

MEDIMMUNE INC /DE
Form 10-Q/A
August 05, 2004

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

FORM 10-Q/A

(Amendment No.1)

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.)

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

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

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. Yes 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.

EXPLANATORY NOTE

This Amendment No. 1 to MedImmune, Inc.'s (MedImmune or the Company) Quarterly Report on Form 10-Q/A for the quarterly period ended June 30, 2003 amends and restates Management's Discussion and Analysis, or Item 2 of Part I of the original Form 10-Q, to eliminate references to or discussions of non-GAAP financial measures within our discussion of Results of Operations. No other information included in the original Form 10-Q is amended hereby.

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.

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

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

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>	<u>50%</u>

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.

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.

Ethylol Ethylol accounted for approximately 29% of our product sales in both Q2 2003 and Q2 2002. Worldwide Ethylol 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 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 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.

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

Research and development expenses of \$28.9 million in Q2 2003 decreased 16% from \$34.5 million in 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

Selling, general and administrative (SG&A) expenses increased 17% to \$55.5 million in Q2 2003 compared to \$47.4 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

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. 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.

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)

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.

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

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

Net Earnings / (Loss)

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 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%
	\$ 518.3	\$ 378.0	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-Plough Corporation (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

Research and development expenses of \$59.6 million in YTD 2003 decreased 24% from \$78.6 million in 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. Additionally, there was a decrease in stock compensation expense for unvested stock options assumed in the Acquisition and for retention payments and stock compensation expense for acceleration of stock options for certain executives of MedImmune Vaccines in conjunction with the Acquisition.

Selling, General, and Administrative Expenses

Selling, general and administrative (SG&A) expenses increased 21% to \$173.6 million in YTD 2003 compared to \$143.0 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

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. The decrease is mainly 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. We also experienced decreases in stock compensation expense for unvested stock options assumed in the Acquisition and for retention payments and stock compensation expense for acceleration of stock options for certain executives of MedImmune Vaccines in conjunction with the Acquisition.

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)

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.

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

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

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

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.

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.

Date: August 5, 2004

/s/ DAVID M. MOTT

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

Date: August 5, 2004

/s/ LOTA S. ZOTH

Lota S. Zoth
Senior Vice President and Chief Financial Officer