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

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K/A

(Amendment No.1)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF
THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2003
Commission File Number: 000-19131

MEDIMMUNE, INC.

(Exact name of registrant as specified in its charter)

Delaware	**52-1555759**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

One MedImmune Way
Gaithersburg, Maryland 20878
(Address of principal executive office)
(Zip Code)

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

Securities Registered pursuant to Section 12(b) of the Act: None

Securities Registered pursuant to Section 12(g) of the Act:
Common Stock, $.01 par value
(Title of Class)

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 ý No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K ý.

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act). Yes ý No o

Aggregate market value of the 250,941,192 shares of voting and non-voting common equity held by non-affiliates of the registrant, based on the closing price on June 30, 2003, was $9.1 billion. Common Stock outstanding as of February 29, 2004: 248,227,030 shares.

Documents Incorporated by Reference:

Portions of the registrant's definitive proxy statement for the annual meeting of stockholders to be held May 20, 2004 (Part III).

EXPLANATORY NOTE

This Amendment No. 1 to MedImmune, Inc. s (MedImmune or the Company) Annual Report on Form 10-K/A for the fiscal year ended December 31, 2003 amends and restates Management s Discussion and Analysis, or Item 7 of Part I of the original Form 10-K, 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-K is amended hereby.

ITEM 7. 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 this document.

INTRODUCTION

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 a California-based vaccines company (the Acquisition) subsequently renamed MedImmune Vaccines, Inc. The operating results of MedImmune Vaccines, Inc. have been included in our consolidated operating results beginning January 10, 2002.

MedImmune currently actively markets four products, Synagis, Ethyol, CytoGam and FluMist and has a diverse pipeline of development-stage 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.

Aviron s leading product candidate at the time of the Acquisition was FluMist, the first U.S. vaccine delivered as a nasal mist. On June 17, 2003, the biologics license application for the commercial sale of FluMist was approved by the FDA. 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 Wyeth.

OVERVIEW

The Company s financial condition strengthened from 2002 to 2003, with cash and marketable securities increasing from $1.4 billion to $1.9 billion. We improved our capital structure by issuing $500 million of 1% Convertible Senior Notes (the 1% Notes) on favorable terms. We used the proceeds from the 1% Notes to reinvest in our company through the repurchase of $229.8 million in common shares which are held in treasury and capital expansion of our research and development, manufacturing and administrative facilities. From an operating results perspective, our diluted earnings per share in 2003 were $0.72 compared to a net loss per share in 2002 of $4.40. Excluding the impact of the Acquisition, diluted earnings per share grew 81% from $0.42 in 2002 to $0.76 in 2003. We also surpassed the one billion dollar mark for revenues, which totaled $1.05 billion in 2003. While we were disappointed with the launch year results of the recently-approved FluMist product, the Company continued to show strong top-line and bottom-line year-over-year growth, and improved financial condition as of December 31, 2003.

As we look to the future, we intend to continue commercializing our core products and developing our pipeline, with the long-term goal of strong revenue and earnings growth. The disappointing launch of FluMist in 2003 caused us to reassess our expectations of near-term growth for FluMist. We have completed a reevaluation of the FluMist program, and we intend to continue to develop the product. We are refocusing on this development over the next two or three years, and we do not expect FluMist to be profitable before 2007. We have not yet made final decisions regarding price, forecast or structure of the Wyeth relationship for the 2004/2005 influenza season and beyond.

Other product development objectives include a target of three new INDs in each of 2004, 2005 and 2006. We anticipate that we will have four products in Phase 3 in 2005. Further, we anticipate having at least two new product introductions over the next five years.

We also have the following expectations for 2004:

Product sales We believe that the growth rate of our product sales, while still at double-digit levels, will decelerate in 2004. 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. We do not expect FluMist sales in the 2004/2005 influenza season to exceed sales from the 2003/2004 influenza season.

Other revenues We anticipate the level of other revenues to decrease in 2004 largely due to decreases in milestone payments associated with the approval and 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 upon the extent to which we enter into these types of arrangements, and are not expected to be significant for 2004 or thereafter.

Gross margin We expect that gross margins may vary significantly from quarter to quarter, based on the product mix. We expect that our gross annual margin percentage for 2004 will be lower than 2003, largely the result of the low volume of FluMist revenues to cover the manufacturing costs of the product.

Research and development expense We expect research and development expenses to increase significantly in 2004 compared to 2003. This is largely due to the initiation of four Phase 2 studies for Vitaxin, post-marketing commitments and additional trials associated with FluMist, and the continued progress of Numax and our other pipeline candidates.

In the event that MedImmune were to allow Wyeth to exit from the FluMist relationship in 2004, we would write off approximately $75 million of unamortized intangible assets and would likely incur additional operating expenses.

Over the next five years, we believe our financial position will strengthen, as we anticipate that our cash and marketable securities, net of debt repayments, repurchases of common stock, capital expansion funding and research and development expenditures, will grow.

CRITICAL ACCOUNTING ESTIMATES

The preparation of consolidated financial statements requires us to make estimates and judgments with respect to the selection and application of accounting policies that affect the reported amounts of assets, liabilities, revenues and expenses, and the disclosures of contingent assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions. We believe the following critical accounting estimates have the greatest impact on the preparation of our consolidated financial statements.

Revenue Recognition- We recognize revenue from product sales when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed or determinable, and collectibility is reasonably assured. During 2003, we shipped 4.1 million doses of FluMist to Wyeth and received payments totaling $51.9 million. Wyeth is contractually responsible for distributing the product to third parties. At the end of the influenza season, Wyeth s actual net sales for the season are used to calculate the final transfer price per dose and the amount of product royalties due to MedImmune. 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, taxes and freight. Prior to the calculation of actual net sales, our ability to recognize revenue is dependent upon our ability to estimate the sales volume for the season and the expected impact of the reduction to sales. As of December 31, 2003, we concluded that the variables associated with the product transfer price were not determinable, largely due to low sales volume and the lack of returns history and comparable rebate redemption rates for rebates for this new product. As a result, we have not recognized the revenue associated with the 4.1 million doses shipped to Wyeth during 2003. We believe the transfer price for the 2003/2004 flu season will be determinable when actual net sales are calculated in 2004, at which time we will record the associated product sales 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 agreements, as amended. We have not recorded any royalty revenue from Wyeth as of December 31, 2003. The same variables discussed above that affect actual net sales for Wyeth also impact the product royalties that Wyeth is required to remit to us. When the variables are determinable in 2004, we expect to record the product royalties as other revenue.

Revenue from 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. We may record deferred revenues related to milestone payments and other up front 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 research and development cost reimbursement contracts is recognized as the related costs are incurred.

Inventory We capitalize inventory costs associated with marketed products and certain products prior to regulatory approval and product launch, based on management s judgment of probable future commercial use and net realizable value. We could be required to expense previously capitalized costs related to pre-approval or pre-launch inventory upon a change in such judgment, due to a denial or delay of approval by regulatory bodies, a delay in commercialization, or other potential factors. Conversely, our gross margins may be favorably impacted if some or all of the related production costs were expensed prior to the product being available for commercial sale.

We are required to state our inventory at lower of cost or market. In assessing the ultimate realization of inventories, we are required to make judgments as to multiple factors affecting our inventories and compare these with current or committed inventory levels. In the highly regulated industry in which we operate, raw materials, work-in-process and finished goods inventories have expiration dates that must be factored into our judgments about the recoverability of inventory costs. Additionally, if a product s pricing is such that we may not fully recover the cost of inventory, we must consider that in our judgments as well.

FluMist inventories have required a significant amount of judgment since the Acquisition in January 2002. One reason is that the finished FluMist product has a shelf life of nine months. Most of the inventory components for FluMist have expiration dates that range from nine to 24 months. The annual FluMist production cycle begins in October of the year prior to the influenza season in which the product will be consumed. For example, the production cycle for the 2002/2003 season began in October 2001. All production costs for the 2002/2003 season were fully reserved as we assessed the probability of approval by the FDA in time to commercialize the product for the 2002/2003 season was remote. During 2003, we disposed of $18.7 million of fully reserved inventory related to the 2002/2003 flu season.

Beginning in October 2002, production costs incurred for the 2003/2004 season were partially reserved based on management s assessment of the probability of approval and net realizable value. Approval was received from the FDA on June 17, 2003. At that time, approximately one-half of the annual production costs for the 2003/2004 season had already been fully reserved, $22.3 million in Q4 2002 and $19.6 million in Q1 2003. The production cycle for the 2003/2004 season ended in mid-October 2003.

The production cycle for the 2004/2005 season began in mid-October 2003. For all inventory components on hand as of December 31, 2003, we reviewed the following assumptions to determine the amount of any necessary reserves: the expected sales volume; the expected price to be received for the product; potential changes in the influenza strains recommended by the Centers for Disease Control and Prevention for each season s vaccine; and anticipated changes in the manufacturing process. During the fourth quarter of 2003, we determined that additional reserves of approximately $37.5 million were required to reflect total FluMist inventories at estimated realizable value. These reserves are comprised of the following: raw materials and work-in-process components $13.3 million; 2003/2004 finished goods inventory $13.3 million; and 2004/2005 finished goods inventory $10.9 million.

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

	Gross Inventory	Reserves	Net Inventory
FluMist Details			
As of December 31, 2002	$ 62.5	$(47.5)	$ 15.0
Q1 production, net	19.6	(19.6)	--
Q1 disposals	(3.1)	3.1	--
Q2 production, net	20.7	--	20.7
Q2 disposals	(13.1)	13.1	--
Q3 production, net	18.8	0.1	18.9
Q3 disposals	(2.5)	2.5	--
Q4 production, net	20.7	(17.7)	3.0
Q4 disposals	(1.5)	0.5	(1.0)
Q4 valuation adjustments	--	(20.3)	(20.3)
December 31, 2003	$ 122.1	$(85.8)	$ 36.3

For our other products, we periodically assess our inventory balances to determine whether net realizable value is below recorded cost. Factors we consider include expected sales volume, production capacity and expiration dates. No significant inventory adjustments were recorded for the other products.

Sales Allowances and Other Sales Related Estimates

Reductions to Gross Product Sales
The Company records allowances for discounts, returns, chargebacks and rebates due to government purchasers as reductions to gross product sales. The timing of actual returns, chargebacks and discounts taken, and rebates paid to government purchasers can lag the sale of the product by several periods and varies by state. As such, a significant amount of judgment is required when estimating the impact of sales allowances on gross sales for a reporting period. Our starting point for estimating each of these is our historical experience by product, updated for changes in facts and circumstances as appropriate. Because of the seasonal nature of our largest product, Synagis, our sales discounts, returns, chargebacks and rebates fluctuate throughout the year. If our historical trends are not indicative of the future, or our actual sales are materially different from projected amounts, or if our assessments prove to be materially different than actual occurrence, our results could be affected.

We estimate the amount of rebates due to government purchasers quarterly based on historical experience, along with updates, and based on our best estimate of the proportion of sales that will be subject to this reimbursement, largely comprised of Medicaid payments to state governments. During the first quarter of 2003, we lowered our estimate of rebates due to government purchasers to reflect favorable historical experience and a change in our estimate of the proportion of the sales that are subject to reimbursement. As we reviewed our estimates in the second and third quarters of 2003, there were no new significant facts or circumstances that indicated a need for further adjustment. During the fourth quarter of 2003, we became aware of recent efforts by several states to collect rebates for product administered in certain settings for which reimbursement was not sought in the past. After analyzing the situation, we determined that the new facts and circumstances warranted an increase in our estimate of rebates due to government purchasers. As such, we recorded additional reserves for rebates due to government purchasers of approximately $13.7 million during the fourth quarter of 2003. In addition, we increased our estimate of the proportion of current sales that will be subject to reimbursement, given the change in circumstance.

For the years ended December 31, 2003, 2002, and 2001, allowances for discounts, returns, chargebacks and rebates due to government purchasers resulted in a net reduction to gross product sales of approximately 9% each year. Reserves for discounts, returns, chargebacks and rebates that were accrued and not yet paid as of December 31, 2003 and 2002 were $51.4 million and $35.9 million, respectively. Reserves for discounts, returns, and chargebacks are netted against trade receivables and reserves for government reimbursements are included in accrued expenses in the accompanying balance sheets.

Selling, General and Administrative Expenses
We estimate our co-promotion expense and sales commissions by applying an estimated rate that is based upon an estimate of projected sales for the season to our actual sales for the period. We decreased co-promotion expense by $2.0 million in 2003 and increased co-promotion expense by $2.1 million in 2002, resulting from the final reconciliation of net sales for the 2002/2003 and 2001/2002 contract years.

We estimate the level of bad debts as a percentage of gross trade accounts receivable balances outstanding at the end of the period, based upon our assessment of the concentration of credit risk, the financial condition and environment of our customers, and the level of credit insurance we obtain on our customers balances. Because of the seasonal nature of our largest product, Synagis, our accounts receivable balances fluctuate significantly. Accordingly, our allowance for doubtful accounts also fluctuates. Our accounts receivable balances tend to be highest at the end of December and March, while the September balances are somewhat lower as our selling season is just beginning, and the June balances are negligible, reflecting the close-out of the prior season. For the year ended December 31, 2003, we recorded a $3.8 million reduction in bad debt expense, largely based on our current assessment of the factors above. For all periods presented, we have reclassified bad debt expense as selling, general and administrative expense in our Consolidated Statements of Operations.

Income 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 were 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 would 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. A tax reserve is recorded when the Company cannot assert that it is probable that a tax position claimed on a return will be sustained upon challenge by the tax authority. Any change in the balance of a tax reserve during the year is treated as an adjustment to current year tax expense.

Intangible Assets We have recorded and valued significant intangible assets that we acquired as a result of the Acquisition. We engaged independent valuation experts who reviewed our critical assumptions and assisted us in determining a value for the identifiable intangibles. Of the $129.4 million of acquired intangible assets, $90.0 million was assigned to the worldwide collaborative agreement with Wyeth for the development, manufacture, distribution, marketing, promotion, and sale of FluMist. The Company estimated the fair value of the Wyeth agreement using the sum of the probability-adjusted scenarios under the income approach. In applying this method, the Company relied on revenue assumptions, profitability assumptions and anticipated approval dates. The remaining $39.0 million was assigned to a contract manufacturing agreement with Evans Vaccines Limited. The Company estimated the fair value of the Evans agreement using the cost approach, which is based on the theory that a prudent investor would pay no more for an asset than the amount for which the asset could be replaced. In its

analysis, the Company reduced replacement cost for such factors as physical deterioration and functional or economic obsolescence. We review intangible assets for impairment annually or when an event that could result in an impairment occurs. As of December 31, 2003, we have not identified any impairment of the intangible assets, of which $96.7 million remain unamortized.

During 2003, we reduced goodwill recorded in the Acquisition by $2.4 million, reflecting additional deferred tax assets for adjustments relating to pre-acquisition items.

RESULTS OF OPERATIONS
Comparison of 2003 to 2002
Revenues Product Sales

(In Millions)

	2003	2002	Growth
Synagis	$ 849.3	$ 671.7	26%
Ethyol	100.2	81.2	23%
FluMist	--	--	--
Other Products	43.1	38.0	13%
	$ 992.6	$ 790.9	25%

Product sales grew 25% in 2003 to $992.6 million as compared to $790.9 million in 2002, primarily due to increased sales of Synagis. Of the overall increase in product sales, approximately 16 points of the 25 percentage points were due to an increase in domestic sales volumes, while price increases, net of increases in sales allowances contributed five points to sales growth. The remaining four points of growth are due to an increase in our international sales.

Synagis Synagis accounted for approximately 86% and 85% of our 2003 and 2002 product sales, respectively. We achieved a 21% increase in domestic Synagis sales to $777.1 million in 2003, up from $641.3 million in 2002. This growth was largely due to increased sales volume in the United States, which resulted in a 16% increase in domestic units sold. Also aiding growth was a price increase that took effect in June 2003, partially offset by an increase in sales allowances, which are accounted for as a reduction of product sales. Our reported international sales of Synagis to AI, our exclusive distributor of Synagis outside of the United States, more than doubled to $72.2 million in 2003 compared to $30.4 million in 2002, driven primarily by a more than two-fold increase in unit volumes over 2002 levels. The increase in unit volume was offset by an decrease in the realized per unit sales price recognized upon delivery of product to AI under the terms of our international distribution agreement. We record Synagis international product sales based on AI s sales price to customers, as defined in the agreement.

Ethyol Ethyol accounted for approximately 10% of our product sales in both 2003 and 2002. Domestic Ethyol sales increased 25% to $94.4 million in 2003, up from $75.5 million in 2002. This 25% increase is the result of a 15% increase in domestic units sold in 2003 compared to 2002 and a price increase which occurred in August 2003. Our 2003 international sales of Ethyol to our distribution partner, Schering, were consistent with 2002 sales of $5.7 million. We record Ethyol international product sales based on a percentage of Schering s end-user sales, as defined in our agreement.

FluMist During 2003, we shipped 4.1 million doses of FluMist to Wyeth and received payments totaling $51.9 million. Wyeth is contractually responsible for distributing the product to third parties. At the end of the influenza season, actual net sales for the season will be used to calculate the final transfer price per dose and the amount of product royalties due to MedImmune. 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. Prior to the calculation of actual net sales, our ability to recognize revenue is dependent upon our ability to estimate the sales volume for the season and the expected impact of the reduction to sales. As of December 31, 2003, we concluded that the variables associated with the product transfer price were not determinable, largely due to low sales volume and the lack of returns history and comparable redemption rates for rebates for this new product. As a result, we have not recognized the revenue associated with the 4.1 million doses shipped to Wyeth during 2003. We believe the transfer price will be determinable when actual net sales are calculated in 2004, at which time we will record the associated product sales and cost of goods sold.

Other Products Sales of other products in 2003, which include sales of CytoGam, NeuTrexin, RespiGam, and by-products that result from the CytoGam manufacturing process, increased $5.1 million, or 13% compared to last year. The increase was largely due to a 10% increase in our sales of CytoGam.

Revenues Other Revenues

Other revenues for 2003 remained consistent with 2002 at $61.8 million. Other revenues in 2003 are largely comprised of contractual payments received from Wyeth under our collaborative agreement for FluMist. The payments, which amounted to $45.9 million, related to milestone payments, supply goal payments, and funding for clinical development and marketing programs. We also received $7.5 million in 2003 from AI for achieving a milestone related to international sales levels of Synagis and we recorded $3.1 million in revenue under other collaborative agreements. Other revenues in 2002 are comprised largely of $32.7 million in payments from Wyeth for compensation of 2002 FluMist manufacturing costs and funding for clinical development and marketing programs In 2002, we also received $17.2 million from the sale of excess production capacity to a third party and $8.7 million in revenue recorded under other collaborative agreements.

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

Cost of Sales

Cost of sales for 2003 increased 44% to $289.8 million from $201.8 million for 2002, mainly due to increases in product sales volumes and inventory valuation adjustments for FluMist of $37.5 million. Gross margins on product sales for 2003 were 71%, down three percentage points from last year, largely due to the valuation adjustments for FluMist inventory. Partially offsetting this decrease were lower costs for CytoGam, and a favorable impact of a value-added tax refund for transfers of Synagis manufactured in Europe.

Research and Development Expenses

Research and development expenses of $156.3 million in 2003 increased 6% from $147.9 million in 2002. The increase is due largely to payments made in 2003 associated with gaining access to new data and technologies, net of a decrease in clinical trials expense and a decrease 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. During 2003, we made a $10.0 million payment to Critical Therapeutics, Inc. as part of a new collaboration to co-develop biologic products to treat severe inflammatory diseases. Additionally in 2003, the Company initiated four Phase 2 studies for Vitaxin and agreed to pay $10.0 million for data from the completed international Phase 3 studies for a liquid formulation of the live, attenuated influenza virus vaccine. 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.

In 2002, the Company completed several late-stage clinical trials, including Phase 2 clinical trials with siplizumab, and the Phase 3 Synagis clinical trial in congenital heart disease patients that led to approval of an expanded indication by the FDA in September 2003.

During 2003, we incurred significant costs related to the development of various products and product candidates. A summary of our more significant research and development efforts is as follows:

Product Candidates	Description	Stage of Development
Vitaxin	Melanoma, Prostate Cancer, Rheumatoid Arthritis, Psoriasis	Phase 2
CAIV-T (liquid FluMist)	A liquid, refrigerator-stable version of FluMist	Phase 3
FluMist-Frozen	Intranasally delivered virus vaccine to prevent influenza infection	Phase 4 and label expansion
Ethyol	Subcutaneous administration in NSCLC patients-reduction of esophogitis and pneumocytis	Phase 2
Numax	Third-generation anti-RSV antibody	Phase 1

Additionally, we have multiple programs in preclinical development.

Selling, General, and Administrative Expenses

Selling, general and administrative ("SG&A") expenses increased 14% to $340.9 million in 2003 compared to $299.6 million for the 2002 period, largely due to increased co-promotion expense, reflective of the increase in Synagis sales. As a percentage of product sales, SG&A

expense decreased to 34% of product sales in the 2003 period from 38% in the 2002 period, due to product sales growing at a faster rate than expenses.

Other Operating Expenses

Other operating expenses, which reflect manufacturing start-up costs and other manufacturing-related costs, were $26.1 million in 2003 compared to $100.0 million in 2002. The decrease in other operating expenses is principally due to the shift in the costs of FluMist manufacturing that are capitalized in inventory beginning in the second quarter of 2003, but were expensed as other operating costs in the prior year. Additionally, 2002 other operating expenses include impairment charges of $12.9 million relating to the write-off of certain plasma manufacturing assets, as the Company outsourced its production of CytoGam during 2002. 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 $56.9 million for 2003, compared to $49.4 million in 2002, reflecting higher cash balances available for investment, partially offset by a decrease in interest rates, which lowered the overall portfolio yield. Interest expense for 2003, net of amounts capitalized, was $10.3 million, up from $9.1 million for 2002, principally due to interest expense generated by the 1% Notes issued in July 2003.

Gain (Loss) on Investment Activities

We incurred a gain on investment activities of $3.4 million for 2003, compared to a loss of $14.1 million for 2002. The 2003 gain consisted of gains on the sale of our publicly traded equity investments, net of declines in fair value of other investments that were judged to be other than temporary. Investment losses in 2002 consisted primarily of impairment charges on investments related to declines in fair value that were judged to be other than temporary.

Income Taxes

We recorded income tax expense of $108.0 million for the year ended December 31, 2003, based on an effective tax rate of 37.1%. Excluding items not deductible for tax purposes, principally the write-off of purchased in-process research and development, the resulting effective tax rate for 2002 was 37.2%.

Net Earnings / (Loss)

Net earnings for 2003 were $183.2 million, or $0.73 per share basic and $0.72 per share diluted, compared to a net loss for 2002 of $1.1 billion or $4.40 per share. Shares used in computing basic and diluted earnings per share in 2003 were 250.1 and 253.8, respectively. Shares used in computing net loss per share for 2002 were 249.6 million. We do not believe inflation had a material effect on our financial statements.

2002 Compared to 2001

Revenues - Product Sales

(In Millions)

	2002	2001	Growth
Synagis	$ 671.7	$ 518.0	30%
Ethyol	81.2	20.5	296%
Other Products	38.0	43.0	(12%)

2002	2001	Growth
$ 790.9	$ 581.5	36%

Product sales grew 36% to $790.9 million, compared to $581.5 million in 2001, primarily due to increased sales of Synagis and the impact of reacquiring the domestic marketing rights to Ethyol from ALZA as of October 1, 2001.

Synagis Synagis accounted for approximately 85% and 89%, respectively, of our 2002 and 2001 product sales. We achieved a 33% increase in domestic Synagis sales to $641.3 million in 2002, up from $481.3 million in 2001. This growth was largely due to increased demand in the United States, and resulted in a 30% increase in domestic units sold. Also aiding growth was a 3.5% price increase that took effect in June 2002, partially offset by an increase in sales allowances, which were accounted for as a reduction to product sales. Our reported international sales of Synagis decreased 17% to $30.4 million in 2002 compared to $36.7 million in 2001, due to a 40% decrease in units sold to AI, our exclusive distributor of Synagis outside of the United States. We believe that the decrease was due to reductions in the inventory stocking levels of AI, rather than reduced product demand by end users. The decrease in unit volume was offset by an increase in the per unit sales price recognized upon delivery of product to AI under the terms of our international distribution agreement. Based on information received from AI, we believe that end-user sales have increased over the 2001 year. We recorded Synagis international product sales based on AI s sales price to customers, as defined in the agreement.

Ethyol Ethyol accounted for approximately 10% and 4% of our product sales in 2002 and 2001, respectively. On October 1, 2001 we reacquired domestic marketing rights to Ethyol from ALZA and have since recorded all revenues from domestic sales of Ethyol to wholesalers and distributors. As part of this agreement, no third quarter 2001 supply sales were made to ALZA, and we purchased ALZA s remaining Ethyol inventory at their original purchase price, which was recorded as a reduction to product sales. Beginning April 1, 2002, we pay ALZA a declining royalty through 2011 based on net sales of Ethyol in the United States. Domestic Ethyol sales were $75.5 million in 2002, as compared to $14.4 million in 2001. The increase was primarily attributable to a three-fold increase in domestic units sold in 2002 versus the 2001 year, which included nine months of revenues generated under our product supply agreement with ALZA and three months of sales to wholesalers and distributors. Further, two domestic price increases occurred during 2002, including a 9% increase in April 2002 and a 6% increase in September 2002. In addition, 2001 included net returns of $2.3 million, relating to our assumption of Ethyol marketing rights. Prior to October 1, 2001, we recorded Ethyol domestic product sales based on ALZA s net unit selling price as defined in the agreement. Our international sales of Ethyol to our distribution partner, Schering, were $5.6 million for 2002, down 7% from the prior year sales of $6.0 million.

Other Products Sales of other products in 2002, which included sales of CytoGam, NeuTrexin, RespiGam, and by-products that resulted from the CytoGam manufacturing process, decreased $5.0 million, or 12% compared to 2001. The decrease was due to marginal declines in all of our other product lines.

Revenues Other Revenues

Other revenues increased 58% to $61.8 million for 2002 compared to $39.2 million in 2001. The increase was largely attributable to $25 million received from Wyeth, our marketing partner for FluMist, for compensation of 2002 FluMist manufacturing costs under amendments to the collaborative agreements. An increase of $9.7 million in revenues from the sale of excess production capacity to a third party and $7.7 million in funding for FluMist clinical development and sales and marketing activities from Wyeth also contributed to the growth over 2001. Partially offsetting these increases was a decrease of $15.5 million in revenue recorded under collaborative agreements, including a $2.7 million decrease in clinical funding received for our HPV vaccine candidate as we were nearing completion of Phase 1 and 2 clinical trials and our preparation of clinical material.

Cost of Sales

Cost of sales for 2002 increased 46% to $201.8 million from $138.7 million in 2001, due to the increase in sales volumes and additional royalties owed for Synagis, partially offset by manufacturing cost reductions following implementation of an improved manufacturing process at the FMC which enhanced the yields for Synagis. As a result, gross margins for 2002 were down two percentage points to 74% from 76% for the year ended December 31, 2001.

Research and Development Expenses

Research and development expenses of $147.9 million in 2002 increased 78% from $83.0 million in 2001. This increase was largely due to the on-going activities of MedImmune Vaccines, payments of approximately $19.0 million to gain access to various technologies and intellectual

property to advance our pipeline and 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. The increases were offset by decreases in clinical trial expenses, as several of our clinical trials were either completed, cancelled or delayed during 2002. During 2002, we completed several important clinical trials, including a successful Phase 3 trial for Synagis in children with congenital heart disease and three Phase 2 trials for siplizumab.

During 2002, we completed the preliminary analysis of three Phase 2 trials for siplizumab involving almost 700 psoriasis patients. While the drug appeared to be generally well tolerated and some patients exhibited an improvement in their psoriatic disease, an anti-antibody response (also known as immunogenicity) was observed in the laboratory tests of over 50 percent of the patients. This anti-antibody response did not appear to cause any clinical complications. We also completed two Phase 2 trials of our *E. coli* urinary tract infection vaccine, and have determined that there was not a sufficient level of efficacy in prevention of urinary tract infections to proceed with additional trials. Our ongoing clinical program also included several product candidates in various phases of evaluation, including a Phase 1 trial in adults using a liquid formulation of Synagis and certain trials for FluMist. Additionally, we had multiple programs in preclinical development.

Selling, General, and Administrative Expenses

Selling, general and administrative (SG&A) expenses increased 52% to $299.6 million in 2002 compared to $196.8 million for the 2001 period. As a percentage of product sales, SG&A expense increased to 38% of product sales in the 2002 period from 34% in the 2001 period. The increase in this ratio was largely reflective of the impact of the Acquisition and the inclusion of MedImmune Vaccines ongoing expenses and Acquisition related expenses including: amortization of intangibles, stock compensation expense for unvested stock options assumed, retention payments and stock compensation expense for acceleration of stock options for certain executives of MedImmune Vaccines. Additionally, we incurred increased co-promotion expense directly related to the growth in domestic sales of Synagis, higher salaries and sales commissions, as well as increased Synagis marketing expense. SG&A expenses for 2002 also included a $5.0 million charge associated with the settlement of a contractual dispute in August 2002 regarding an agreement with the Massachusetts Biologic Laboratories of the University of Massachusetts (MBL) to transfer certain technology relating to the Company s monoclonal antibody manufacturing operations. The comparison to 2001 was favorably impacted as $13.4 million of expenses related to our accelerated acquisition of Ethyol marketing rights from ALZA was included in SG&A for 2001.

Other Operating Expenses

Other operating expenses, which reflected manufacturing start-up costs and other manufacturing related costs, increased to $100.0 million in 2002 from $9.6 million in 2001. The increase over 2001 was primarily related to $56.9 million of pre-production costs and inventory reserves for FluMist and Acquisition related expenses including: amortization of intangibles, stock compensation expense for unvested stock options assumed, retention payments and stock compensation expense for acceleration of stock options for certain executives of MedImmune Vaccines. The majority of the pre-production costs incurred for FluMist was associated with preparing for the aborted 2002 commercial launch. Additionally, we incurred a $12.9 million charge for the write-off of CytoGam manufacturing equipment as the Company had outsourced CytoGam production activities as of November 2002. Also included in other operating expense for both periods was excess capacity costs associated with the plasma production section of the FMC.

In-Process Research and Development

We incurred charges of $1,179.3 million for the year ended December 31, 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 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 believe that there would be any alternative future use for the in-process technologies that were written off.

FluMist is a live, attenuated vaccine delivered via a nasal mist for the prevention of influenza. It is a frozen vaccine requiring freezer storage. A liquid influenza vaccine is currently being developed by our partner Wyeth. While there are other flu vaccines currently marketed by other companies, FluMist is, to our knowledge, the only live virus vaccine administered as a nasal mist.

The valuation of the acquired in-process research and development was based upon certain estimates and assumptions by management. The valuation was based upon management s estimates of the probability of FDA approval and commercial success for FluMist. 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.

Interest Income and Expense

We earned interest income of $49.4 million for 2002, compared to $36.5 million in 2001, reflecting higher cash balances available for investment, largely due to the Acquisition, partially offset by a decrease in interest rates, which lowered the overall portfolio yield. Interest expense for 2002, net of amounts capitalized, was $9.1 million, up $8.5 million over 2001. The increase over 2001 was principally due to the related interest expense assumed in the Acquisition.

Loss on Investment Activities

We incurred $14.1 million in losses on investment activities for 2002. The losses consisted primarily of impairment charges of $4.5 million on our publicly traded equity investments and $9.5 million on our minority interest investments related to declines in fair value that were judged to be other than temporary.

Income Taxes

We recorded income tax expense of $48.2 million for the year ended December 31, 2002. Excluding items not deductible for tax purposes, principally the write-off of purchased in-process research and development, the resulting effective tax rate was 37.2%. This was compared to tax expense of $79.5 million recorded for the year ended December 31, 2001, based on an effective tax rate of 34.8%. The higher effective tax rate for 2002 versus 2001 is due to lower credits estimated to be available for research and development activities, including credits earned for orphan drug status of certain research and development activities.

Net loss

Net loss for the year ended December 31, 2002 was $1.1 billion, or $4.40 per share compared to net earnings for the year ended December 31, 2001 of $149.0 million or $0.70 basic and $0.68 diluted earnings per share. Shares used in computing net loss per share in 2002 were 249.6 million. Shares used in computing basic and diluted earnings per share for 2001 were 213.4 million and 220.1 million, respectively. The increase in share count primarily reflects the 34.0 million additional shares issued in conjunction with the Acquisition.

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

LIQUIDITY AND CAPITAL RESOURCES

Sources and Uses of Cash

The Company s capital requirements have been funded from operations, cash and investments on hand, and issuance of common stock and convertible debt. Cash and marketable securities increased 34% to $1.9 billion at December 31, 2003 from $1.4 billion at December 31, 2002. This increase is largely due to cash received from the issuance of $500 million in 1% Notes due in July 2023 as well as cash generated from operations. Working capital increased 49% to $712.0 million at December 31, 2003 from $476.8 million at December 31, 2002, primarily due to cash received from the issuance of the 1% Notes.

Operating Activities Net cash provided by operating activities increased to $357.7 million in the year ended December 31, 2003 as compared to $263.5 million in the comparable 2002 period, primarily as the result of net earnings for the period and the utilization of deferred tax assets to offset our current tax liability. Also affecting cash generated from operating activities were increases in accounts receivable and inventories, partially offset by an increase in accrued co-promotion expense for Synagis.

Investing Activities Cash used for investing activities during 2003 was $238.3 million, as compared to $347.0 million in 2002. Cash used for investing activities in 2003 included net additions to our investment portfolio of $95.0 million and $112.9 in capital expenditures, primarily for land purchases and construction of the first phase of our new corporate headquarters in Gaithersburg, Maryland, and for the continued expansion of our manufacturing facilities in Pennsylvania, and Speke, the United Kingdom. We also invested $30.4 million in preferred equity securities and convertible bonds through our venture capital subsidiary.

Financing Activities Financing activities generated $266.2 million in cash for 2003, as compared to $42.0 million in 2002. Approximately $44.4 million was received upon the issuance of common stock relating primarily to the exercise of employee stock options in 2003, as compared to $46.7 million received in 2002, reflecting increased option exercises by employees subsequent to the Acquisition in 2002.

In July 2003, the Company completed the issuance of $500 million of 1% Notes due 2023. Net proceeds to the Company were $489.4 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 1% 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 December 31, 2003, we have repurchased and retired $32.4 million principal amount of the 5 ¼% notes at a cost of $33.1 million. A gain of $0.5 million was recorded in accordance with the transactions, representing the acceleration of the premium recorded on these notes in accordance with the Acquisition.

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 6.2 million shares of our common stock at a total cost of $229.8 million, or an average cost of $36.83 per share through December 31, 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 0.7 million shares were purchased under the 10b5-1 trading plan. As of February 29, 2004, we had not purchased any additional shares since October 7, 2003, but intend to resume repurchasing during 2004. The Company will hold repurchased shares as treasury shares and intends to use them for general corporate purposes, including but not limited to acquisition-related transactions and for issuance upon exercise of outstanding stock options.

We expect to make capital expenditures in the range of $100-125 million during 2004 for projects such as continued construction of our corporate headquarters in Gaithersburg, Maryland and FluMist manufacturing facilities in Speke, the United Kingdom, construction of a new pilot plant in Gaithersburg, Maryland, and land purchases relating to future expansion phases of our headquarters facility. The Company anticipates these projects will be funded from cash generated from operations and investments on hand. We expect to take occupancy of the first phase of our headquarters facility, a complex of approximately 220,000 square feet, in March 2004. The majority of our existing space in Gaithersburg is leased through 2006, a portion of which will be offered for sublease. There can be no guarantee that we will be successful in subleasing the space.

The Company s 5 ¼% Notes are redeemable beginning in February 2004. The Company intends to redeem the entire remaining amount of the issue at approximately 103% of its principal amount in the first quarter of 2004. The redemption is expected to be financed from cash and investments on hand.

Contractual Obligations and Commitments The following table summarizes our contractual obligations and commitments that will require significant cash outlays in the future:

	Total	2004	2005	2006	2007	2008	Beyond
Contractual Obligations							
Long-term debt[1]	$ 675.7	$ 0.9	$ 1.0	$ 1.0	$ 1.3	$ 168.1	$ 503.4[2]
Facilities leases	54.3	8.8	6.5	4.5	2.8	2.5	29.2
Purchase obligations	136.1	59.2	20.4	11.5	7.5	7.5	30.0
Evans liability	26.8	3.9	22.9	--	--	--	--
Total contractual obligations	$ 892.9	$ 72.8	$ 50.8	$ 17.0	$ 11.6	$ 178.1	$ 562.6
Other Commercial Commitments							
Standby letters of credit	$ 2.2	$ 2.2	$ --	$ --	$ --	$ --	$ --
Obligations under Collaborative Agreements[3]	16.6	7.5	2.3	1.9	1.1	0.8	3.0
Total other commercial commitments	$ 18.8	$ 9.7	$ 2.3	$ 1.9	$ 1.1	$ 0.8	$ 3.0

1 The 2008 amount includes the aggregate principal amount of the 5 ¼% Notes. They are recorded at a premium on the balance sheet, which represents their fair value at the time of the Acquisition. These notes are due in 2008; however, in February 2004 the Board of Directors approved their redemption, which is expected to be completed by March 31, 2004.

2 The 1% Notes can be put to MedImmune by the holders for cash in 2006.

[3] We participate in a number of research and development collaborations to develop and market certain technologies and products. The amounts indicated as obligations under collaborative agreements represent committed funding obligations to our collaborative partners under our various development programs. The amounts do not include any milestone payments or royalty payments related to these collaborations since the amount, timing, and likelihood of the payments is unknown as they are dependent on the occurrence of future events that may or may not occur.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

MEDIMMUNE, INC.

Date: August 5, 2004

/s/ DAVID M. MOTT

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

Date: August 5, 2004

/s/ LOTA S. ZOTH

Lota S. Zoth
Senior Vice President and Chief Financial Officer
Principal Accounting and Financial Officer