

MEDIMMUNE INC /DE  
Form 10-Q  
May 07, 2004

**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 March 31, 2004

**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.)

One MedImmune Way, Gaithersburg, MD 20878  
(Address of principal executive offices) (Zip Code)

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

35 West Watkins Mill Road, Gaithersburg, MD 20878  
(Former name, former address and former fiscal year, if changed since last report)

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 April 30, 2004, 248,753,764 shares of Common Stock, par value \$0.01 per share, were outstanding.

**MEDIMMUNE, INC.**  
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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 March 31, 2004. 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>March 31,<br/>2004</b> | <b>December 31,<br/>2003</b> |
|-----------------------------|---------------------------|------------------------------|
|                             | <b>(Unaudited)</b>        |                              |
| <b>ASSETS:</b>              |                           |                              |
| Cash and cash equivalents   | \$ 300,371                | \$ 515,502                   |
| Marketable securities       | 288,113                   | 272,765                      |
| Trade receivables, net      | 149,847                   | 161,229                      |
| Inventory, net              | 59,308                    | 91,703                       |
| Deferred tax assets         | 22,699                    | 29,322                       |
| Other current assets        | 23,387                    | 32,233                       |
|                             | <hr/>                     | <hr/>                        |
| Total Current Assets        | 843,725                   | 1,102,754                    |
| Marketable securities       | 1,370,307                 | 1,111,882                    |
| Property and equipment, net | 281,657                   | 273,597                      |
| Deferred tax assets, net    | 106,962                   | 151,280                      |
| Intangible assets, net      | 92,592                    | 96,694                       |

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|  | <b>March 31,</b>    | <b>December 31,</b> |
|--|---------------------|---------------------|
| Goodwill   | 13,614              | 13,614              |
| Other assets   | 51,516              | 44,849              |
|  | <hr/>               | <hr/>               |
| Total Assets   | <b>\$ 2,760,373</b> | <b>\$ 2,794,670</b> |
|  | <hr/>               | <hr/>               |
| <b>LIABILITIES AND SHAREHOLDERS' EQUITY:</b>   |                     |                     |
| Accounts payable   | \$ 19,342           | \$ 22,116           |
| Accrued expenses   | 246,221             | 217,915             |
| Product royalties payable  | 82,936              | 81,808              |
| Advances from Wyeth  | 24,401              | 51,910              |
| Taxes Payable  | 25,294              | 120                 |
| Other current liabilities  | 11,899              | 16,846              |
|  | <hr/>               | <hr/>               |
| Total Current Liabilities  | 410,093             | 390,715             |
|  | <hr/>               | <hr/>               |
| Long-term debt   | 506,903             | 681,223             |
| Obligations to Evans   | 21,765              | 21,627              |
| Other liabilities  | 1,790               | 1,887               |
|  | <hr/>               | <hr/>               |
| Total Liabilities  | 940,551             | 1,095,452           |
|  | <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; outstanding 248,258 at March 31, 2004 and 248,036 at December 31, 2003 | 2,545               | 2,543               |
| Paid-in capital  | 2,675,430           | 2,673,059           |
| Deferred compensation  | (889)               | (1,379)             |
| Accumulated deficit  | (661,908)           | (772,936)           |
| Accumulated other comprehensive income   | 34,446              | 27,733              |
|  | <hr/>               | <hr/>               |
|  | 2,049,624           | 1,929,020           |
| Less: Treasury stock at cost; 6,239 shares at March 31, 2004 and December 31, 2003   | (229,802)           | (229,802)           |
|  | <hr/>               | <hr/>               |
| Total Shareholders' Equity   | 1,819,822           | 1,699,218           |
|  | <hr/>               | <hr/>               |
| Total Liabilities and Shareholders' Equity   | <b>\$ 2,760,373</b> | <b>\$ 2,794,670</b> |
|  | <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)

|               | <b>For the</b>            |             |
|---------------|---------------------------|-------------|
|               | <b>three months ended</b> |             |
|               | <b>March 31,</b>          |             |
|               | <b>2004</b>               | <b>2003</b> |
|               | <hr/>                     | <hr/>       |
| Revenues:     |                           |             |
| Product sales | \$ 483,209                | \$ 431,109  |

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|  | <b>For the</b> |            |
|--|----------------|------------|
| Other revenue  | 5,792          | 3,511      |
| Total revenues   | 489,001        | 434,620    |
| Costs and expenses:                                      |                |            |
| Cost of sales  | 158,193        | 103,340    |
| Research and development                                 | 49,764         | 31,671     |
| Selling, general and administrative                      | 123,732        | 115,244    |
| Other operating expenses                                 | 1,818          | 21,456     |
| Total expenses   | 333,507        | 271,711    |
| Operating income   | 155,494        | 162,909    |
| Interest income  | 16,673         | 12,990     |
| Interest expense   | (2,166)        | (1,799)    |
| Gain (loss) on investment activities                     | 6,234          | (257)      |
| Earnings before income taxes                             | 176,235        | 173,843    |
| Provision for income taxes                               | 65,207         | 64,322     |
| Net earnings   | \$ 111,028     | \$ 109,521 |
| Basic earnings per share                                 | \$ 0.45        | \$ 0.44    |
| Shares used in calculation of basic earnings per share   | 248,180        | 251,499    |
| Diluted earnings per share                               | \$ 0.44        | \$ 0.43    |
| Shares used in calculation of diluted earnings per share | 250,896        | 256,514    |

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

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

(in thousands)

|   | <b>For the three months ended</b> |             |
|---|-----------------------------------|-------------|
|   | <b>March 31,</b>                  |             |
|   | <b>2004</b>                       | <b>2003</b> |
| <b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>  |                                   |             |
| Net earnings  | \$ 111,028                        | \$ 109,521  |
| Adjustments to reconcile net earnings to net cash provided by operating activities: |                                   |             |
| Deferred taxes  | 45,371                            | 66,247      |
| Deferred revenue  | (122)                             | (1,676)     |
| Advances from Wyeth   | (27,509)                          | --          |
| Depreciation and amortization   | 10,624                            | 10,736      |
| Amortization of premium on marketable securities                                    | 3,541                             | 3,258       |
| Amortization of deferred compensation   | 360                               | 1,641       |
| Amortization of premium on convertible subordinated notes                           | (391)                             | (466)       |
| Amortization of bond issuance costs   | 891                               | --          |
| Realized (gains) losses on investments  | (6,234)                           | 257         |

|  | <b>For the three months ended</b> |            |
|--|-----------------------------------|------------|
| Gain on early redemption of convertible notes        | (1,010)                           | --         |
| Losses on write downs of inventory                   | 18,572                            | 20,786     |
| Increase (decrease) in sales allowances              | 18,082                            | (3,500)    |
| Other  | (632)                             | 449        |
| Other changes in assets and liabilities              | 62,686                            | 16,583     |
|  | <hr/>                             | <hr/>      |
| Net cash provided by operating activities            | 235,257                           | 223,836    |
|  | <hr/>                             | <hr/>      |
| <b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>         |                                   |            |
| Increase in marketable securities                    | (251,935)                         | (106,926)  |
| Capital expenditures                                 | (14,472)                          | (21,793)   |
| Investments in strategic alliances                   | (12,500)                          | --         |
|  | <hr/>                             | <hr/>      |
| Net cash used in investing activities                | (278,907)                         | (128,719)  |
|  | <hr/>                             | <hr/>      |
| <b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>         |                                   |            |
| Proceeds from issuance of common stock               | 1,424                             | 8,182      |
| Debt prepayments                                     | (172,677)                         | --         |
| Repayments on long-term obligations                  | (220)                             | (206)      |
|  | <hr/>                             | <hr/>      |
| Net cash (used in) provided by financing activities  | (171,473)                         | 7,976      |
|  | <hr/>                             | <hr/>      |
| Effect of exchange rate changes on cash              | (8)                               | (54)       |
| Net (decrease) increase in cash and cash equivalents | (215,131)                         | 103,039    |
| Cash and cash equivalents at beginning of period     | 515,502                           | 130,056    |
|  | <hr/>                             | <hr/>      |
| Cash and cash equivalents at end of period           | \$ 300,371                        | \$ 233,095 |
|  | <hr/>                             | <hr/>      |

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

**MEDIMMUNE, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**(UNAUDITED)**

**1. Organization**

MedImmune, Inc., a Delaware corporation (together with its subsidiaries, the Company), is a biotechnology company headquartered in Gaithersburg, Maryland. The Company currently actively markets four products, Synagis, Ethyol, CytoGam, and FluMist, and maintains a diverse research and development pipeline. The Company is focused on developing 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 for the three months ended March 31, 2004 (Q1 2004) and for the three months ended March 31, 2003 (Q1 2003) 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, 2003.

*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

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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, SFAS 148 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 were 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):

|  | Q1<br>2004 | Q1<br>2003 |
|--|------------|------------|
| Net earnings, as reported  | \$ 111.0   | \$ 109.5   |
| Add: stock-based employee compensation expense included in historical results for the vesting of stock options assumed in conjunction with the acquisition of Aviron, 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        | 1.0        |
| Deduct: stock-based employee compensation expense determined under the fair value based method for all awards, net of related tax effect   | (16.2)     | (24.3)     |
| Pro forma net earnings   | \$ 95.0    | \$ 86.2    |
| Basic earnings per share, as reported  | \$ 0.45    | \$ 0.44    |
| Basic earnings per share, pro forma  | \$ 0.38    | \$ 0.34    |
| Diluted earnings per share, as reported  | \$ 0.44    | \$ 0.43    |
| Diluted earnings per share, pro forma  | \$ 0.38    | \$ 0.34    |

### *Reclassifications*

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

### 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 March 31, 2004 are comprised of the following (in millions):

|   |         |
|---|---------|
| Worldwide collaboration with Wyeth          | \$ 90.0 |
| Contract manufacturing agreement with Evans | 39.0    |
| Other intangible assets                     | 0.4     |
|   | 129.4   |
| Less accumulated amortization               | (36.8)  |
|   | \$ 92.6 |

Amortization of intangible assets is computed on the straight-line method based on the estimated useful lives of the assets. Amortization expense for Q1 2004 and Q1 2003 was \$4.4 million and \$4.2 million, respectively. As of March 31, 2004, FluMist inventory includes approximately \$0.3 million of amortization costs associated with the contract manufacturing agreement with Evans. The estimated aggregate amortization for the Evans agreement for the remainder of 2004 through 2006 is as follows: 2004, \$6.5 million; 2005, \$8.7 million; and 2006, \$4.4 million.

As a result of entering into agreements to dissolve the collaboration with Wyeth during April 2004 (see Note 11), assuming consummation of the transactions contemplated by these agreements, the Company will record a permanent impairment loss of \$73.0 million during the quarter ended June 30, 2004 to write off the remaining unamortized cost of the intangible asset.

#### 4. Inventory

Inventory, net of write-downs, is comprised of the following (in millions):

|                      | March 31,<br>2004 | December 31,<br>2003 |
|----------------------|-------------------|----------------------|
| <i>By Component</i>  |                   |                      |
| Raw Materials, net   | \$ 11.8           | \$ 11.6              |
| Work in Process, net | 38.4              | 39.3                 |
| Finished Goods, net  | 9.1               | 40.8                 |
|                      | \$ 59.3           | \$ 91.7              |

During Q1 2004, the Company recorded permanent inventory write downs totaling \$13.5 million in cost of goods sold to reflect total FluMist inventories at net realizable value. During Q1 2003, prior to regulatory approval, the Company recorded permanent inventory write downs totaling \$19.6 million to other operating expenses to reflect total FluMist inventories at net realizable value.

#### 5. Earnings per Share

The following is a reconciliation of the denominators of the diluted EPS computation for Q1 2004 and Q1 2003. There are no reconciling items to the numerator for the EPS computation for the periods reported (in millions).

|  | Q1<br>2004 | Q1<br>2003 |
|--|------------|------------|
| Denominator:                                   |            |            |
| Weighted average shares<br>outstanding         | 248.2      | 251.5      |
| Effect of dilutive securities:                 |            |            |
| Stock options, warrants, and convertible notes | 2.7        | 5.0        |
| Denominator for diluted EPS                    | 250.9      | 256.5      |

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. As a result, options to purchase 21.5 million shares of the Company's common stock with exercise prices ranging from \$23.84 to \$83.25 per share were outstanding during Q1 2004, but were excluded from the computation of diluted earnings per share. Additionally, options to purchase 15.0 million shares of the Company's common stock with exercise prices ranging from \$30.16 to \$83.25 were outstanding during Q1 2003, but were excluded from the computation of diluted earnings per share. The Company's 1% Convertible Senior Notes (the 1% Notes) are considered contingent convertible securities, meaning they are eligible for conversion to common stock only if certain requirements are met, and were excluded from the diluted earnings per share calculations for all periods presented. The 1% Notes represent 7.3 million potential shares of common stock issuable upon conversion.

#### 6. Income Taxes

The reported effective tax rate for Q1 2004 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 Q1 2003 was based on an estimated annual effective tax rate on pretax income of 37%.

As a result of the dissolution of the collaboration with Wyeth during April 2004 (see Note 11), the Company anticipates that its effective tax rate will be approximately 43% for the year ended December 31, 2004. The increase in the effective rate is the result of: 1) a portion of the in-process research and development charge is not deductible for tax purposes; and 2) the relationship of the non-deductible portion of the in-process research and development charge to the Company's income before taxes, which is significantly reduced by this charge, as well as other transition-related expenses.

## 7. Comprehensive Income

|  | Q1<br>2004      | Q1<br>2003      |
|--|-----------------|-----------------|
| Net earnings   | \$ 111.0        | \$ 109.5        |
| Change in foreign currency translation adjustment                                  | (0.02)          | 0.8             |
| Change in unrealized gain on investments, net of tax                               | 4.3             | 3.7             |
| Reclassification adjustments for losses on cash flow hedges included in net income | 3.1             | --              |
| Change in unrealized gain on cash flow hedges, net of tax                          | (0.5)           | (0.2)           |
| Comprehensive income   | <u>\$ 117.7</u> | <u>\$ 113.8</u> |

## 8. 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. The Company has adopted FIN No. 46 and has determined that it does not currently hold interests in any entities that are subject to the consolidation provisions of this interpretation.

## 9. Debt

On March 31, 2004, the Company redeemed the remaining outstanding \$168.6 million principal amount of the MedImmune Vaccines, Inc. 5¼% convertible subordinated notes due February 2008 for approximately \$172.7 million. The redemption resulted in a net ordinary gain of \$1.0 million, reflecting the accelerated amortization of bond premium net of a 3% call premium, which is included in interest expense in the Consolidated Statement of Operations.

## 10. 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 alleged 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. That dismissal was upheld on appeal on July 17, 2003. Celltech sought appellate review by the House of Lords and that request was denied in January 2004, bringing an end to this particular litigation.

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. This matter was tried before the High Court of Justice from March 31 to April 7, 2004. The Company is awaiting the Court's decision.

The Company has become aware that a new United States patent was issued on October 14, 2003 in the name of Celltech Therapeutics Limited, which the Company understands is an affiliated entity of Celltech (the Adair Patent ). If the manufacture or sale of Synagis® or any of the Company's other products is ultimately found to be covered by any valid claim of this new patent and/or any other Celltech patent that is the subject of the January 19, 1998 license agreement, the Company's total royalty obligation would equal 2% of the net sales of the products that are so covered. To date, the Company has not made any royalty payments to Celltech under the January 19, 1998 license agreement. In January 2004, the Company filed a declaratory judgment action in the United States District Court for the District of Columbia concerning the Adair Patent and alleging patent invalidity and non-infringement with regard to Synagis. On March 12, 2004 Celltech moved to dismiss the non-infringement portion of the Company's complaint, asserting that the courts of England have exclusive jurisdiction over the non-infringement claim pursuant to the 1998 license agreement. On March 22, 2004 Celltech filed an action in the U.K. against the Company based on the same Adair Patent seeking payment of a 2% royalty based on net sales of Synagis made or sold in the U.S. pursuant to the 1998 license agreement.

## 10. Legal Proceedings



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The Company has made an application to stay Celltech's U.K. action to allow the U.S. court to consider the non-infringement and invalidity claims together.

In April 2003, the Company filed a suit against Genentech, Inc. ( Genentech ), Celltech R&D Ltd. and City of Hope National Medical Center ( City of Hope ) 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 covering United States Patent No. 6,331,415B1 (the Cabilly Patent ). In the complaint, the Company alleged 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 alleged that the Cabilly Patent is invalid and unenforceable under federal patent law and is not infringed. In December 2003, the Court granted Celltech and Genentech's motion to dismiss the antitrust claims, and denied MedImmune's motion to amend its complaint in January 2004. The Company filed an appeal in March, 2004 to the Federal Circuit on the antitrust claims. Based on the Gen-Probe decision discussed above, Genentech and City of Hope moved to dismiss the patent claims alleging that there was no subject matter jurisdiction where a licensee was making royalty payments called for pursuant to a license agreement, while attempting to challenge the validity of the underlying patent. On April 23, 2004 the Court granted Genentech and City of Hope's motion and dismissed the case.

In April 2002, the Company filed a suit against Centocor, Inc. ( Centocor ) in the United States District Court for the District of Maryland. That action was amended in January 2003 to add the Trustees of Columbia University in the City of New York ( Columbia ) and the Board of Trustees of the Leland Stanford University ( Stanford ) as the owners of the patent. The Company currently pays Centocor a royalty for sales of Synagis made or sold in the United States pursuant to a patent Sublicense Agreement between the parties (the 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. Centocor and the Universities moved on March 22, 2004 to dismiss this suit for lack of subject matter jurisdiction based on the decision in *Gen-Probe, Inc. v. Vysis, Inc.*, 359 F.3d 1376 (Fed. Cir. March 5, 2004). The Company has opposed that motion and is awaiting a decision from the Court.

In January 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. In August 2003, the County of Westchester, New York ( Westchester ) filed and served a similar suit against the Company and approximately 25 other pharmaceutical and biotechnology defendants. Likewise, in September 2003, the County of Rockland, New York ( Rockland ) also filed and served a similar suit against the Company and approximately 25 other pharmaceutical and biotechnology defendants. Suffolk, Westchester and Rockland allege that the defendants manipulated the average wholesale price ( AWP ) causing the Counties to pay artificially inflated prices for covered drugs. In addition, the Counties argue that the defendants (including the Company) did not accurately report the best price under the Medicaid program. The plaintiffs seek declaratory and injunctive relief, disgorgement of profits, treble and punitive damages suffered as a result of defendants' alleged unlawful practices related prescription medication paid for by Medicaid. All three of these cases have been consolidated (for pre-trial purposes) and transferred to the United States Court for the District of Massachusetts in *Re: Pharmaceutical Industry Average Wholesale Price Litigation (AWP Multidistrict Litigation)*. A motion to dismiss the complaint against the Company relative to the County of Suffolk has been argued before the Court and a decision is pending.

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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. In its ordinary course of business, the Company has provided indemnification to various parties for certain product liability claims and claims that the Company's products were not manufactured in accordance with applicable federal standards. While the Company is not aware of any current claims under these provisions, there can be no assurance that such claims will not arise in the future or that the effect of such claims will not be material to the Company.

### 11. Subsequent Event

On April 27, 2004, the Company announced that it had entered into agreements to dissolve the collaboration with Wyeth for the nasal flu vaccine FluMist and all related technology, including an investigational second-generation, refrigerator-stable formulation of FluMist, Cold Adapted Influenza Vaccine-Trivalent (CAIV-T). As a result of the dissolution, MedImmune will reacquire the rights to this technology, and will assume full responsibility for the manufacturing, marketing, and sale of FluMist and any subsequent related product. As part of the dissolution, the Company will acquire Wyeth's distribution facility in Louisville, Kentucky. Wyeth will provide bulk manufacturing materials and will transfer clinical trial data, as well as provide manufacturing services, during a transition that the companies expect to complete in large part by the fourth quarter of 2004. Under the terms of the agreement, MedImmune will make an upfront payment of \$26.3 million to Wyeth plus an

additional amount to reconcile outstanding balances under the collaboration agreements and for the transfer of certain other assets. In addition, MedImmune has agreed to pay up to \$10 million in milestone payments contingent upon achievement of certain future development and regulatory events, and royalties on future product sales. In connection with the transaction, the Company expects to record a charge to in-process research and development of approximately \$30 million during 2004, based on a preliminary valuation, and expects to take certain non-recurring charges if and when certain milestone criteria are achieved, as well as a permanent impairment charge of approximately \$73 million to write off the remaining unamortized cost of the Wyeth intangible asset. Should the necessary clearance under federal antitrust laws not be received, the Company and Wyeth will revert to the original collaboration arrangement as governed by the collaborative agreements.

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## 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 and assumptions of our management. Readers are cautioned that these forward-looking statements are only predictions 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, 2003.*

### INTRODUCTION

Since 1988, MedImmune has been focused on using biotechnology to produce innovative products to prevent or treat infectious disease, autoimmune disease and cancer. MedImmune currently actively markets four products, Synagis, FluMist, Ethyol, and CytoGam and has a diverse pipeline of development-stage products.

### OVERVIEW OF Q1 2004

The Company's financial condition strengthened in the first quarter of 2004, with cash and marketable securities reaching nearly \$2.0 billion. We decreased our long-term debt with an early pay down of the remaining outstanding MedImmune Vaccines, Inc. 5¼% Convertible Subordinated Notes due 2008. From an operating results perspective, our diluted earnings per share in Q1 2004 were \$0.44 compared to \$0.43 in Q1 2003. We achieved a 13% growth in revenues in Q1 2004, reflecting growth in Synagis sales and our initial recognition of FluMist product sales revenues related to the 2003/2004 flu season.

Our efforts for Q1 2004 were focused on the development of our pipeline of product candidates and our determination of the future of FluMist following its disappointing launch in 2003. On the research and development front, we completed enrollment for two of our Phase 2 clinical trials for Vitaxin; we initiated a Phase 1 and 2 program with Numax, and we announced preliminary data from two Phase 3 trials with CAIV-T, a refrigerator-stable version of frozen FluMist, that were conducted by Wyeth. We also filed a supplemental biologics license application for liquid Synagis.

### DISSOLUTION OF THE COLLABORATION WITH WYETH

On April 27, 2004, the Company announced that it had entered into agreements to dissolve the collaboration with Wyeth for the nasal flu vaccine FluMist and all related technology, including CAIV-T and any subsequent products. As a result of the dissolution, MedImmune will reacquire the rights to this technology, and will assume full responsibility for the manufacturing, marketing, and selling of FluMist and any subsequent related products. We anticipate this transaction to have the following material financial impact for 2004, assuming consummation of the dissolution:

**Revenue-** Upon consummation of the dissolution, we will no longer receive any reimbursement from Wyeth for development and commercialization costs, nor will we receive milestone payments. We expect all future FluMist product sales will be recorded as the sales price to customers less customary sales reserves.

**Research and Development-** We anticipate expenses in this line item to increase significantly as we assume full responsibility and the operational lead for the continued development and/or regulatory approval of FluMist and CAIV-T. The increase in expense will be comprised of non-recurring costs to transition certain research and development activities from Wyeth to us as well as recurring incremental costs for us to continue those and other research and development activities.

**Intangible Assets-** We anticipate the write-off of the remaining value assigned to the worldwide collaborative agreement with Wyeth of approximately \$73 million.

**In-Process Research and Development-** We anticipate recording an in-process research and development charge of approximately \$30 million. The charge would represent the fair value of purchased in-process technologies at the acquisition date, based on a preliminary valuation.

**Income Taxes-** We anticipate that our effective tax rate will be approximately 43% for the year ended December 31, 2004 as compared to our current effective rate of 37%. The increase in the effective rate is anticipated because: 1) a portion of the in-process research and development charge will not be deductible for tax purposes; and 2) the relation of the non-deductible portion of the in-process research and development charge to the Company's income before taxes, which is significantly reduced by this charge as well as other transition-related expenses.

Should the necessary clearance under federal antitrust laws not be received, the Company and Wyeth will revert to the original collaboration arrangement as governed by the collaborative agreements.

## 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. 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.

**Revenue Recognition-** We recognize revenue from product sales when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed or determinable, and collectibility is reasonably assured. FluMist revenues for the 2003/2004 flu season consist of amounts paid by Wyeth, the Company's collaboration partner for the vaccine, for a transfer price, royalties, and reimbursements. Wyeth has been contractually responsible for distributing the product to third parties, and the transfer price and royalty amounts due from Wyeth are largely dependent upon their net sales to end users. Wyeth's net sales consist of any amounts actually received by them for the sale of FluMist less agreed-upon amounts paid or credited by Wyeth related to the sale of the product such as for returns, promotional discounts, rebates, taxes and freight. During 2003, we shipped 4.1 million doses of FluMist to Wyeth and received payments totaling \$51.9 million. Due to the low sales volume for the 2003/2004 season, the calculation of the product transfer price was highly sensitive to the amount of returns and rebates for FluMist. Because FluMist was launched in September 2003, we concluded as of December 31, 2003 that the variables associated with the product transfer price were not determinable, largely due to low sales volume and the lack of returns history and comparable rebate redemption rates for this new product. As a result, we did not recognize any revenue associated with the 4.1 million doses shipped to Wyeth during 2003. At March 31, 2004, approximately the end of the influenza season, we were able to reasonably estimate the variables associated with the product transfer price based on actual results for the influenza season. As a result, we recorded product sales revenue associated with the 4.1 million doses shipped to Wyeth during 2003 of \$25.9 million and we recorded royalty revenue of \$3.1 million.

**Inventory-** We capitalize inventory costs associated with marketed products and 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 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 regulatory bodies, a delay in commercialization, or other potential factors. Conversely, our gross margins may be favorably impacted if some or all of the related production costs were expensed prior to the product being available for commercial sale.

We are required to state our inventory at lower of cost or market. In assessing the ultimate realization of inventories, we are required to make judgments as to multiple factors affecting our inventories and compare these with current or committed inventory levels. In the highly regulated industry in which we operate, raw materials, work-in-process and finished goods inventories have expiration dates that must be factored into our judgments about the recoverability of inventory costs. Additionally, if our estimate of a product's pricing is such that we may not fully recover the cost of inventory, we must consider that in our judgments as well. In the context of reflecting inventory at the lower of cost or market, we will record inventory write-downs (inventory reserves) 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. The finished FluMist product has a shelf life of nine months. Additionally, our work-in-process inventory consists of multiple components, each having different expiration dates that range from nine to 24 months. Further, the annual FluMist production cycle begins in October of the year prior to the influenza season in which the product will be consumed. For example, the production cycle for the 2004/2005 season began in October 2003.

For all inventory components on hand as of March 31, 2004, we reviewed the following assumptions to determine the amount of any necessary reserves: expected production levels and estimated cost per dose, the expected sales volume; the expected price to be received for the product; and potential changes in the influenza strains recommended by the Centers for Disease Control and Prevention for each season's vaccine. As of

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December 31, 2003, we reevaluated our inventories based upon the factors above. In our analysis, we considered the disappointing results of our launch of FluMist, which became available in late 2003, and the Company's revised sales estimates of FluMist for both the 2003/2004 and 2004/2005 flu seasons. As a result, we revised our sales volume estimates and decreased the estimated price expected to be received per dose for the 2004/2005 flu season. In addition, we decreased our estimated production levels based on our anticipated decrease in sales volumes, which increased the estimated price per dose to produce FluMist. Using these assumptions, we compared the expected amount to be received from FluMist sales to the expected cost to produce it to estimate the net realizable value of FluMist inventories to be produced throughout the season. As of March 31, 2004, we updated our analysis and determined that our December 31, 2003 estimates had not changed materially. We therefore used the same methodology to calculate any additional adjustments required to value our FluMist inventories as of March 31, 2004 at net realizable value. This resulted in additional reserves of \$13.5 million for inventories which were produced during Q1 2004.

The table below summarizes the activity within the components of FluMist inventories:

|  | <u>Gross Inventory</u> | <u>Reserves</u>  | <u>Net Inventory</u> |
|--|------------------------|------------------|----------------------|
| <i>FluMist Details</i>                                 |                        |                  |                      |
| As of December 31, 2003                                | \$ 122.1               | (\$ 85.8)        | \$ 36.3              |
| Q1 raw materials purchases                             | 3.5                    | (0.2)            | 3.3                  |
| Q1 cost of good sold recognized on 2003/2004 inventory | (34.2)                 | 5.0              | (29.2)               |
| Q1 production, net                                     | 15.0                   | (13.3)           | 1.7                  |
| Q1 disposals   | (50.3)                 | 49.6             | (0.7)                |
|  | <u>56.1</u>            | <u>(\$ 44.7)</u> | <u>\$ 11.4</u>       |
| As of March 31, 2004                                   | \$ 56.1                | (\$ 44.7)        | \$ 11.4              |

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. No significant inventory adjustments were recorded for our other products.

### Sales Allowances and Other Sales Related Estimates

#### *Reductions to Gross Product Sales*

The Company records allowances for discounts, returns, chargebacks and rebates due to government purchasers as reductions to gross product sales. The timing of actual returns, chargebacks and discounts taken, and rebates paid to government purchasers can lag behind the sale of the product by several periods and varies by state. As such, a significant amount of judgment is required when estimating the impact of sales allowances on gross sales for a reporting period. Our starting point for estimating each of these is our historical experience by product, updated for changes in facts and circumstances as appropriate. Because of the seasonal nature of our largest product, Synagis, our sales discounts, returns, chargebacks and rebates fluctuate throughout the year. 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.

We estimate the amount of rebates due to government purchasers quarterly based on historical experience, along with updates, and based on our best estimate of the proportion of sales that will be subject to this reimbursement, largely comprised of Medicaid payments to state governments. We continually monitor the matter and adjust our reserve estimates when necessary. For the quarter ended March 31, 2004, allowances for discounts, returns, chargebacks and rebates due to government purchasers resulted in a net reduction to gross product sales of approximately 10% as compared to 9% in Q4 2003 and 6% in Q1 2003. The increase in allowances in Q1 2004 as compared to Q1 2003 largely results from a reduction in reserves for rebates due to government purchasers recorded in Q1 2003 to reflect favorable historical experience and a change in our estimate of the proportion of the sales that are subject to reimbursement. During the fourth quarter of 2003, we became aware of recent efforts by several states to collect rebates for product administered in certain settings for which reimbursement was not sought in the past. Based on our analysis of that information, we increased our estimate of the proportion of current sales that will be subject to reimbursement. Reserves for discounts, returns, chargebacks and rebates that were accrued and not yet paid as of March 31, 2004 and December 31, 2003 were \$69.5 million and \$51.4 million, respectively. Reserves for discounts, returns, and chargebacks are netted against trade receivables and reserves for government reimbursements are included in accrued expenses in the accompanying balance sheets.

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

We estimate our co-promotion expense and sales commissions 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 outstanding at the end of the period, 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. Because of the seasonal nature of our largest product, Synagis, our accounts receivable balances fluctuate significantly. Accordingly, our allowance for doubtful accounts also fluctuates. Our accounts receivable balances tend to be highest at the end of December and March, while the September balances are somewhat lower as our selling season is just beginning, and the June balances are negligible, reflecting the close-out of the prior season. For the quarter ended March 31, 2004, we recorded a net reduction in bad debt expense of \$0.1 million, largely based on our current assessment of the factors above.

**In-process Research and Development** When we enter into significant agreements for access to late-stage technology or product candidates, we generally perform a valuation of the transaction to determine the fair value of the purchased in-process technologies at the acquisition date, calculated as the sum of probability-adjusted commercial scenarios. This method is usually based upon management's estimates of the probability of FDA approval and commercial success for the product candidate, which can include the estimated impact of key factors, including price, volume, timing of regulatory approval and any potential failure to commercialize the product. Our most recent product candidate, FluMist, was acquired through the acquisition of Aviron in January 2002 (the Acquisition), was approved for commercialization in June 2003 and was launched in September 2003. FluMist was considered to be a late-stage product candidate, and as such, we used the methodology described above to value the amount of the purchased in-process research and development at the transaction date. The value of the in-process research and development was determined to be \$1,179.3 million, which was charged to income in Q1 2002.

As a result of multiple factors, which were unforeseen at the time of the Acquisition, FluMist did not achieve the level of initial commercial success that we had projected for the first season. After a thorough analysis of the product subsequent to the first season, we are focusing on the next generation refrigerator-stable formulation and consider FluMist a significant development program toward that end that happens to be a commercial product. As such, we do not presently believe that the FluMist franchise will be a meaningful contributor to revenue growth before 2007, when the Company hopes to launch the next generation of the product, CAIV-T. Had we known at the time of the Acquisition that we would have a more narrow indication than expected or that our sales volumes would be much lower than expected, the value of the purchased in-process research and development would likely have been significantly lower than the original valuation.

## RESULTS OF OPERATIONS

### Comparison of Q1 2004 to Q1 2003

#### Revenues Product Sales

(In Millions)

|                | Q1<br>2004 | Q1<br>2003 | Growth |
|----------------|------------|------------|--------|
| Synagis        | \$ 421.7   | \$ 391.3   | 8%     |
| Ethyol         | 24.4       | 26.8       | (9%)   |
| FluMist        | 25.9       | --         | N/A    |
| Other Products | 11.2       | 13.0       | (14%)  |
|                | \$ 483.2   | \$ 431.1   | 12%    |

Product sales grew 12% in Q1 2004 to \$483.2 million as compared to \$431.1 million in Q1 2003, primarily due to increased sales of Synagis and due to our initial FluMist product sale revenues, recorded for the 2003/2004 flu season, in Q1 2004. Of the overall increase in product sales, approximately 11 of the 12 percentage points were due to an increase in domestic sales volumes, including new sales of FluMist, while two points of growth are due to an increase in our international sales. The effect of price increases, which added approximately five points to growth, was offset by increases in sales allowances, which reduced growth by approximately 6 points.

**Synagis** Synagis accounted for approximately 87% and 91% of our Q1 2004 and Q1 2003 product sales, respectively. Domestic Synagis sales increased 5% to \$390.1 million in 2004, up from \$369.9 million in 2003. This growth was due to increased sales volume in the United States, which resulted in a 7% increase in domestic units sold. Also aiding growth was a price increase that took effect in June 2003. These increases were partially offset by an increase in sales allowances, which are accounted for as a reduction of product sales. Additionally, in Q1 2003, we recorded a favorable adjustment to our sales reserves of approximately \$14 million, reflecting a reduction in our estimate of rebates due to

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government purchasers. Absent that favorable adjustment, domestic Q1 2004 Synagis sales would have increased approximately 10% over Q1 2003. Our reported international sales of Synagis to Abbott International ( AI ), our exclusive distributor of Synagis outside of the United States, increased \$10.2 million, or 48% to \$31.6 million in 2004 from \$21.4 million in 2003, driven primarily by a 50% increase in unit volumes over Q1 2003 levels. Also contributing to sales growth was an increase in the sales price caused by a change in the mix of countries to which we sell Synagis internationally that impacted the average sales price, and the favorable currency translation impact of a weakened U.S. dollar. We record Synagis international product sales based on AI's sales price to customers, as defined in our agreement with them.

**FluMist** Our Q1 2004 sales of FluMist amounted to \$25.9 million and include transfer price revenues for product shipped to Wyeth for the entire 2003/2004 season. During 2003, we shipped 4.1 million doses of FluMist to Wyeth and received payments totaling \$51.9 million. Wyeth is contractually responsible for distributing the product to third parties. As described in the Critical Accounting Estimates section, we recorded FluMist revenues during Q1 2004 because the product transfer price was now considered to be fixed or determinable. We launched FluMist in September 2003, and thus have not previously recorded any product sales revenues for this product.

**Ethylol** Ethylol accounted for approximately 5% and 6% of our product sales in Q1 2004 and Q1 2003, respectively. Domestic Ethylol sales decreased 7% to \$23.3 million in Q1 2004, from \$25.1 million in Q1 2003. The decrease is due to lower domestic sales volumes for Q1 2004 as compared to Q1 2003, which we believe is largely due to the depletion of wholesaler inventories from December 31, 2003 levels to accommodate end-user demand. In the Q1 2003 period, we experienced an increase in wholesaler inventories from December 31, 2002 levels. The decrease in domestic volume was partially offset by a price increase, which occurred in August 2003. Our Q1 2004 international sales of Ethylol to our distribution partner, Schering-Plough Corporation ( Schering ), were down \$0.6 million from Q1 2003 sales. We record Ethylol 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 Q1 2004, which include sales of CytoGam, NeuTrexin, RespiGam, and by-products that result from the CytoGam manufacturing process, decreased \$1.8 million. The decrease was largely due to a decrease in our sales of RespiGam, which has been replaced in the marketplace by our second generation RSV product, Synagis. During 2003, the Company determined that RespiGam would no longer be manufactured and thus expects to have minimal sales of RespiGam for 2004 and no sales thereafter.

### Revenues Other Revenues

Other revenues for Q1 2004 increased \$2.3 million to \$5.8 million, compared to Q1 2003 other revenues of \$3.5 million. Other revenues in Q1 2004 are largely comprised of contractual payments received from Wyeth under our collaboration for FluMist for royalties and corporate funding for clinical development and sales and marketing programs. Other revenues in Q1 2003 are comprised largely of revenues under collaborative agreements and corporate funding for FluMist clinical development and marketing programs.

We have accounted for major collaborative agreements entered into before January 1, 2002 using the contingency-adjusted performance model and have deferred a portion of the upfront and milestone payments received. Based on current estimates, we expect to record the remaining revenues from our collaboration with Schering of \$0.8 million ratably over 2004 and 2005.

### Cost of Sales

Cost of sales for Q1 2004 increased 53% to \$158.2 million from \$103.3 million for Q1 2003, due to cost of goods sold and inventory valuation adjustments for FluMist and increases in product sales volumes. We recorded our first FluMist product sales as well as cost of product sales in Q1 2004. Gross margins on product sales for Q1 2004 were 67%, down nine percentage points from Q1 2003, largely due to cost of sales recorded on FluMist sales as well as for permanent valuation adjustments for FluMist inventory produced in Q1 2004. See our discussion of FluMist inventory valuation adjustments in the Critical Accounting Estimates section of Management's Discussion and Analysis. The FluMist inventory valuation adjustments accounted for approximately three points of the nine percentage point decrease in margins. We expect the cost of FluMist production in 2004 to continue to exceed its net realizable value. In addition, one percentage point of the margin decrease can be attributed to higher production costs for Synagis, due to the loss of some product caused by a contamination that occurred during the manufacturing process.

### Research and Development Expenses

Research and development expenses of \$49.8 million in Q1 2004 increased 57% from \$31.7 million in Q1 2003. 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. During Q1 2004, we advanced several product candidates: we completed patient enrollment for two Phase 2 trials with Vitaxin; we initiated an RSV treatment trial for Numax, and we continued planning the post-marketing studies for FluMist. We expect research and development expenses to continue to increase in future periods as we work toward

our goal of moving several product candidates into clinical development and launching two new products into the market by 2009.

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

Selling, general and administrative ( SG&A ) expenses increased 7% to \$123.7 million in Q1 2004 compared to \$115.2 million for Q1 2003. The increase is largely attributable to increases in legal costs associated with the ongoing litigation described in Part 2 Item 1, Legal Proceedings, outside consulting, and increases in marketing programs for Synagis and co-promotion expense, reflective of the increase in Synagis sales. As a percentage of product sales, SG&A expense decreased to 26% of product sales in Q1 2004 from 27% in Q1 2003, mainly due to the growth in product sales.

### **Other Operating Expenses**

Other operating expenses, which reflect manufacturing start-up costs and other manufacturing-related costs, decreased to \$1.8 million in Q1 2004 from \$21.5 million in Q1 2003. Other operating expense in Q1 2003 includes pre-production costs and inventory reserves for FluMist prior to FDA approval in June 2003. Subsequent to FDA approval, these costs were recorded to cost of sales. Other operating expenses in both Q1 2004 and Q1 2003 also include excess capacity charges associated with the plasma production section of the Frederick Manufacturing Center.

### **Interest Income and Expense**

We earned interest income of \$16.7 million for Q1 2004, compared to \$13.0 million for Q1 2003 reflecting a net gain of \$1.0 million on the redemption of the MedImmune Vaccines 5¼% Convertible Subordinated Notes in March 2004 and higher cash balances available for investment, partially offset by a decrease in the overall portfolio yield as a result of a decrease in interest rates and the average maturity of investments. Interest expense for Q1 2004, net of amounts capitalized, was \$2.2 million, up from \$1.8 million in Q1 2003, due to additional interest expense generated by the 1% Notes issued in July 2003. We anticipate interest expense, as well as capitalized interest, in future periods to decrease due to the retirement of MedImmune Vaccines 5¼% Convertible Subordinated Notes in March 2004.

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

We earned \$6.2 million on investment activities in Q1 2004, compared to a loss of \$0.3 million for Q1 2003. The Q1 2004 gain principally consists of realized gains on the sale of our publicly traded equity investments. Investment losses in Q1 2003 related to recording our portion of our minority investees' operating results as required by the equity method of accounting.

### **Income Taxes**

We recorded income tax expense of \$65.2 million for Q1 2004, compared to income tax expense of \$64.3 million in Q1 2003. Our effective tax rate in both periods was 37.0%.

### **Net Earnings**

Net earnings for Q1 2004 were \$111.0 million, or \$0.45 per share basic and \$0.44 per share diluted, compared to a net earnings for Q1 2003 of \$109.5 million, or \$0.44 per share basic and \$0.43 per share diluted.

Shares used in computing basic and diluted earnings per share in Q1 2004 were 248.2 million and 250.9 million, respectively, while shares used in computing basic and diluted earnings per share in Q1 2003 were 251.5 million and 256.5 million, respectively. The decrease in share count primarily reflects the 6.2 million treasury shares purchased in the second half of 2003 in accordance with our share repurchase program, initiated in 2003.

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 \$1,958.8 million at March 31, 2004 versus \$1,900.1 million at December 31, 2003, an increase of 3%. The increase in cash is primarily due to cash generated by the Company's ongoing business operations, offset by our March 31, 2004 retirement of MedImmune Vaccines 5¼% Convertible Senior Notes. Working capital decreased to \$433.6 million at March 31, 2004 from \$712.0 million at December 31, 2003, primarily due to our use of cash and marketable securities to fund the retirement of the MedImmune Vaccines notes as well as the investment of excess cash in longer term securities where we earn higher returns.

### *Operating Activities*

Net cash provided by operating activities increased to \$235.3 million in Q1 2004 as compared to \$223.8 million in Q1 2003, primarily as the result of net earnings for the period and the use of deferred tax assets to offset current tax liabilities. Additionally, we received a large income tax refund during Q1 2004 and our inventory balances decreased, largely due to the wind down of the Synagis season and the relief of FluMist inventories in conjunction with the recognition of FluMist product sales for the 2003/2004 flu season. Increases in accruals for co-promotion expense and income taxes payable also contributed to cash provided from operating activities. These increases in cash are net of a decrease in advances from Wyeth, due to our recognition of FluMist product sales for the season.

### *Investing Activities*

Cash used for investing activities during the first quarter of 2004 amounted to \$278.9 million, as compared to \$128.7 million in Q1 2003. Cash used for investing activities in Q1 2004 included net additions to our investment portfolio of \$251.9 million; capital expenditures totaling \$14.5 million, 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 \$12.5 million through our venture capital subsidiary.

### *Financing Activities*

Financing activities used \$171.5 million in cash for the first quarter of 2004, as compared to \$8.0 million generated in the comparable period of 2003. Approximately \$1.4 million was received upon the exercise of employee stock options in Q1 2004, as compared to \$8.2 million received in Q1 2003, reflecting decreased stock option exercises by employees. Additionally, we used \$172.7 million in cash to retire the remaining portion of our 5¼% Convertible Subordinated Notes.

The Company currently generates cash from operations primarily from product sales, and expects to continue generating cash from these sources. The Company expends cash to finance its 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, MedImmune Ventures, Inc. or through other means; to fund capital projects; and to finance the production of inventories. 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. 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.

In 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. Through April 30, 2004, we have not repurchased any stock under the stock repurchase program in 2004, but may resume repurchasing throughout 2004, depending on market conditions. The Company also entered into a 10b5-1 trading plan to repurchase shares in the open market during those periods each quarter when trading in our common stock is restricted under our insider trading policy. No shares were purchased in 2004 under the 10b5-1 trading plan as of April 30, 2004. 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.

On March 31, 2004, we redeemed the remaining \$168.6 million principal amount of the 5¼% Convertible Subordinated Notes due 2008 for approximately \$172.7 million. The redemption resulted in a net ordinary gain of \$1.0 million, reflecting the net of the redemption price and the accelerated amortization of bond premium.

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

We believe our primary market risk as of March 31, 2004 is the exposure to loss resulting from changes in interest rates, foreign currency exchange rates, and equity prices. Market risk exposure exceeds that as of December 31, 2003 due to the increase in the size of our investment portfolio.



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We are exposed to equity price risks and risk of impairment related to our minority interest investments. MedImmune Ventures, Inc., the Company's wholly owned venture capital subsidiary, manages the Company's current portfolio of minority interest investments and endeavors to make additional investments in public or private biotechnology companies focused on discovering and developing human therapeutics. MedImmune Ventures will invest primarily in areas of strategic interest to the Company, including infectious disease, immunology and oncology. The cost basis of MedImmune Venture's investment holdings was \$50.0 million as of March 31, 2004, and is expected to increase in the future as it continues to invest in accordance with its investment strategy.

MedImmune Venture's minority interest investments are subject to adjustment for other-than-temporary impairments. We have historically experienced volatility in the fair value of our minority investments and thus, the value assigned to the investments could change significantly from period to period. We did not incur any impairment losses for Q1 2004 or Q1 2003.

The remainder of MedImmune Venture's portfolio as of March 31, 2004 consists of minority interest investments in privately held biotechnology companies. The investments are maintained on the cost or equity method of accounting, according to the facts and circumstances of the individual investment. For investments carried on the equity method, the Company's proportionate share of the investee's gains or losses is recorded on a quarterly basis. As of March 31, 2004, these investments had a cost basis of \$44.2 million.

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, 2003.

### **ITEM 4. CONTROLS AND PROCEDURES**

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

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

In addition, the management of the Company, with the participation of the Company's Chief Executive Officer, President and Vice Chairman and Senior Vice President and Chief Financial Officer, have determined that there was no change in the Company's internal control over financial reporting that occurred during Q1 2004 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 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, 2003.

**ITEM 2. CHANGES IN SECURITIES, USE OF PROCEEDS AND ISSUER PURCHASES OF EQUITY SECURITIES NONE**

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

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

**ITEM 5. OTHER INFORMATION NONE**

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

(a) Exhibits:

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 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:

| <b><u>Report Date</u></b> | <b><u>Event Reported</u></b>   |
|---------------------------|--|
| January 9, 2004           | MedImmune Announces Departure of Chief Financial Officer.                              |
| January 29, 2004          | MedImmune Reports Record Revenues and Earnings for 2003.                               |
| March 1, 2004             | MedImmune Provides Financial Guidance for 2004 and Long-Term Perspective Through 2009. |

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**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.

**MEDIMMUNE, INC.**

(Registrant)

/s/ David M. Mott

David M. Mott

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Chief Executive Officer, President and Vice Chairman

Date: May 7, 2004

/s/ Lota S. Zoth

Lota S. Zoth  
Senior Vice President and Chief Financial Officer

Date: May 7, 2004