

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 September 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 November 5, 2003, 247,535,950 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 September 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 to 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 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.

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. During Q3 2003, we began shipping FluMist to Wyeth, which is contractually responsible for distributing the product to third parties. At the time of shipment, Wyeth is contractually obligated to remit a product transfer payment per dose shipped, which is calculated using an agreed upon formula that consists of several variables, including Wyeth's returns and actual net sales. Actual net sales consists of any amounts actually received by Wyeth 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, sales taxes and freight. As of September 30, 2003, we concluded that the product transfer price was not determinable, largely due to the lack of sales and returns history for this new product. As a result, we have not recognized the revenue associated with approximately 2.4 million doses shipped to Wyeth during Q3 2003. Further, we have \$21.0 million in inventory on the balance sheet representing the carrying value of the 2.4 million doses shipped to Wyeth. During Q3 2003, we have billed Wyeth \$29.5 million for the 2.4 million doses, and have received payments from Wyeth of \$13.1 million as of September 30, 2003. These payments are reflected on the balance sheet under the caption Advances from Wyeth. At the time we believe the transfer price is determinable, we will record the associated revenue and cost of goods sold.

We receive royalties from licensees, which are based on third-party sales of licensed products or technologies. Royalties are recorded as earned in accordance with the contract terms when third-party results can be reliably measured and collectibility is reasonably assured. We receive royalties from Wyeth based on its sales of FluMist under our worldwide collaborative agreement, as amended. We have not recorded any royalty revenue from Wyeth as of September 30, 2003.

Revenue from non-refundable upfront license fees and certain guaranteed payments where we continue involvement through a development collaboration or an obligation to supply product is recognized ratably over the development or supply period. As of September 30, 2003, we recognized \$7.3 million of a \$12.5 million supply goal payment for the first influenza season from Wyeth. The remaining \$5.2 million has been recorded as deferred revenue to be recognized as the remaining doses are shipped to Wyeth in the fourth quarter.

We may record deferred revenues related to milestone payments and other upfront payments. Deferred revenue for manufacturing obligations is recognized as product is delivered. Deferred revenue associated with performance milestones is recognized based upon the achievement of the milestones, as defined in the respective agreements, as long as the milestones are substantive and at risk. Revenue under R&D cost reimbursement contracts is recognized as the related costs are incurred.

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 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 necessary

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

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.

Most of the inventory components for FluMist have expiration dates that range from nine to 24 months. During the last quarter of 2002 and in 2003, we incurred inventoriable costs associated with FluMist manufacturing in anticipation of commercial launch for the 2003/2004 flu season. 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, at the time were considered unlikely to be recovered. Further, we have disposed of \$18.7 million of fully-reserved inventory related to the 2002/2003 flu season. As of September 30, 2003, we have \$103.0 million of FluMist inventory against which we have a reserve of \$48.3 million, resulting in a net inventory balance of \$54.7 million. With respect to FluMist inventory on hand as of September 30, 2003, we reviewed the following factors 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.

As a result of the review of FluMist inventory described above, approximately one-half of the annual production costs have been fully reserved. Therefore, gross margins in the fourth quarter of 2003 are expected to be higher than what they would have been had those production costs not been fully reserved.

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

Reductions of Gross Product Sales

We estimate the amount of sales discounts and sales returns by applying rates determined by our past experience and current discount structure to actual sales for the period. We estimate the aggregate amount of rebates due to government purchasers, recorded as a reduction of 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. Because of the seasonal nature of our largest product, Synagis, our sales discounts, returns 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.

During 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 \$14.3 million higher for the first nine months of 2003. Allowances for government reimbursements were \$10.8 million and \$26.2 million as of September 30, 2003 and December 31, 2002, respectively, and are included in accrued expenses in the accompanying balance sheets.

Selling, General & 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 smaller as our selling season is just beginning and the June balances are negligible reflecting the close-out of the prior season. For the nine months ended September 30, 2003, we decreased our reserves for bad debts by approximately \$6.3 million, largely as a consequence of the overall reduction in accounts receivable balances. In the three and nine month periods ended September 30, 2003 and 2002, we have reclassified bad debt expense from net sales to selling, general and administrative expense in our Consolidated Statements of Operations.

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. Each quarter we reevaluate such factors to determine whether continued use of the cost method is appropriate. 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

Q3 2003 compared to Q3

Revenues Product Sales 2002

(in millions)

	Q3 2003	Q3 2002	Growth
Synagis	\$ 48.6	\$ 31.4	55%
FluMist	\$ --	\$ --	N/A
Ethyol	\$ 20.6	\$ 20.5	--%
Other Products	\$ 13.1	\$ 8.9	47%
	<u>\$ 82.3</u>	<u>\$ 60.8</u>	<u>35%</u>

For Q3 2003, product sales grew 35% to \$82.3 million as compared to \$60.8 million in Q3 2002, primarily due to increased sales of Synagis.

Synagis Synagis accounted for approximately 59% and 52% of our product sales in Q3 2003 and Q3 2002, respectively. We achieved a 31% increase in domestic Synagis sales to \$35.4 million for 2003, up from \$27.0 million in 2002. This strong growth was driven primarily by an increase in unit sales. A price increase which took effect in June of 2003 was offset by an increase in sales allowances. We record Synagis international product sales when we ship product to AI, and 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 tripled from \$4.4 million in Q3 2002 to \$13.2 million in Q3 2003, largely due restocking of depleted inventories by AI reflecting increased demand for the product.

Ethyol Ethyol accounted for approximately 25% of our product sales in Q3 2003 versus 34% in Q3 2002. Worldwide Ethyol sales remained consistent at \$20.6 million in Q3 2003, as compared to \$20.5 million in Q3 2002. This was due to the combination of a domestic price increase which was offset by an increase in sales allowances and a decrease in domestic unit sales, largely due to the depletion of wholesaler inventories to accommodate end-user demand. Sales to our international partner, Schering-Plough Corporation (Schering) also remained consistent from Q3 2002 to Q3 2003. We record Ethyol 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 Q3 2003, which include sales of CytoGam, NeuTrexin, RespiGam, and by-products that result from the CytoGam manufacturing process, increased \$4.2 million, or 47% from Q3 2002. The increase is due to a 47% increase in CytoGam sales. We believe this increase was largely the result of an increase in wholesaler inventory levels during the third quarter of 2003.

Forward-looking commentary Due to the significant contribution of Synagis, we believe our revenues and operating results will reflect for the foreseeable future the seasonality of that product's use to prevent RSV disease, which occurs primarily during the winter months. 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.

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

During Q3 2003, we began shipping FluMist to Wyeth, but we have not recorded any transfer payment revenues. As of September 30, 2003, we concluded that the product transfer price was not determinable, largely due to the lack of sales and returns history for this new product. As of September 30, 2003, we billed Wyeth \$29.5 million for 2.4 million doses shipped. Along with Wyeth, we are currently evaluating and implementing certain promotional rebate and discount programs, which may reduce actual net sales and might impact the time at which the product transfer price will be determinable. At the time we believe the transfer price has become determinable, we will record associated revenue and cost of goods sold.

Revenues Other Revenues

Other revenues increased \$3.7 million to \$17.1 million for Q3 2003 compared to \$13.4 million in Q3 2002, primarily due to increased revenues under collaborative agreements. As of September 30, 2003, we recognized \$7.3 million of a \$12.5 million supply goal payment for the first influenza season from Wyeth. In addition, we recorded \$5.0 million in milestone revenues associated with the inclusion of FluMist in the American Academy of Pediatrics *Influenza Vaccine Implementation Information for 2003/2004*. These increases are partially offset by the impact of last year's nonrecurring payments totaling \$9.0 million, which was for the sale of excess production capacity to a third party.

Forward-looking commentary We anticipate the level of other revenues for the fourth quarter of 2003 to increase significantly largely due to milestone and royalty payments associated with the commercialization of FluMist. We have not recorded any royalty revenue from Wyeth as of September 30, 2003, but anticipate recording royalty revenue during the fourth quarter of 2003. We also plan to recognize the remaining \$5.2 million of a \$12.5 million supply goal payment for the first influenza season from Wyeth as the remaining FluMist doses relating to that supply goal payment are shipped to Wyeth in the fourth quarter of 2003. 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, for which we have deferred a portion of the up-front and milestone payments received under the contingency adjusted performance model, is as follows: \$0.1 million in the fourth quarter of 2003; \$0.4 million in 2004; and \$0.4 million in 2005.

Cost of Sales

Cost of sales for Q3 2003 increased 35% to \$30.1 million from \$22.3 million in Q3 2002, due principally to an increase in product sales volumes. Gross margins on product sales were 63% in both Q3 2003 and Q3 2002 as a result of increases in gross margins on all products that were offset by the impact of higher unplanned scrap costs.

Forward-looking commentary We expect that gross margin may vary significantly from quarter to quarter, based on changes in the product mix due to seasonality. 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 \$52.7 million in Q3 2003 increased 66% from \$31.8 million in Q3 2002. The increase is primarily due to payments related to accessing rights to data and developmental opportunities for two technologies. In July 2003, the Company agreed to make a \$10.0 million payment to Critical Therapeutics, Inc. as a part of a newly established collaboration to co-develop biologic products targeting a novel pro-inflammatory cytokine to treat severe inflammatory diseases. In connection with the September 30, 2003 supplemental agreement with Wyeth, MedImmune agreed to pay \$10.0 million for data from the completed international phase 3 studies for a liquid formulation of FluMist. This data may have the potential to accelerate the evolution of MedImmune's long-range plans for its intranasally delivered flu vaccine program in the United States.

Forward-looking commentary For the remainder of 2003, we anticipate having continued year-over-year growth in our research and development expenditures, in part due to clinical trials for Vitaxin and Ethyol.

Selling, General, and Administrative Expenses

Selling, general and administrative (SG&A) expenses increased slightly to \$53.4 million in Q3 2003 compared to \$52.8 million in Q3 2002, primarily due to increased co-promotion expenses for Synagis associated with the product's domestic sales growth which were offset by a decrease in the provision for bad debts and the impact of settling a contractual dispute in 2002.

Other Operating Expenses

Other operating expenses, which reflect manufacturing start-up costs and other manufacturing-related costs, were \$1.9 million in Q3 2003 compared to \$24.1 million in Q3 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.

Interest Income and Expense

We earned interest income of \$14.5 million for Q3 2003, compared to \$13.3 million in Q3 2002, reflecting higher cash balances available for investment, net of a decrease in short-term interest rates that decreased the overall portfolio yield. Interest expense for Q3 2003, net of amounts capitalized, was \$3.0 million, up from \$2.3 million in Q3 2002, reflecting a higher long term debt balance due to the issuance of \$500 million of our convertible senior notes in July 2003.

Gain (Loss) on Investment Activities

We realized a \$1.2 million gain on investment activities during Q3 2003 as compared to a loss incurred in Q3 2002 of \$10.6 million. The 2003 period includes a gain on the sale of common stock, net of minor losses recorded as our portion of minority investees' operating results as required by the equity method of accounting. The Q3 2002 loss consists primarily of impairment write-downs due to the decline in the fair value of certain of our publicly traded equity investments and other investments in private companies below their cost basis that were judged to be other than temporary and minor losses recorded as our portion of minority investees' operating results as required by the equity method of accounting.

Taxes

We recorded a benefit for income taxes of \$9.6 million for Q3 2003, resulting in an effective tax rate of 37.0%. Comparatively, we recorded an income tax benefit of \$20.1 million for Q3 2002, resulting in an effective tax rate of 35.7%. The increase in the estimated effective tax rate between 2003 and 2002 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 Loss

Net loss for Q3 2003 was \$16.4 million, or \$0.07 per basic and diluted share, compared to a net loss for Q3 2002 of \$36.3 million or \$0.14 per share.

Shares used in computing basic and diluted earnings per share for Q3 2003 were 249.4 million, while shares used for computing basic and diluted earnings per share for Q3 2002 were 250.8 million. The decrease in share count reflects our purchase of 5.9 million shares of treasury stock during Q3 2003 in accordance with our share buy back program, which was initiated in July 2003. We do not believe inflation had a material effect on our financial statements.

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

YTD 2003 compared to YTD 2002

Revenues Product Sales

(in millions)

	YTD 2003	YTD 2002	Growth
Synagis	\$ 490.8	\$ 357.4	37%
FluMist	\$ --	\$ --	NA
Ethiol	71.5	55.6	29%
Other Products	31.7	26.9	18%
	\$ 594.0	\$ 439.9	35%

For YTD 2003, product sales grew 35% to \$594.0 million as compared to \$439.9 million in YTD 2002, primarily due to a 37% increase in sales of Synagis to \$490.8 million and by a 29% increase in sales of Ethiol to \$71.5 million.

Synagis Synagis accounted for approximately 83% versus 81% of our product sales for YTD 2003 and YTD 2002, respectively. We achieved a 32% increase in domestic Synagis sales to \$451.0 million for YTD 2003, up from \$341.6 million in YTD 2002. This strong growth was driven primarily by an increase in unit sales that contributed 26 of the 32 percentage points and an increase in price that contributed 6 points. Our reported international sales of Synagis more than doubled to \$39.8 million in YTD 2003 compared to \$15.8 million in YTD 2002, largely due to an almost four-fold increase in units sold to AI. We believe the growth is due to AI replenishing their depleted inventory levels as well as increased product demand by end users. 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 12% and 13% of our product sales in YTD 2003 and YTD 2002, respectively. Worldwide Ethiol sales grew 29% to \$71.5 million in YTD 2003, as compared to \$55.6 million in YTD 2002. This growth was driven by a number of contributing factors, including: an increase in domestic unit sales that contributed 14 of the 29 percentage points; an increase in price that contributed 9 points, and a decrease in sales reserves that contributed 6 points.

Revenues Other Revenues

Other revenues increased 83% to \$52.5 million for YTD 2003 compared to \$28.8 million in YTD 2002, largely due to an increase in revenue recorded under collaborative agreements, partially offset by the impact of \$11.9 million in non-recurring revenues from the sale of excess production capacity to a third party in 2002. Other revenues for YTD 2003 include approximately \$25.0 million in milestone payments for the approval of FluMist and for the inclusion of FluMist in the American Academy of Pediatrics *Influenza Vaccine Implementation Information for 2003/2004*. Also, as of September 30, 2003, we recognized \$7.3 million of a \$12.5 million supply goal payment for the first influenza season from Wyeth. The remaining \$5.2 million has been recorded as deferred revenue to be recognized as the remaining doses are shipped to Wyeth in the fourth quarter. Other revenue for 2003 also includes \$7.5 million for exceeding \$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 \$156.1 million from \$117.8 million for YTD 2002. Gross margins on product sales were 74% for YTD 2003, compared to 73% 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 and higher unplanned scrap costs.

Research and Development Expenses

Research and development expenses of \$112.3 million in YTD 2003 increased 2% from \$110.4 million in YTD 2002. The increase is largely due to the payments associated with gaining access to new data and technologies. The increase was partially offset by the completion of several

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

late-stage clinical trials by the end of 2002, including Phase 2 clinical trials with siplizumab, and the Phase 3 Synagis clinical trial in congenital heart disease patients that led to the approval of an expanded indication by the FDA in September 2003 and decreases in stock compensation expense for unvested stock options assumed in the Acquisition and in 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 12% to \$220.4 million in YTD 2003 compared to \$196.9 million in YTD 2002, due primarily to increases in co-promotion expenses for Synagis, partially offset by a decrease in bad debt expense and the impact of settling a contractual dispute in 2002.

Other Operating Expenses

Other operating expenses, which reflect manufacturing start-up costs and other manufacturing-related costs, decreased to \$24.8 million in YTD 2003 from \$68.1 million in YTD 2002. The decrease is due to the shift in the costs of FluMist manufacturing that are in inventory this year, but were expensed as other operating costs in the prior year. We also experienced decreases in stock compensation expense for unvested stock options assumed in the Acquisition and in 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 \$41.8 million for YTD 2003, compared to \$37.2 million in YTD 2002, reflecting higher cash balances available for investment, net of a decrease in short-term interest rates that lowered the overall portfolio yield. Interest expense for YTD 2003, net of amounts capitalized, was \$6.4 million, down from \$7.0 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., partially offset by the impact of the issuance of \$500 million of our convertible senior notes in July 2003.

Gain (Loss) on Investment Activities

We incurred a gain on investment activities of \$0.8 million for YTD 2003, compared to a loss of \$10.7 million in YTD 2002. The 2003 period includes a gain on the sale of common stock, net of minor losses recorded as our portion of minority investees' operating results as required by the equity method of accounting. The YTD 2002 loss consists primarily of impairment write-downs and minor losses recorded as our portion of minority investees' operating results as required by the equity method of accounting.

Taxes

We recorded income tax expense of \$62.6 million for YTD 2003, resulting in an effective tax rate of 37.0%. Comparatively, we recorded an income tax benefit of \$1.7 million for YTD 2002, resulting in an effective tax rate of 35.2% 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 2003 and 2002 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 \$106.6 million, or \$0.42 basic and diluted earnings per share compared to a net loss for YTD 2002 of \$1.2 billion or \$4.75 per share.

Shares used in computing basic and diluted earnings per share for YTD 2003 were 251.0 million and 254.7 million, respectively, while shares used for computing basic and diluted earnings per share for YTD 2002 were 249.1 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 \$1,712.8 million at September 30, 2003 versus \$1,423.1 million at December 31, 2002, an increase of 20%. The increase in cash is primarily due to our issuance of \$500 million in convertible senior notes in July 2003, offset by our purchase of \$218.9 million of the Company's common stock, as well as cash generated by the Company's ongoing business operations. Working capital increased to \$632.0 million at September 30, 2003 from \$476.8 million at December 31, 2002, primarily due to an increase in cash as a result of our convertible debt offering, net of a decrease in trade accounts receivable, caused by the seasonal nature of Synagis. As of September, the Synagis selling season is just beginning and sales and accounts receivable have not yet peaked as compared to seasonally high accounts receivable balances in December and March.

Operating Activities

Net cash provided by operating activities increased to \$97.5 million in YTD 2003 as compared to \$43.2 million in YTD 2002, primarily as the result of net earnings for the period, the use of deferred tax assets to offset current tax liabilities, and cash received from Wyeth for the transfer of FluMist in preparation for the FluMist selling season. These increases are partially offset by increases in inventory balances (including approximately \$21 million related to FluMist doses transferred to Wyeth), 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 of Synagis.

Investing Activities

Cash used for investing activities during YTD 2003 amounted to \$164.1 million, as compared to \$132.5 million in YTD 2002. Cash used for investing activities in YTD 2003 included net additions to our investment portfolio of \$72.4 million; capital expenditures totaling \$74.9 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 \$16.8 million through our venture capital subsidiary.

Financing Activities

Financing activities provided \$287.9 million in cash for YTD 2003, as compared to \$36.5 million in YTD 2002. Approximately \$36.0 million was received upon the exercise of employee stock options in YTD 2003, as compared to \$40.9 million received in YTD 2002, reflecting increased stock option exercises by employees of MedImmune Vaccines in 2002 subsequent to the Acquisition. We received a net of \$489.5 million in connection with the issuance of senior convertible debt, and we used \$218.9 million in cash to purchase treasury stock under our share repurchase plan initiated in July 2003. We also used \$14.1 million to retire a portion of our 5 ¼% convertible subordinated notes and we paid down other debt in YTD 2003 in the amount of \$4.5 million, as compared to YTD 2002 paydowns of \$4.4 million.

In July 2003, the Company completed the issuance of \$500 million of 1% convertible senior notes due 2023. Net proceeds to the Company were \$489.5 million, net of expenses, underwriters' discounts and commissions. At the time of issuance, we stated our intent to use a portion of the proceeds from the convertible senior notes to repurchase shares of our common stock under the stock repurchase program, and for general corporate purposes, which may include the retirement of existing debt obligations, possible acquisitions or other external growth opportunities. As of September 30, 2003, we have repurchased and retired \$13.8 million principal amount of the 5 ¼% convertible notes at a cost of \$14.1 million. A gain of \$0.3 million was recorded in accordance with the transaction.

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. Under the stock repurchase program, we repurchased 5.9 million shares of our common stock at an average cost of \$37.05 per share through September 30, 2003. 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. Of the shares repurchased, approximately 0.3 million shares were purchased under the 10b5-1 trading plan. As of November 5, 2003, we had purchased 0.3 million additional shares at an average

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

cost of \$33.04 per share. 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.

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. 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.

We expect to have approximately \$155 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 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 \$10.0 million to Critical Therapeutics to acquire an exclusive, worldwide license for technology associated with the HMGB-1 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 minority interest investments in Micromet in Q3 2003 and in Critical Therapeutics in October 2003.

Effective for the upcoming RSV season, we reduced the number of U.S. specialty distributors in our Synagis network by approximately 85%. In addition, we reduced the number of Synagis wholesalers and home health care agencies that we will use. The changes were made 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 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