 per share.

### Loss on Investment Activities

We incurred \$0.1 million in losses on investment activities during both Q2 2003 and Q2 2002 related to recording our portion of our minority investees' operating results as required by the equity method of accounting.

### Taxes

We recorded a provision for income taxes of \$7.9 million for Q2 2003, resulting in an effective tax rate of 37%. Comparatively, we recorded an income tax benefit of \$16.5 million for Q2 2002, resulting in an effective tax rate of 36%.

The increase in the estimated effective tax rate between 2002 and 2003 is primarily due to a decrease in estimated credits available for research and development activities, including credits earned for Orphan Drug status of certain research and development activities, relative to the growth in earnings. These credits will vary from year to year depending on the activities of the Company.

### Net Earnings / (Loss) (in millions)

Q2 2003			Q2 2002		
Historical	Acquisition-Related Adjustments	Adjusted	Historical	Acquisition-Related Adjustments	Adjusted
\$13.5	\$1.7	\$15.2	(\$29.5)	4.2	(\$25.3)

Net earnings for Q2 2003 were \$13.5 million, or \$0.05 per basic and diluted share, compared to a net loss for Q2 2002 of \$29.5 million or \$0.12 per share. Excluding the after-tax impact of the Acquisition-related adjustments totaling \$1.7 million for Q2 2003, and \$4.2 million for Q2 2002, adjusted net earnings for Q2 2003 were \$15.2 million, or \$0.06 per basic and diluted share, compared to an adjusted net loss for Q2 2002 of \$25.3 million or \$0.10 per share.

Shares used in computing basic earnings per share and basic adjusted earnings per share for Q2 2003 were 252.1 million, while shares used for computing diluted earnings per share and adjusted diluted earnings per share were 258.2 million. Shares used in computing net loss per share and adjusted net loss per share for Q2 2002 were 250.2 million.

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

**Forward-looking commentary** For the remainder of the year and on an annualized basis, we expect to generate net earnings per diluted share in 2003. The level of net earnings will depend on many factors, including, but not limited to, the degree of acceptance of our products in the marketplace and adequate product supply to meet demand. As a result of our recently announced share repurchase program, we expect that shares used for computing basic and diluted shares for the remainder of the year will decrease slightly, reflecting repurchases of approximately

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

2.9 million shares already completed through August 5, 2003, and additional repurchases during the second half of 2003.

### YTD 2003 compared to YTD 2002

#### Revenues Product Sales

(in millions)

	YTD 2003	YTD 2002	Growth
Synagis	\$ 447.2	\$ 325.5	37%
Ethiol	51.8	34.8	49%
Other Products	19.3	17.7	9%
	<u>\$ 518.3</u>	<u>\$ 378.0</u>	37%

For YTD 2003, product sales grew 37% to \$518.3 million as compared to \$378.0 million in YTD 2002, primarily due to a 37% increase in sales of Synagis to \$447.2 million and by a 49% increase in sales of Ethiol to \$51.8 million.

**Synagis** Synagis accounted for approximately 86% of our product sales for both YTD 2003 and YTD 2002. We achieved a 34% increase in domestic Synagis sales to \$420.6 million for YTD 2003, up from \$314.1 million in YTD 2002. This strong growth was driven primarily by an increase in unit sales that contributed 24 of the 34 percentage points, an increase in price that contributed 6 points and a decrease in sales allowances that contributed 4 points, reflecting a reduction in our estimate of reserves for bad debts and rebates due to government purchasers. Our reported international sales of Synagis more than doubled to \$26.6 million in YTD 2003 compared to \$11.4 million in YTD 2002, largely due to an almost five-fold increase in units sold to AI. We believe the growth is due to increased product demand by end users, particularly in Japan, where the product was approved for use in 2002. Also contributing to international Synagis sales growth is the additional amount due from AI in YTD 2003 compared to YTD 2002, calculated as the difference between the contractually stipulated transfer price and our share of AI's sales price to end-users. Sales growth was also aided by the impact of a weaker U.S. dollar.

**Ethiol** Ethiol accounted for approximately 10% and 9% of our product sales in YTD 2003 and YTD 2002, respectively. Worldwide Ethiol sales grew 49% to \$51.8 million in YTD 2003, as compared to \$34.8 million in YTD 2002. This growth was driven by a number of contributing factors, including: an increase in domestic unit sales that contributed 24 of the 49 percentage points; an increase in price that contributed 15 points; a decrease in sales allowances that contributed seven points; and an increase in sales to our international partner, Schering, that contributed three points.

#### Revenues Other Revenues

Other revenues increased \$20.0 million to \$35.4 million for YTD 2003 compared to \$15.4 million in YTD 2002, largely due to an increase in revenue recorded under collaborative agreements, partially offset by a decrease of \$4.4 million in revenues from the sale of excess production capacity to a third party. Other revenues for YTD 2003 include approximately \$27.5 million in milestone payments for the approval of FluMist and for achieving in excess of \$100 million in end-user sales of Synagis outside the U.S. during a single respiratory syncytial virus (RSV) season.

#### Cost of Sales

Cost of sales for YTD 2003 increased 32% to \$126.0 million from \$95.5 million for YTD 2002. Gross margins on product sales were 76% for YTD 2003, compared to 75% for YTD 2002, due to higher margins, particularly for Synagis, which are largely a result of lower sales allowances that increased net product sales. This favorable impact was partially offset by higher royalties payable to ALZA Corporation on Ethiol.

#### Research and Development Expenses

(in millions)

YTD 2003	YTD 2002
<u>Acquisition-Related</u>	<u>Acquisition-Related</u>



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

YTD 2003			YTD 2002		
Historical	Adjustments	Adjusted	Historical	Adjustments	Adjusted
\$59.6	(\$2.1)	\$57.5	\$78.6	(\$ 4.5)	\$74.1

Research and development expenses of \$59.6 million in YTD 2003 decreased 24% from \$78.6 million in YTD 2002. Excluding Acquisition-related adjustments in both periods, research and development expenses for YTD 2003 were \$57.5 million, down 22% from YTD 2002. The decline is largely due to the completion of several late-stage clinical trials by the end of 2002, including certain Phase 2 studies with siplizumab in psoriasis, and the Phase 3 Synagis clinical trial in congenital heart disease patients, the results of which were submitted to the FDA in November 2002.

## Selling, General, and Administrative Expenses (in millions)

YTD 2003			YTD 2002		
Historical	Acquisition-Related Adjustments	Adjusted	Historical	Acquisition-Related Adjustments	Adjusted
\$173.6	(\$4.2)	\$169.4	\$143.0	(\$ 5.9)	\$137.1

Selling, general and administrative ( SG&A ) expenses increased 21% to \$173.6 million in YTD 2003 compared to \$143.0 million in YTD 2002. Excluding Acquisition- related adjustments, adjusted SG&A expenses for YTD 2003 were \$169.4 million, up 24% over \$137.1 million in YTD 2002, due primarily to increases in co-promotion expenses for Synagis. This increase was partially offset by lower administrative spending and synergies associated with the Acquisition.

## Other Operating Expenses (in millions)

YTD 2003			YTD 2002		
Historical	Acquisition-Related Adjustments	Adjusted	Historical	Acquisition-Related Adjustments	Adjusted
\$22.9	(\$3.2)	\$19.7	\$44.0	(\$ 11.0)	\$33.0

Other operating expenses, which reflect manufacturing start-up costs and other manufacturing related costs, decreased to \$22.9 million in YTD 2003 from \$44.0 million in YTD 2002. Adjusted other operating expenses were \$19.7 million for YTD 2003, compared to \$33.0 million in YTD 2002. The decrease is due to the shift in the costs of FluMist manufacturing that are in inventory this year, but were expensed as other operating costs in the prior year.

## In-Process Research and Development

We incurred charges of \$1,179.3 million in the first quarter of 2002 for the write-off of purchased in-process research and development in conjunction with the Acquisition. The write-off represented the fair value of purchased in-process technologies at the acquisition date, calculated as the sum of probability-adjusted commercial scenarios. This method was based upon management's estimates of the probability of FDA approval and commercial success for FluMist.

## Interest Income and Expense

We earned interest income of \$27.3 million for YTD 2003, compared to \$23.8 million in YTD 2002, reflecting higher cash balances available for investment, partially offset by a decrease in short-term interest rates that lowered the overall portfolio yield. Interest expense for YTD 2003, net of amounts capitalized, was \$3.4 million, down from \$4.5 million in YTD 2002. This decrease is largely due to interest expense capitalized in connection with several large construction projects currently undertaken by the Company, including construction of the new corporate headquarters in Maryland, and manufacturing facilities in Pennsylvania and the U.K. that intensified during the second half of 2002.

## Loss on Investment Activities

We incurred \$0.4 million in losses on investment activities for YTD 2003, compared to \$0.1 million in YTD 2002, related to recording our portion of our minority investees' operating results as required by the equity method of accounting.

## Taxes

We recorded income tax expense of \$72.2 million for YTD 2003, resulting in an effective tax rate of 37%. Comparatively, we recorded income tax expense of \$18.4 million for YTD 2002, resulting in an effective tax rate of 36% that excluded a write-off of in-process research and development purchased during the first quarter of 2002, which was not deductible for tax purposes.

The increase in the estimated effective tax rate between 2002 and 2003 is primarily due to a reduction in the estimated credits available for research and development activities, including credits earned for Orphan Drug status of certain research and development activities in 2003, relative to our earnings growth. These credits will vary from year to year depending on the activities of the Company.

## Net Earnings / (Loss) (in millions)

YTD 2003			YTD 2002		
Historical	Acquisition-Related Adjustments	Adjusted	Historical	Acquisition-Related Adjustments	Adjusted
\$123.0	\$5.3	\$128.3	(\$1,146.3)	\$1,192.6	\$46.3

Net earnings for YTD 2003 were \$123.0 million, or \$0.49 basic and \$0.48 diluted earnings per share compared to a net loss for YTD 2002 of \$1.1 billion or \$4.62 per share. Excluding the after-tax impact of the Acquisition-related adjustments totaling \$5.3 million for YTD 2003, and \$1.2 billion for YTD 2002, adjusted net earnings for YTD 2003 and YTD 2002 were \$128.3 million and \$46.3 million, respectively, or \$0.50 and \$0.18 adjusted earnings per diluted share, respectively.

Shares used in computing basic earnings per share and basic adjusted earnings per share for YTD 2003 were 251.8 million, while shares used for computing diluted earnings per share and adjusted diluted earnings per share were 257.4 million. Shares used in computing net loss per share for YTD 2002 were 248.1 million. Shares used in computing adjusted earnings per diluted share for YTD 2002 were 254.8 million.

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 \$1,588.0 million at June 30, 2003 versus \$1,423.1 million at December 31, 2002, an increase of 12%. Increases in cash are primarily due to cash generated by the Company's ongoing business operations. Working capital decreased to \$362.4 million at June 30, 2003 from \$476.8 million at December 31, 2002, primarily due to the decrease in trade accounts receivable. As the Synagis selling season winds down during the second quarter of the calendar year, accounts are collected and excess cash is invested in longer term investments, in accordance with our investment guidelines.

## Operating Activities

Net cash provided by operating activities increased to \$194.6 million in YTD 2003 as compared to \$155.3 million in YTD 2002, primarily as the result of net earnings for the period and the use of deferred tax assets to offset current tax liabilities, partially offset by increases in inventory balances as the Company prepares for the launch of FluMist in the third quarter of 2003, increases in non-trade accounts receivable for certain milestone payments due from our collaborative partners, and decreases in accrued expenses and product royalties payable as amounts paid for co-promotion expense and royalties increased year-over-year, reflecting the increase in net sales.

## Investing Activities

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

Cash used for investing activities during YTD 2003 amounted to \$238.9 million, as compared to \$274.7 million in YTD 2002. Cash used for investing activities in YTD 2003 included net additions to our investment portfolio of \$183.6 million; \$43.6 million for capital expenditures, primarily for the construction of our new corporate headquarters, and the expansion of our FluMist manufacturing and filling and packaging facilities in Speke, England and Philadelphia, Pennsylvania; and minority interest investments in strategic partners totaling \$11.8 million through our venture capital subsidiary, MedImmune Ventures, Inc. During July 2003, we made a minority interest investment in Tercica, a late stage biopharmaceutical company that focuses on endocrinology.

### Financing Activities

Financing activities generated \$19.9 million in cash for YTD 2003, as compared to \$37.8 million in YTD 2002. Approximately \$20.3 million was received upon the exercise of employee stock options in YTD 2003, as compared to \$38.1 million received in YTD 2002, reflecting increased stock option exercises by employees of MedImmune Vaccines in 2002 subsequent to the Acquisition. In both YTD 2003 and YTD 2002, repayments on long-term debt were \$0.4 million.

**Forward-looking commentary** The Company currently generates cash from operations primarily from product sales, and expects to continue generating cash from these sources. The Company believes that its existing funds and cash generated from operations are adequate to satisfy its working capital and capital expenditure requirements in the foreseeable future. During July 2003, the Company completed the issuance of \$500 million of 1% Convertible Notes due 2023. The Company may raise additional capital in the future to take advantage of favorable conditions in the market or in connection with the Company's development activities.

During July 2003, our Board of Directors authorized the repurchase, over a two-year period, of up to \$500 million of the Company's common stock in the open market or in privately negotiated transactions, pursuant to terms management deems appropriate and at such times it may designate. The Company will hold repurchased shares as treasury shares and intends to use them for general corporate purposes, including but not limited to acquisition-related transactions and for issuance upon exercise of outstanding stock options. Through August 5, 2003, the Company had repurchased approximately 2.9 million shares at a cost of \$112.3 million.

We intend to use a portion of the proceeds from the Convertible Notes due 2023 to fund a substantial portion of our stock repurchase program, enabling us to acquire our stock opportunistically in the market at prices lower than the \$68.18 at which the Notes are convertible. In addition, the proceeds may be used to fund the retirement of the 5¼ percent debt convertible at \$58.14 per share that we assumed through the Aviron acquisition and which becomes callable in February 2004, or for other general corporate purposes.

We expect to have approximately \$190 million in capital expenditures during 2003. Construction of the first phase of the new corporate headquarters facility and pilot plant, as well as major construction projects at our facilities in Pennsylvania and in England, will be funded from cash generated from operations and investments on hand. We expect to take occupancy of the first phase of our new corporate headquarters, a complex of approximately 220,000 square feet, in late fall of 2003 to early 2004. At that time, we expect to sublease a portion of our existing space in Gaithersburg, which is leased through 2006. There can be no guarantee that we will be successful in subleasing the space.

During June 2003, we entered into a research and development collaboration with Micromet, a private German biotechnology company. Together with Micromet, we plan to develop MT103 for B cell tumors, such as non-Hodgkin's Lymphoma. We also plan to develop novel drug candidates using Micromet's proprietary Bi-Specific T cell Engager (BiTE) platform technology. During July 2003, we made an upfront payment of \$12.5 million to Critical Therapeutics to acquire an exclusive, worldwide license for technology associated with the HMG-B1 technology. We will develop the commercial production process for any and all potential drug products resulting from the collaboration. In conjunction with these collaborations, we are obligated to pay up to an aggregate of \$178.5 million for various milestone payments, subject to the achievement of specified clinical, regulatory, and sales milestones, and fund certain research and development costs. Additionally, we are obligated to pay royalties on any future sales, if any, of products resulting from the collaborations. In connection with the collaborations, our venture capital subsidiary made a minority interest investment in Micromet and has committed to participating in the next round of financing for Critical Therapeutics.

Effective for the upcoming RSV season, we reduced the number of U.S. specialty distributors in our Synagis network from over 100 in the 2002/2003 season to about a dozen specialty distributors going forward. In addition, we reduced the number of Synagis wholesalers and home health care agencies that we will use. The changes were made in order to achieve a higher level of service to patients via contractual requirements for downstream service related to Synagis. The selection criteria used in this process should also mitigate any risks associated with a higher concentration of credit among fewer creditors.

### ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our primary market risks as of June 30, 2003 are the exposures to loss resulting from changes in interest rates, foreign currency exchange rates, and equity prices. Market risk exposure exceeds that of December 31, 2002 due to the increase in the size of our investment portfolio.

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

Expenditures relating to our manufacturing operations in England and the Netherlands are paid in local currency. We have not hedged our expenditures relating to these manufacturing operations and, therefore, foreign currency exchange rate fluctuations may result in increases or decreases in the amount of expenditures recorded. Additionally, certain of our distribution agreements outside the United States provide for us to be paid based upon sales in local currency. As a result, changes in foreign currency exchange rates could adversely affect the amount we expect to collect under these agreements.

During July 2003, we issued \$500 million of Convertible Notes due 2023. The notes bear interest at one percent per annum payable semi-annually in arrears. Beginning with the six-month interest period commencing July 15, 2006, if the average trading price of the notes during specified periods equals or exceeds 120% of the principal amount of such notes, we will pay contingent interest equal to 0.175% per six-month period of the average trading price of the notes during such periods. As a result, if the market value of the notes appreciates significantly in the future, we could be obligated to pay significant amounts of contingent interest beginning in 2006.

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, 2002.

### ITEM 4. CONTROLS AND PROCEDURES

Based on an evaluation of the Company's disclosure controls and procedures in connection with the Company's filing of this quarterly report on Form 10-Q for Q2 2003, our management, with the participation of our principal executive officers and principal financial officers, namely our Vice Chairman and Chief Executive Officer; President and Chief Operating Officer; Senior Vice President and Chief Financial Officer; and Vice President and Controller; has concluded that the Company's disclosure controls and procedures were effective as of June 30, 2003.

Based on an evaluation of changes in the Company's internal control over financial reporting that occurred during Q2 2003, our management, with the participation of our principal executive officers and principal financial officers, namely our Vice Chairman and Chief Executive Officer; President and Chief Operating Officer; Senior Vice President and Chief Financial Officer; and Vice President and Controller; has concluded that there were no changes in the Company's internal control over financial reporting during Q2 2003 that have materially affected, or are 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 11 of Part I, Item 1 Consolidated 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, 2002.

### ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS - NONE

### ITEM 3. DEFAULTS UPON SENIOR SECURITIES - NONE

### ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITIES HOLDERS - NONE

On May 22, 2003 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, and four proposals were also approved by vote of the Company's stockholders, as follows:

	For	Against	Withheld	Abstain/ Non-vote
Wayne T. Hockmeyer	206,971,546	--	3,815,171	--
David M. Mott	207,149,836	--	3,636,881	--
Melvin D. Booth	207,150,567	--	3,636,150	--
Franklin H. Top, Jr	207,150,582	--	3,636,135	--
M. James Barrett	201,989,182	--	8,797,535	--
James H. Cavanaugh	201,989,164	--	8,797,533	--
Barbara H. Franklin	201,988,641	--	8,798,076	--
Gordon S. Macklin	201,236,197	--	9,550,520	--

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

				Abstain/ --
Elizabeth H. S. Wyatt	206,971,389	--	3,815,328	--
To amend the Restated Certificate of Incorporation to increase the authorized number of shares of common stock from 320,000,000 to 420,000,000	205,438,945	3,711,188	--	1,614,383
To amend the 1999 Stock Option Plan to increase the maximum number of shares of common stock authorized for issuance under the Plan from 25,250,000 to 31,250,000	178,025,540	30,997,714	--	1,741,262
To approve the 2003 Non-employee Directors Stock Option Plan and reserve 800,000 shares of common stock for issuance thereunder	181,157,859	27,855,112	--	1,751,545
Appointment of PricewaterhouseCoopers LLP as independent auditors	197,418,301	11,958,819	--	1,388,196

## ITEM 5. OTHER INFORMATION - NONE

## ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

### (a) Exhibits:

Exhibit 3.1.4 -- Certificate of Amendment to the Restated Certificate of Incorporation of MedImmune, Inc., dated May 23, 2003.

Exhibit 31.1 -- Certification pursuant to 18 USC Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

Exhibit 31.2 -- Certification pursuant to 18 USC Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

Exhibit 31.3 -- Certification pursuant to 18 USC Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

Exhibit 31.4 -- Certification pursuant to 18 USC Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

Exhibit 32 -- 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.

### (b) Reports on Form 8-K:

April 24, 2003 -- MedImmune reports 2003 first quarter results.

June 18, 2003 -- MedImmune, Inc. and Wyeth announce the approval of FluMist by the U.S. Food and Drug Administration.

June 30, 2003 -- MedImmune announces a business review meeting to provide an overview of opportunities for long-term growth.

## 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 hereunto duly authorized.

SIGNATURES

**MEDIMMUNE, INC.**

BY: /s/ Gregory S. Patrick

Gregory S. Patrick  
Senior Vice President and Chief Financial Officer  
Principal Financial Officer

Dated: August 8, 2003

BY: /s/ Lota S. Zoth

Lota S. Zoth  
Vice President and Controller  
Principal Accounting Officer

Dated: August 8, 2003