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)

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

For the quarterly period ended March 31, 2003

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

Delaware	0-19131	52-1555759
(State or other jurisdiction of incorporation or organization)	(Commission File No.)	(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 [X] No [ ]

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

As of April 30, 2003, 252,076,974 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 March 31, 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 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.

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 are believed to be 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 Reserves Most of the inventory components for FluMist have expiration dates that range from nine to 24 months. During 2002, we produced inventory in anticipation of FDA approval for the 2002/2003 influenza (flu) season. When it became probable that FDA approval would not be received in time for a launch for that flu season, we recorded a full reserve for the inventory components we believed would not be used prior to reaching their expiration dates. Certain of the inventory components may be used in subsequent flu seasons, dependent on the timing of FDA approval, which is currently anticipated to occur in Q2 2003. During Q1 2003, we began producing additional inventory components in anticipation of a possible launch for the 2003/ 2004 flu season. With respect to all inventory components on hand as of March 31, 2003, we reviewed the following assumptions to determine the amount of any additional reserves: the expected date of approval; the expected sales volume; the concentration of viral material in our vaccine; the influenza strains recommended by the Centers for Disease Control and Prevention; anticipated changes in the manufacturing process; and other variables associated with product launch efforts. As of March 31, 2003, we have $59.6 million of inventory against which we have a reserve of $44.3 million, resulting in a net inventory balance of $15.3 million. Should FluMist be approved for the 2003/2004 flu season and sales levels are higher than expected, we may be able to utilize more inventory than anticipated and, as such, our margins would be favorably impacted in those periods when the inventory is sold. Conversely, should FluMist not be approved, or if 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 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. For Q1 2003, we decreased our reserves for bad debts by approximately $1.3 million, based on our current assessment of these factors. 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. For Q1 2003, we decreased our reserves for rebates due to government purchasers by approximately $1.2 million. 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 $10 million higher.

Taxes We record a valuation allowance to reduce our deferred tax assets to the amount that is anticipated to be realized. We consider future taxable income and ongoing tax planning strategies in assessing the need for the valuation allowance. Should we determine that we will be able to realize more than the recorded amounts of net deferred tax assets in the future, our net income would increase in the period such determination was made. Likewise, should we determine that we will not be able to realize all or part of the net deferred tax asset in the future, our net income would decrease in the period such determination was made.

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 or other 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; and other extraordinary voting rights. 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.

Acquired In-Process Research and Development We recorded a charge of $1,179.3 million during Q1 2002 for the write-off of purchased in-process research and development in conjunction with the Acquisition. The write-off represents the fair value of purchased in-process technologies at the acquisition date, calculated as the sum of probability-adjusted commercial scenarios. This method is based upon management s estimates of the probability of FDA approval and commercial success for FluMist. As with all biotechnology products, the probability of FDA approval and commercial success for any particular research and development project is highly uncertain. Management s projections were based on assumptions, which may or may not remain valid for the relevant period, including the estimated impact of four key factors: price per dose; dose volume; launch date; and the potential failure of the frozen or liquid formulations of the influenza vaccine. Based on current information, management believes that the estimates and assumptions underlying the fair value analysis are substantially accurate.

RESULTS OF OPERATIONS
Q1 2003 compared to Q1 2002
Revenues Product Sales

(in millions)

	Q1 2003	Q1 2002	Growth
Synagis	$ 392,301	$ 293,049	34%
Ethyol	27,021	18,182	49%
Other Products	13,113	9,437	39%
	$ 432,435	$ 320,668	35%

For Q1 2003, product sales grew 35% to $432.4 million as compared to $320.7 million in Q1 2002, primarily due to increased sales of Synagis.

Synagis Synagis accounted for approximately 91% of our first quarter product sales in both 2003 and 2002. We achieved a 29% increase in domestic Synagis sales to $370.9 million for the 2003 quarter, up from $287.0 million in the 2002 quarter. This strong growth was driven primarily by an increase in unit sales that contributed 22 of the 29 percentage points, an increase in price that contributed five points and a decrease in sales allowances that contributed two points, reflecting a reduction in our estimate of rebates due to government purchasers. 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 increased 252% to $21.4 million in Q1 2003 compared to $6.1 million in Q1 2002, largely due to an eight-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 Q1 2002. Also contributing to international Synagis sales growth is the additional amount due from AI in Q1 2003 compared to Q1 2002, calculated as the difference in the contractually stipulated transfer price and our share of AI s sales price to customers for inventory sold. Sales growth was also aided by the impact of a weaker U.S. dollar.

Ethyol Ethyol accounted for approximately 6% of our product sales in Q1 2003 and Q1 2002. Worldwide Ethyol sales grew 49% to $27.0 million in Q1 2003, as compared to $18.2 million in Q1 2002. This growth was driven by a number of contributing factors, including: a strong increase in domestic unit sales that contributed 18 of the 49 percentage points; an increase in price that contributed 19 points, reflecting two price increases in last twelve months; a decrease in sales allowances that contributed ten points; and an increase in sales to our international partner, Schering-Plough Corporation (Schering), that contributed two points. 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 Q1 2003, which include sales of CytoGam, NeuTrexin, RespiGam, and by-products that result from the CytoGam manufacturing process, increased $3.7 million, or 39% from Q1 2002. The increase is driven by a 32% increase in CytoGam sales. We do not believe this increase is due to increased demand for the product and do not anticipate this level of sales to be sustained in future periods.

Forward-looking commentary We believe that the growth rate of our product sales, while remaining at double-digit levels, will decelerate during the remainder of 2003. However, the level of future product sales will depend on several factors, including, but not limited to: the timing and extent of future regulatory approvals of our products and product candidates; potential limitations on pricing and profitability by government or third-party payors; availability of finished product inventory; approval and commercialization of competitive products; and the degree of acceptance of our products in the marketplace. 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.

Revenues Other Revenues

Other revenues decreased $5.5 million to $3.5 million for Q1 2003 compared to $9.0 million in Q1 2002. The decrease is largely attributable to a decrease of $4.1 million in revenues from the sale of excess production capacity to a third party, and a decrease of $0.9 million in revenue recorded under collaborative agreements.

Forward-looking commentary- We anticipate the level of other revenues to increase in 2003 largely due to milestone and royalty payments associated with the approval and commercialization of FluMist and milestone payments expected to be received under certain of our distribution agreements with collaborative partners. 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 upon the extent to which we enter into these types of arrangements, and are not expected to be significant for 2003 or thereafter.

The expected timing of annual revenues to be recognized through 2005 under major collaborative agreements entered into before January 1, 2002, which we have accounted for using the contingency adjusted performance model and deferred a portion of the up-front and milestone payments received, based on current estimates of costs to complete, is as follows (in millions):

	Q2-Q4 2003	2004	2005
Abbott Laboratories	$ 1.1	$ --	$ --
Schering-Plough Corporation	0.3	0.4	0.4
Total	$ 1.4	$ 0.4	$ 0.4

Cost of Sales

Cost of sales for Q1 2003 increased 29% to $102.8 million from $79.9 million in Q1 2002, due to an increase in sales volumes. Gross margin for Q1 2003 was 76% as compared to 75% in Q1 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 Ethyol.

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. We expect that on an annual basis, our gross margin percentage for 2003 should be lower than 2002, as a result of the anticipated launch of FluMist.

Research and Development Expenses

Research and development expenses of $30.7 million in Q1 2003 decreased 30% from $44.1 million in Q1 2002. The decline is largely due to decreases in clinical trial expenses, due to the timing of certain clinical studies, including completion in 2002 of certain Phase 2 studies with siplizumab in psoriasis and the Phase 3 cardiac study for Synagis. Our ongoing clinical programs also include several product candidates in various stages of development, including a pediatric trial of a liquid formulation of Synagis, and trials for FluMist and Vitaxin. Additionally, we have multiple programs in the preclinical development stage. Also contributing to the decrease in research and development expenses 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.

Forward-looking commentary 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 FluMist and Vitaxin and the continued progress of other pipeline candidates, partially offset by the impact of the conclusion of trials and studies as described above.

The development programs efforts listed above, as well as other research and development projects may never reach clinical trials, achieve success in the clinic, be submitted to the appropriate regulatory authorities for approval, or be approved for marketing or manufacturing by the appropriate regulatory authorities. Further, we rely on numerous third parties to assist us in various stages of the development process. Should they be unable to meet our needs, we may incur substantial additional costs. Any of such uncertainties, if they should occur, could have a material adverse effect on our financial condition and results of operations.

Selling, General, and Administrative Expenses

Selling, general and administrative (SG&A) expenses increased 23% to $118.1 million in Q1 2003 compared to $95.6 million in Q1 2002, due primarily to increased co-promotion expenses for Synagis. This increase was partially offset by lower administrative spending and synergies associated with the Acquisition. As a percentage of product sales, SG&A expenses decreased to 27% of product sales in Q1 2003 period from 30% in Q1, due primarily to the increase in product sales.

Other Operating Expenses

Other operating expenses, which reflect manufacturing start-up costs and other manufacturing related costs, decreased slightly to $21.5 million in Q1 2003 from $21.8 million in Q1 2002, primarily due to higher pre-production expenses for FluMist, driven by higher headcount and outside testing charges, net of 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.

Forward-looking commentary- We expect the level of other operating expenses to decline significantly in 2003 assuming that approval of FluMist will occur in Q2 2003, at which time FluMist manufacturing costs will be expensed to cost of sales as product is sold to Wyeth.

In-Process Research and Development

We incurred charges of $1,179.3 million in Q1 2002 for the write-off of purchased in-process research and development in conjunction with the Acquisition. The write-off represents the fair value of purchased in-process technologies at the acquisition date, calculated utilizing the sum of the probability-adjusted scenarios under the income approach using a discount rate of 18.7%, and certain in-process research and development projects, primarily FluMist. We do not anticipate that there will be any alternative future use for the in-process technologies that were written off.

We are currently progressing towards obtaining approval of FluMist. We met with the FDA s Vaccines and Related Biological Products Advisory Committee in December 2002, which voted favorably on questions regarding safety and efficacy for FluMist in preventing influenza in healthy children, adolescents and adults from ages five through 49 years, and on questions regarding safety for healthy individuals aged 50-64 years. On January 29, 2003, we received a third Complete Response Letter from the FDA containing five questions, to which we responded in early February 2003.

The valuation of the acquired in-process research and development is based upon certain estimates and assumptions by management. The valuation is based upon management s estimates of the probability of FDA approval and commercial success for FluMist. As with all biotechnology products, the probability of FDA approval and commercial success for any particular research and development project is highly uncertain. Management s projections were based on assumptions, which may or may not remain valid for the relevant period, including the estimated impact of four key factors: price per dose; dose volume; launch date; and the potential failure of the frozen or liquid formulations of the influenza vaccine. Based on current information, management believes that the estimates and assumptions underlying the fair value analysis are substantially accurate. In addition, as of March 31, 2003, none of the existing manufacturing facilities involved in the production of FluMist had been licensed by any regulatory agency and FluMist had not yet been manufactured at a sustained commercial scale. There can be no assurance that these facilities can achieve licensure by the FDA or any other regulatory agency, nor can there be any assurances that if licensed, commercial scale production could be achieved or sustained. If we fail to obtain FDA approval for the marketing and manufacture of FluMist, we will absorb all of the related ongoing expenses while recording no corresponding revenue.

Interest Income and Expense

We earned interest income of $13.0 million for Q1 2003, compared to $11.9 million in Q1 2002, reflecting higher cash balances available for investment, partially offset by a decrease in interest rates that lowered the overall portfolio yield. Interest expense for Q1 2003, net of amounts capitalized, was $1.8 million, down from $2.8 million in Q1 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 had not yet begun in Q1 2002.

Loss on Investment Activities

We incurred $0.3 million in losses on investment activities for Q1 2003 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 $64.3 million for Q1 2003, resulting in an effective tax rate of 37%. Comparatively, we recorded income tax expense of $34.9 million for Q1 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 decrease in estimated credits available for research and development activities, including credits earned for Orphan Drug status of certain research and development activities in 2003. These credits will vary from year to year depending on the activities of the Company.

Net Earnings / (Loss)

Net earnings for Q1 2003 were $109.5 million, or $0.44 basic and $0.43 diluted earnings per share compared to a net loss for Q1 2002 of $1.1 billion or $4.54 per share.

Shares used in computing basic earnings per share for Q1 2003 were 251.5 million, while shares used for computing diluted earnings per share were 256.5 million. Shares used in computing net loss per share for Q1 2002 were 245.8 million.

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

Forward-looking commentary In 2003, we expect to generate net earnings per diluted share. The level of net earnings will depend on many factors, including, but not limited to, the timing and extent of regulatory approvals of our products and product candidates, the degree of acceptance of our products in the marketplace and adequate product supply to meet demand.

LIQUIDITY AND CAPITAL RESOURCES

Sources and uses of cash- The Company s capital requirements have generally been funded from cash generated from operations, cash and investments on hand, and the issuance of common stock. Cash and marketable securities were $1,633.5 million at March 31, 2003 versus $1,423.1 million at December 31, 2002, an increase of 15%. Increases in cash are primarily due to cash generated by the Company s ongoing business operations. Working capital increased to $483.7 million at March 31, 2003 from $476.8 million at December 31, 2002.

Operating Activities
Net cash provided by operating activities increased to $223.8 million in Q1 2003 as compared to $148.7 million in Q1 2002, primarily as the result of net earnings for the period, the use of deferred tax assets to offset current tax liabilities and increases in accrued liabilities, net of increases in trade accounts receivable. The increase in accrued expenses primarily results from increased amounts due to Abbott Laboratories for Synagis co-promotion expense, associated with the increase in domestic Synagis sales.

Investing Activities
Cash used for investing activities during the first quarter of 2003 amounted to $128.7 million, as compared to $40.2 million in 2002. Cash used for investing activities in 2003 included net additions to our investment portfolio of $106.9 million and $21.8 million for capital expenditures, primarily for the construction of our new corporate headquarters, and for the expansion of our FluMist manufacturing and filling and packaging facilities in Speke, England and Philadelphia, Pennsylvania.

Financing Activities
Financing activities generated $8.0 million in cash for the first quarter of 2003, as compared to $18.0 million in 2002. Approximately $8.2 million was received upon the exercise of employee stock options in 2003, as compared to $18.2 million received in 2002, reflecting increased

employee stock option exercises of MedImmune Vaccines in 2002, subsequent to the Acquisition. In 2003 and 2002, repayments on long-term debt were $0.2 million.

Forward-looking commentary Future expenditures related to our ongoing construction projects are expected to be funded using cash 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 the fall of 2003. At that time, a portion of our existing space in Gaithersburg, which is leased through 2006, is expected to be subleased. There can be no guarantee that we will be successful in subleasing the space.

Through our wholly-owned subsidiary MedImmune Ventures, Inc., we plan to invest up to $100 million over the next several years in minority interest investments in strategic partners that are either public or early-to-late stage private biotechnology companies focused on discovering and developing human therapeutics.

The Company currently generates cash from operations primarily from product sales. In the future, the Company 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. However, the Company may raise additional capital to take advantage of favorable conditions in the market or in connection with the Company s development activities.

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