MEDIMMUNE INC /DE
Form 10-Q
October 21, 2004

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D. C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2004

0-19131
(Commission File No.)

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, 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 October 19, 2004, 248,721,909 shares of Common Stock, par value $0.01 per share, were outstanding.

MEDIMMUNE, INC.
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Unless otherwise indicated, this quarterly report is as of September 30, 2004. This quarterly report will not be updated as a result of new information or future events.

Part I FINANCIAL INFORMATION
ITEM 1. CONSOLIDATED FINANCIAL STATEMENTS
MEDIMMUNE, INC.
CONSOLIDATED
BALANCE SHEETS
(in thousands)

	September 30, 2004	December 31, 2003
	(Unaudited)	
ASSETS:		
Cash and cash equivalents	$ 17,580	$ 515,502
Marketable securities	189,031	272,765
Trade receivables, net	67,829	161,229
Inventory, net	79,660	91,703
Deferred tax assets	36,816	29,322
Other current assets	16,994	32,233
Total Current Assets	407,910	1,102,754
Marketable securities	1,375,830	1,111,882
Property and equipment, net	306,887	273,597
Deferred tax assets, net	183,922	151,280
Intangible assets, net	15,271	96,694
Goodwill	13,614	13,614
Other assets	33,145	44,849
Total Assets	$ 2,336,579	$ 2,794,670
LIABILITIES AND SHAREHOLDERS' EQUITY:		
Accounts payable	$ 20,600	$ 22,116

	September 30,	December 31,
Accrued expenses	123,613	218,035
Product royalties payable	19,635	81,808
Advances from Wyeth	--	51,910
Other current liabilities	11,921	16,846
Total Current Liabilities	175,769	390,715
Long-term debt	506,428	681,223
Other liabilities	19,946	23,514
Total Liabilities	702,143	1,095,452
Commitments and Contingencies		
SHAREHOLDERS' EQUITY:		
Preferred stock, $.01 par value; authorized 5,525 shares; none issued or outstanding	--	--
Common stock, $.01 par value; authorized 420,000 shares; issued 255,315 at September 30, 2004 and 254,275 at December 31, 2003	2,553	2,543
Paid-in capital	2,686,830	2,673,059
Deferred compensation	(290)	(1,379)
Accumulated deficit	(833,680)	(772,936)
Accumulated other comprehensive income	14,973	27,733
	1,870,386	1,929,020
Less: Treasury stock at cost; 6,657 shares at September 30, 2004 and 6,239 shares at December 31, 2003	(235,950)	(229,802)
Total Shareholders' Equity	1,634,436	1,699,218
Total Liabilities and Shareholders' Equity	$ 2,336,579	$ 2,794,670

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

MEDIMMUNE, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(in thousands, except per share data)

	For the three months ended September 30,		For the nine months ended September 30,	
	2004	2003	2004	2003
Revenues:				
Product sales	$ 92,276	$ 82,283	$ 666,229	$ 593,988
Other revenue	306	17,076	9,030	52,522
Total revenues	92,582	99,359	675,259	646,510
Costs and expenses:				
Cost of sales	40,379	30,526	235,900	157,529
Research and development	84,329	53,654	202,014	115,149
Selling, general and administrative	68,062	51,994	250,654	216,079
Other operating expenses	2,502	1,935	6,361	24,806
Impairment of intangible asset	--	--	72,957	--
Acquired in-process research and development	3,790	--	28,503	--

	For the		For the	
Total expenses	199,062	138,109	796,389	513,563
Operating (loss) earnings	(106,480)	(38,750)	(121,130)	132,947
Interest income	17,237	14,523	49,982	41,823
Interest expense	(1,996)	(2,971)	(6,258)	(6,374)
(Loss) gain on investment activities	(11,919)	1,214	(4,748)	818
(Loss) earnings before income taxes	(103,158)	(25,984)	(82,154)	169,214
(Benefit) provision for income taxes	(38,122)	(9,614)	(27,833)	62,609
Net (loss) earnings	$ (65,036)	$ (16,370)	$ (54,321)	$ 106,605
Basic (loss) earnings per share	($ 0.26)	($ 0.07)	($ 0.22)	$ 0.42
Shares used in calculation of basic (loss) earnings per share	248,869	249,371	248,590	250,981
Diluted (loss) earnings per share	($ 0.26)	($ 0.07)	($ 0.22)	$ 0.42
Shares used in calculation of diluted (loss) earnings per share	248,869	249,371	248,590	254,684

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

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

	For the nine months ended September 30,	
	2004	2003
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net (loss) earnings	$ (54,321)	$ 106,605
Adjustments:		
Impairment of intangible asset	72,957	--
Writedown of acquired in-process research and development	28,503	--
Deferred taxes	(24,780)	33,629
Deferred revenue	(320)	(5,899)
Advances from Wyeth	(51,910)	13,096
Depreciation and amortization	28,082	26,152
Amortization of premium on marketable securities	10,347	11,457
Amortization of deferred compensation	828	3,067
Amortization of premium on convertible subordinated notes	(391)	(1,964)
Amortization of bond issuance costs	2,520	732
Realized losses (gains) on investments	4,748	(818)
Gain on early redemption of convertible notes	(1,010)	--
Losses on write downs of inventory	38,117	19,209
Decrease in sales allowances	(27,687)	(31,191)
Other	80	1,129
Other changes in assets and liabilities	(52,690)	(77,744)
Net cash (used in) provided by operating activities	(26,927)	97,460

	For the	
CASH FLOWS FROM INVESTING ACTIVITIES:		
Increase in marketable securities, net	(185,481)	(72,438)
Capital expenditures	(54,232)	(74,860)
Purchase of assets from Wyeth	(32,000)	--
Minority interest investments	(23,068)	(16,780)
Net cash used in investing activities	(294,781)	(164,078)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuances of common stock	12,136	35,989
Proceeds from issuance of long-term debt	--	500,000
Debt issuance costs	--	(10,546)
Repurchases of common stock	(15,017)	(218,939)
Debt prepayments	(172,677)	(14,105)
Repayments on long-term obligations	(670)	(4,479)
Net cash (used in) provided by financing activities	(176,228)	287,920
Effect of exchange rate changes on cash	14	(32)
Net (decrease) increase in cash and cash equivalents	(497,922)	221,270
Cash and cash equivalents at beginning of period	515,502	130,056
Cash and cash equivalents at end of period	$ 17,580	$ 351,326

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

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

1. Organization

MedImmune, Inc., a Delaware corporation (together with its subsidiaries, the Company), is a biotechnology company headquartered in Gaithersburg, Maryland. The Company currently actively markets four products, Synagis, Ethyol, CytoGam and FluMist, and has a diverse pipeline of development-stage products. The Company s research and development efforts are focused on developing vaccines and antibodies that address significant medical needs in the areas of infectious disease, autoimmune disease and cancer.

2. Summary of Significant Accounting Policies

General

The financial information presented as of and for the three months and nine months ended September 30, 2004 (Q3 2004 and YTD 2004, respectively) and as of and for the three months and nine months ended September 30, 2003 (Q3 2003 and YTD 2003, respectively) is unaudited. In the opinion of the Company s management, the financial information presented herein contains all adjustments, which consist only of normal recurring adjustments, necessary for a fair presentation of results for the interim periods presented. Interim results are not necessarily indicative of results for an entire year or for any subsequent interim period. These consolidated financial statements should be read in conjunction with the Company s annual report on Form 10-K, as amended, for the year ended December 31, 2003.

Inventory

All inventories are stated at the lower of cost or market, determined using the first-in, first-out method. The Company evaluates inventories available for commercial sale separately from inventories related to product candidates (pre-approval inventory) that have not yet been approved.

In the lower of cost or market evaluation for inventories available for commercial sale, market value is defined as the lower of replacement cost or estimated net realizable value, based upon management s estimates about future demand and market conditions. When the Company

determines that inventories for commercial sale have expired, become excess or will not generate sufficient revenues to cover costs of production and distribution, the Company measures the amount of the permanent write down as the difference between the historical cost of the inventory and its estimated market value.

The Company may capitalize pre-approval inventories if management believes that 1) commercial approval by the FDA is probable, such as would be evidenced by a favorable recommendation for approval regarding the safety and efficacy of the product candidate by the FDA or one of its advisory bodies (or other regulatory body with authority to grant marketing approval for drugs and biological products for international sale), and 2) it is probable that its manufacturing facilities will be approved by the FDA (or other regulatory body) for the production of inventory as determined by the nature and scope of any unresolved issues and the remediation required.

In the lower of cost or market evaluation for pre-approval inventories, market value is defined as the lower of replacement cost or estimated net realizable value, based upon management s estimates about future demand and market conditions, including probability of market acceptance of the product. When the Company determines that pre-approval inventories will not have a sufficient shelf life to be sold commercially, or if sold, will not generate sufficient revenues to cover costs of production and distribution, the Company measures the amount of permanent write down as the difference between the historical cost and its estimated probable future market value.

Currently, the Company does not have pre-approval inventories.

Stock-based Compensation

Compensation costs attributable to stock option and similar plans are recognized based on any excess of the quoted market price of the stock on the date of grant over the amount the employee is required to pay to acquire the stock, in accordance with the intrinsic-value method under Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees (APB 25). Such amount, if any, is accrued over the related vesting period.

In December 2002, the Financial Accounting Standards Board ("FASB") issued SFAS No. 148, Accounting for Stock-Based Compensation-Transition and Disclosure (SFAS 148). SFAS 148 amends SFAS No. 123, Accounting for Stock-Based Compensation (SFAS 123), to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, this Statement amends the disclosure requirements of SFAS 123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. The alternative methods of transition and additional disclosure requirements of SFAS 148 became effective January 1, 2003.

The following table illustrates the effect on net earnings and earnings per share if the Company had applied the fair value recognition provisions of SFAS 123, as amended by SFAS 148, to stock-based employee compensation (in millions, except per share data):

	Q3 2004	Q3 2003	YTD 2004	YTD 2003
Net (loss) earnings, as reported	$ (65.0)	$ (16.4)	$ (54.3)	$ 106.6
Add: stock-based employee compensation expense included in historical results for the vesting of stock options assumed in conjunction with the Acquisition, calculated in accordance with FIN 44, "Accounting for Certain Transactions Involving Stock Compensation-an Interpretation of APB 25," net of related tax effect	0.1	0.3	0.5	1.9
Deduct: stock-based employee compensation expense determined under the fair value based method for all awards, net of related tax effect	(14.4)	(21.2)	(45.5)	(63.7)
Pro forma net (loss) earnings	$ (79.3)	$ (37.3)	$ (99.3)	$ 44.8
Basic (loss) earnings per share, as reported	$ (0.26)	$ (0.07)	$ (0.22)	$ 0.42
Basic (loss) earnings per share, pro forma	$ (0.32)	$ (0.15)	$ (0.40)	$ 0.18
Diluted (loss) earnings per share, as reported	$ (0.26)	$ (0.07)	$ (0.22)	$ 0.42
Diluted (loss) earnings per share, pro forma	$ (0.32)	$ (0.15)	$ (0.40)	$ 0.18

New Accounting Pronouncements

In January 2003, the FASB issued FIN No. 46, Consolidation of Variable Interest Entities, an interpretation of Accounting Research Bulletin No. 51. FIN No. 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in

the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. The Company has adopted FIN No. 46 and has determined that it does not currently hold interests in any entities that are subject to the consolidation provisions of this interpretation.

In March 2004, the FASB issued a Proposed SFAS, *Share-Based Payment, an amendment of FASB Statements Nos. 123 and 95* (Exposure Draft). The Exposure Draft would eliminate the ability to account for share-based compensation transactions using APB 25, and generally would require such transactions be accounted for using a fair-value-based method and the resulting cost recognized in the financial statements. The Company is closely monitoring developments related to the Exposure Draft and will adopt the final standards, if any, upon issuance.

During July 2004, the FASB s Emerging Issues Task Force (EITF) reached a consensus on Issue No. 02-14, Whether an Investor Should Apply the Equity Method of Accounting to Investments Other Than Common Stock. EITF 02-14 requires investors to apply the equity method of accounting to investments that are in-substance common stock, defined as an investment in an entity that has risk and reward characteristics that are substantially similar to the entity s common stock. The EITF is effective for reporting periods beginning after September 15, 2004. During Q3 2004, the Company early adopted EITF 02-14, with an immaterial impact to the Company s consolidated financial position and results of operations.

During September 2004, the EITF reached a consensus on Issue No. 04-8, The Effect of Contingently Convertible Debt on Diluted Earnings Per Share. EITF 04-8 requires that all contingently convertible debt instruments be included in diluted earnings per share using the if-converted method, regardless if the market price trigger (or other contingent feature) has been met. The EITF is effective for reporting periods ending after December 15, 2004 and requires that prior period earnings per share amounts presented for comparative purposes be restated. Under the provisions of EITF 04-8, the Company s 1% Convertible Senior Notes (the 1% Notes), which represent 7.3 million potential shares of common stock, will be included in the calculation of diluted earnings per share using the if-converted method regardless if the contingent requirements have been met for conversion to common stock. The Company will adopt EITF 04-8 during the fourth quarter of 2004, and has determined that there will not be a material impact on prior periods earnings per share calculations.

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

3. Dissolution of the Collaboration with Wyeth
In April 2004, the Company entered into agreements to dissolve the collaboration with Wyeth for FluMist and to reacquire rights to an investigational second-generation liquid formulation, CAIV-T (Cold Adapted Influenza Vaccine Trivalent), and all related technology. As a result of the dissolution and in exchange for an upfront fee and future milestones and sales-related royalties, MedImmune reacquired the influenza vaccines franchise, and has assumed full responsibility for the manufacturing, marketing, and sale of FluMist and any subsequent related products. Wyeth has provided bulk manufacturing materials and will transfer clinical trial data, as well as provide manufacturing support services, during a transition that the companies expect to complete in large part in the fourth quarter of 2004.

Through September 30, 2004, the Company has made cash payments totaling $69.7 million under the terms of the agreement, representing (1) the final reconciliation of the amounts owed between parties related to the 2003/2004 influenza season, (2) the settlement of commercialization and development expenses owed between parties through the date of the agreement, (3) the purchase of Wyeth s distribution facility in Louisville, Kentucky, (4) the transfer of other assets from Wyeth and (5) the payment of certain milestones for achieving certain goals for transition activities. Additional amounts of $8.8 million due to Wyeth as of September 30, 2004 for milestones and technology transfer and transition activities, but not yet paid, are included in accrued expenses on the Company s consolidated balance sheet. This transaction was accounted for as a purchase of assets, and the purchase price was allocated to each of the components based on their relative fair values as determined by an independent valuation.

In connection with the transaction, the Company recorded charges for in-process research and development of $3.8 million and $28.5 million during Q3 2004 and YTD 2004, respectively, as well as a permanent impairment charge of $73.0 million during YTD 2004 to write off the remaining unamortized cost of the Wyeth intangible asset originally recorded for the collaboration (see Note 4).

4. Intangible Assets
Intangible assets are stated at net amortized cost. The Company reviews its intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Intangible assets at September 30, 2004 are comprised of the following (in millions):

Agreement with Evans	$ 39.0
Other intangible assets	0.4

	39.4
Less accumulated amortization	(24.1)
	$ 15.3

Amortization of intangible assets is computed on the straight-line method based on the estimated useful lives of the assets. Amortization for Q3 2004 and YTD 2004 was $1.6 million and $7.6 million, respectively. As of September 30, 2004, FluMist inventory includes approximately $1.4 million of amortization costs associated with the agreement with Evans Vaccines Limited (Evans), a wholly owned subsidiary of Chiron Corporation. The estimated aggregate amortization for the Evans agreement for the remainder of 2004 through 2006 is as follows: 2004, $2.2 million; 2005, $8.7 million; and 2006, $4.4 million.

As a result of the dissolution of the collaboration with Wyeth in May 2004, the Company recorded a permanent impairment loss of $73.0 million to write off the remaining unamortized cost of the intangible asset recorded for the original worldwide collaboration with Wyeth.

5. Inventory

Inventory, net of reserves, is comprised of the following (in millions):

	September 30, 2004	December 31, 2003
Raw Materials	$ 15.3	$ 11.6
Work in Process	25.1	39.3
Finished Goods	39.3	40.8
	$ 79.7	$ 91.7

The Company recorded permanent inventory write downs totaling $9.8 million and $36.8 million in cost of goods sold to reflect total FluMist inventories at net realizable value during Q3 2004 and YTD 2004, respectively.

6. Earnings per Share

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

	Q3 2004	Q3 2003	YTD 2004	YTD 2003
Denominator:				
Weighted average shares outstanding	248.9	249.4	248.6	251.0
Effect of dilutive securities: stock options, warrants, and convertible notes	--	--	--	3.7
Denominator for diluted EPS	248.9	249.4	248.6	254.7

The Company incurred a net loss for Q3 2004, Q3 2003, and YTD 2004, and accordingly, did not assume exercise or conversion of any of the Company s outstanding stock options, warrants, or convertible notes during the periods because to do so would be anti-dilutive. As a result, options and warrants to purchase 30.6 million, 29.8 million, and 29.6 million shares of common stock were outstanding during Q3 2004, Q3 2003 and YTD 2004, respectively, but were excluded from the calculation of diluted earnings per share. For all periods presented, the Company s 1% Notes, which represent 7.3 million potential shares of common stock issuable upon conversion, were excluded from the diluted earnings per share calculations because the contingent requirements for conversion were not achieved during the periods.

If option exercise prices are greater than the average market price of the Company s common stock for the period presented, the effect of including such options in the earnings per share calculation is anti-dilutive. During YTD 2003, options to purchase 14.1 million shares of common stock at prices ranging from $30.16 to $83.25 per share were outstanding but were not included in the computation of diluted earnings per share because the exercise price of the options exceeded the average market price.

7. Income Taxes

The Company s effective tax rate for Q3 2004, Q3 2003 and YTD 2003 was approximately 37%. The effective tax rate for YTD 2004 was approximately 34%, reflecting the effect of certain charges for acquired in-process research and development (IPR&D) incurred during the second quarter of 2004 which are not deductible for tax purposes. Income tax expense (benefit) is recognized using a projected effective tax rate, which is based on projections of income and expense for the entire year. As required by generally accepted accounting principles (GAAP), the tax effect of separately reported discrete items is recognized in the period in which they occur. Approximately $6.9 million of the acquired IPR&D recognized in the second quarter is not deductible for income tax purposes causing the YTD 2004 effective rate to differ from the projected annual effective rate. All remaining IPR&D charges during 2004 are expected to be deductible. Depending upon the Company s reported earnings before taxes for the remainder of 2004, the impact of the nondeductible IPR&D may cause the Company s year-to-date effective tax rate to fluctuate. In addition, the effective tax rate may be affected in future periods by changes in estimates with respect to the deferred tax assets and other items affecting the overall tax rate.

8. Comprehensive Income

	Q3 2004	Q3 2003	YTD 2004	YTD 2003
Net (loss) earnings	$ (65.0)	$ (16.4)	$ (54.3)	$ 106.6
Change in foreign currency translation adjustment	0.1	0.1	(0.2)	1.1
Change in unrealized (loss) gain on investments, net of tax	7.1	(7.1)	(7.6)	6.2
Reclassification adjustment for realized gains on securities included in net (loss) earnings	(0.4)	--	(7.4)	--
Reclassification adjustment for realized losses on cash flow hedges included in net (loss) earnings	(0.5)	--	2.6	--
Change in unrealized gain (loss) on cash flow hedges, net of tax	0.2	(0.1)	(0.2)	(0.3)
Comprehensive (loss) income	$ (58.5)	$ (23.5)	$ (67.1)	$ 113.6

9. Debt

On March 31, 2004, the Company redeemed the remaining outstanding $168.6 million principal amount on the MedImmune Vaccines, Inc. 5¼ % convertible subordinated notes due February 2008 (the 5 ¼% Notes) for approximately $172.7 million. The redemption resulted in a net ordinary gain of $1.0 million, reflecting the accelerated amortization of bond premium net of a 3% call premium, which is included in interest expense in the Consolidated Statement of Operations.

10. Shareholders Equity

During Q3 2004, the Company repurchased approximately 0.7 million shares at a cost of $15.0 million, or an average cost of $22.50 per share. Through October 20, 2004, the Company has repurchased an additional 0.1 million shares at an average cost of $24.49 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.

11. Minority Interest Investments

During Q3 2004, the Company determined that declines in fair value below the cost basis of certain of its investments in nonmarketable securities were other than temporary, based primarily on the financial condition and prospects of the investee companies, and recorded impairment losses of $13.7 million in the Consolidated Statement of Operations to write-down the cost basis of the investments to fair value.

12. Legal Proceedings

On September 16, 2002, Celltech R&D Limited (Celltech) commenced a legal proceeding against the Company in the U.K. High Court of Justice, Chancery Division, Patents Court, based on a license agreement dated January 19, 1998. Celltech sought payment of a 2% royalty based on net sales of Synagis sold or manufactured in Germany, with interest and certain costs, including attorney fees. This matter was tried before the High Court of Justice from March 31 to April 7, 2004. The Company received a ruling from the U.K. High Court of Justice on May 19, 2004, in which the Court found in the Company s favor and dismissed Celltech s lawsuit against the Company. Celltech has filed an appeal with the U.K. Court of Appeals. The Company expects the appeal to be heard in the first half of 2005.

In January 2004, the Company filed a declaratory judgment action in the United States District Court for the District of Columbia against Celltech R&D Ltd. Concerning U.S. Patent No. 6,632,927 B2 (the Adair Patent) alleging patent invalidity and non-infringement with regard to Synagis. The Adair Patent was issued on October 14, 2003. On March 12, 2004 Celltech moved to dismiss the non-infringement portion of the Company s complaint, asserting that the courts of England have exclusive jurisdiction over the non-infringement claim pursuant to a January 19, 1998 license agreement. On March 22, 2004 Celltech filed an action in the U.K. High Court of Justice, Chancery Division, Patents Court against the Company based on the same Adair Patent seeking payment of a 2% royalty based on net sales of Synagis made or sold in the U.S. pursuant to the 1998 license agreement. The Company filed an application with the U.K. Court to stay Celltech s U.K. action to allow the U.S. Court to consider the non-infringement and invalidity claims together, but that stay application was denied by the U.K. Court in June, 2004. On July 20, 2004 the U.K. Court of Appeal granted the Company s request for an expedited appeal from the stay ruling. A hearing was held before the UK Court of Appeals on October 5, 2004 and on October 21, 2004, the Company received a decision upholding the trial court s decision. As such, a trial of Celltech s action before the U.K. High Court of Justice will begin in March, 2005. If the manufacture or sale of Synagis or any of the Company s other products is ultimately found to be covered by any valid claim of the Adair Patent and/or any other Celltech patent that is the subject of the January 19, 1998 license agreement, the Company s total royalty obligation would equal 2% of the net sales of the products that are so covered. To date, the Company has not made any royalty payments to Celltech under the January 19, 1998 license agreement.

In April 2002, the Company filed a suit against Centocor, Inc. (Centocor) in the United States District Court for the District of Maryland. That action was amended in January 2003 to add the Trustees of Columbia University in the City of New York (Columbia) and the Board of Trustees of the Leland Stanford University (Stanford and together with Columbia, the Universities) as the owners of the patent. The Company currently pays Centocor a royalty for sales of Synagis made or sold in the United States pursuant to a patent Sublicense Agreement between the parties (the Sublicense Agreement). In the litigation, the Company has been seeking a declaratory judgment that it has no obligation to continue paying royalties to Centocor on the basis that the patent is invalid, unenforceable and does not cover Synagis. Additionally, the Company has been seeking an injunction preventing Centocor from enforcing this patent. Centocor and the Universities moved on March 22, 2004 to dismiss this suit for lack of subject matter jurisdiction based on the decision in *Gen-Probe, Inc. v.Vysis, Inc.,* 359 F.3d 1376 (Fed. Cir. March 5, 2004). The Court granted Centocor and the Universities motion on June 17, 2004. The Company has filed an appeal with the Federal Circuit Court of Appeals.

In April 2003, the Company filed a suit against Genentech, Inc. (Genentech), Celltech R&D Ltd. and City of Hope National Medical Center (City of Hope) in the United States District Court for the Central District of California. The Company currently pays Genentech a royalty for sales of Synagis made or sold in the United States pursuant to a patent license agreement between the parties covering United States Patent No. 6,331,415B1 (the Cabilly Patent). In the complaint, the Company has alleged that the Cabilly Patent was obtained as a result of a collusive agreement between Genentech and Celltech that violates federal and California antitrust laws as well as California s unfair business practices act. Additionally, the Company has alleged that the Cabilly Patent is invalid and unenforceable under federal patent law and is not infringed. In December 2003, the Court granted Celltech and Genentech s motion to dismiss the antitrust claims, and denied MedImmune s motion to amend its complaint in January 2004. In March 2004, the Company appealed from the dismissal of the antitrust claims to the United States Court of Appeals for the Federal Circuit. On April 23, 2004 the Court dismissed the remaining claims in the case for lack of subject matter jurisdiction. The Company has filed a second appeal to the United States Court of Appeals for the Federal Circuit, which has been consolidated with the first appeal. Briefing for the appeal has been completed.

In January 2003, a lawsuit was filed by the County of Suffolk, New York (Suffolk) in the United States District Court, Eastern District of New York, naming the Company along with approximately 25 other pharmaceutical and biotechnology companies as defendants. In August 2003, the County of Westchester, New York (Westchester) filed and served a similar suit against the Company and approximately 25 other pharmaceutical and biotechnology companies. Likewise, in September 2003, the County of Rockland, New York (Rockland) also filed and served a similar suit against the Company and approximately 25 other pharmaceutical and biotechnology companies. On August 4, 2004, the City of New York (New York) also filed and served a similar suit against the Company and approximately 60 other pharmaceutical and biotechnology companies. Suffolk, Westchester and Rockland (collectively, the Counties) and New York allege that the defendants manipulated the average wholesale price (AWP) causing the Counties and New York to pay artificially inflated prices for covered drugs. In addition, the Counties and New York argue that the defendants (including the Company) did not accurately report the best price under the Medicaid program. The plaintiffs seek declaratory and injunctive relief, disgorgement of profits, treble and punitive damages suffered as a result of defendants alleged unlawful practices related prescription medication paid for by Medicaid. All four of these cases have been consolidated (for pre-trial purposes) and transferred to the United States Court for the District of Massachusetts as *In re* Pharmaceutical Industry Average Wholesale Price Litigation (AWP Multidistrict Litigation). A motion to dismiss the complaint against the Company relative to Suffolk has been argued before the Court and a decision is pending. On September 30, 2004 the Court issued a ruling on a consolidated Motion to Dismiss filed by the Defendants in the Suffolk Action, and dismissed certain claims of the Suffolk Complaint. The Company is still awaiting a ruling from the Court on its individual motion to dismiss.

On April 16, 2004, an abbreviated new drug application (ANDA) was submitted to the United States Food and Drug Administration for a generic version of Ethyol (amifostine). The application was submitted by Sun Pharmaceutical Industries Limited (Sun). By letter dated June 29, 2004, Sun notified the Company that Sun had submitted its ANDA to the FDA. In the notice, Sun notified the Company that as part of its ANDA Sun had filed certification on the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 335(j)(2)(A)(vii)(IV) with respect to certain patents owned by the Company. On August 10, 2004, MedImmune Oncology filed an action in the United States District Court for the District of Maryland for patent infringement against Sun, arising out of the filing by Sun of the ANDA with

the FDA seeking approval to manufacture and sell the generic version of Ethyol prior to the expiration of various US patents. MedImmune Oncology intends to vigorously enforce its patents.

The Company is also involved in other legal proceedings arising in the ordinary course of its business. After consultation with its legal counsel, the Company believes that it has meritorious defenses to the claims against the Company referred to above and is determined to defend its position vigorously. While it is impossible to predict with certainty the eventual outcome of these proceedings, the Company believes they are unlikely to have a material adverse effect on its financial position but might have a material adverse effect on its results of operations for a particular period. There can be no assurance that the Company will be successful in any of the litigation it has initiated. In its ordinary course of business, the Company has provided indemnification to various parties for certain product liability claims and claims that the Company s products were not manufactured in accordance with applicable federal standards. While the Company is not aware of any current claims under these provisions, there can be no assurance that such claims will not arise in the future or that the effect of such claims will not be material to the Company.

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

This Management s Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements regarding future events and future results that are based on current expectations, estimates, forecasts, and the beliefs, assumptions and judgments of our management. Readers are cautioned that these forward-looking statements are only predictions and are subject to risks and uncertainties 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, as amended, for the year ended December 31, 2003.

INTRODUCTION

MedImmune is focused on using biotechnology to produce innovative products for prevention and treatment in the therapeutic areas of infectious disease, autoimmune disease and cancer. MedImmune s scientific expertise is largely in the areas of monoclonal antibodies and vaccines. MedImmune currently actively markets four products, Synagis, FluMist, Ethyol and CytoGam and has a diverse pipeline of development-stage products. In January 2002, we acquired Aviron, a California-based vaccine company (the Acquisition) subsequently renamed MedImmune Vaccines, Inc.

OVERVIEW OF YTD 2004

During the first nine months of 2004, product sales increased 12% as compared to YTD 2003, reflecting growth in Synagis sales and recognition of FluMist product sales revenues related to the 2003/2004 flu season. We recorded a net loss of $0.22 per share in YTD 2004 compared to diluted net earnings per share of $0.42 in YTD 2003. The decline in net income was primarily attributable to charges incurred in 2004 for the reacquisition of the influenza vaccines franchise from Wyeth, and increased research and development spending due to higher levels of clinical activity. Our YTD 2003 earnings also included milestones and other payments we received for FDA approval of FluMist and achievement of other goals totaling $32.3 million, and $7.5 million received upon achieving $100 million in international end-user Synagis sales.

In April 2004, we entered into agreements with Wyeth to dissolve our collaboration for FluMist and all related technology, including CAIV-T and any other subsequent products. As a result of the dissolution and in exchange for an upfront fee, future milestones and royalties, we reacquired the full rights to this technology, including a second-generation liquid formulation, CAIV-T, which is currently in Phase 3 clinical development. We also assumed full responsibility for the manufacturing, marketing, and selling of FluMist and any subsequent related products (collectively, the influenza vaccines franchise.) We are currently working with Wyeth to transition all FluMist and CAIV-T research, development, clinical, regulatory, and sales and marketing activities to us, and anticipate that the transition will be substantially complete by the end of 2004.

We continued developing our product candidates during the first nine months of 2004 with the advancement of ongoing trials and the initiation of new trials. We have a Phase 1/ 2 program with Numax underway. Numax is a second-generation RSV monoclonal antibody product candidate. Preliminary data was announced from two pediatric Phase 3 trials with CAIV-T, which were conducted by Wyeth, that seem to indicate better protection than the traditional inactivated, injectable influenza vaccine. We continue to advance our oncology program for Vitaxin, with Phase 2 trials currently being conducted in melanoma and prostate cancer. During Q3 2004, we decided to terminate Phase 2 testing of Vitaxin in patients with rheumatoid arthritis and psoriasis, based on preliminary data suggesting lack of clinical benefit in these

inflammatory diseases. We also received approval for a supplemental biologics license application for liquid Synagis on July 23, 2004.

In early October 2004, regulatory actions in the U.K. caused a significant portion of the injectable influenza vaccine supply for the U.S. to be withheld from the market. We have reacted quickly and taken steps to maximize the quantity of FluMist that will be produced for the 2004/2005 season. We are currently in the process of manufacturing about one million additional doses, subject to quality review and release by the FDA, that we anticipate will provide a total of approximately two million doses available for commercial use.

The Company s cash and marketable securities at September 30, 2004 were $1.6 billion as compared to $1.9 billion at December 31, 2003. We expended cash during 2004 for two significant transactions: the redemption and payment of the remaining 5¼% Notes due 2008 and the payments associated with the reacquisition and transition of the influenza vaccines franchise from Wyeth.

DISSOLUTION OF THE COLLABORATION WITH WYETH

In April 2004, we entered into agreements to dissolve the collaboration with Wyeth for FluMist, CAIV-T and all related technology. As a result of the dissolution, MedImmune reacquired the influenza vaccines franchise, and assumed full responsibility for the manufacturing, marketing, and sale of FluMist and any subsequent related product. As part of the dissolution, we acquired Wyeth s distribution facility in Louisville, Kentucky. Wyeth has provided bulk manufacturing materials and will transfer clinical trial data, as well as provide manufacturing support services, during a transition that the companies expect to complete in large part during the fourth quarter of 2004. Through September 30, 2004, we have made payments totaling $69.7 million under the terms of the agreement, representing (1) the final reconciliation of the amounts owed between parties related to the 2003/2004 influenza season, (2) the settlement of commercialization and development expenses owed between parties through the date of the agreement, (3) the purchase of the distribution center, (4) the transfer of other assets from Wyeth and (5) the payment of milestones for achieving certain goals for transition activities. Additional amounts of $8.8 million due to Wyeth as of September 30, 2004 for milestones and technology transfer and transition activities, but not yet paid, are included in accrued expenses on our consolidated balance sheet.

The notable impacts of the transaction, as well as anticipated effects for the remainder of 2004, are as follows:

Revenue We no longer receive any reimbursement from Wyeth for development and commercialization costs, nor do we receive milestone payments. We expect all future FluMist product sales will be recorded as the sales price to our distributor less customary sales allowances.

Research and Development We anticipate research and development charges to continue to increase significantly compared to 2003 as we work with Wyeth to transition research and development activities to us and increase our resources and infrastructure to assume full responsibility and the operational lead for the continued development and regulatory approval of FluMist and CAIV-T.

Impairment of Intangible Asset In conjunction with the Acquisition in 2002, we recorded an intangible asset on our balance sheet that represented the fair value, as determined by an independent valuation, of the original worldwide collaborative agreement with Wyeth for the development, manufacture, distribution, marketing, promotion and sale of FluMist. As a result of the recent agreements to dissolve our original collaboration with Wyeth, we recorded a permanent impairment charge of $73.0 million during the second quarter of 2004 to write off the remaining unamortized cost of the intangible asset recorded for the collaboration.

Acquired In-Process Research and Development We recorded charges for in-process research and development (IPR&D) of $28.5 million during YTD 2004, representing the relative fair value of purchased in-process technologies at the purchase date, as determined by an independent valuation. A portion of the charges that occurred in YTD 2004 relate to milestone payments from us to Wyeth as they achieve certain contractual deliverables. Additional milestone payments, estimated to be approximately $1 million, are projected to occur in the fourth quarter of 2004. Most of these additional milestone payments will also be recorded as IPR&D charges on a relative fair value basis. See further explanation of the calculation of the IPR&D charge in the Critical Accounting Estimates section.

Income Taxes Our effective tax rate for YTD 2004 was a benefit of 34%, as compared to our 2003 effective rate of approximately 37%, reflecting the impact of the portion of IPR&D incurred during the second quarter that is not deductible for tax purposes. Income tax expense (benefit) is recognized using a projected effective tax rate, which is based on projections of income and expense for the entire year. As required by generally accepted accounting principles (GAAP), the tax effect of separately reported discrete items is recognized in the period in which they occur. Approximately $6.9 million of the acquired IPR&D recognized in the second quarter is not deductible for income tax purposes causing the effective rate for YTD 2004 to differ from the projected annual effective rate. All additional IPR&D charges during 2004 are expected to be deductible. Depending upon the Company s reported earnings before taxes for the remainder of 2004, the impact of the nondeductible IPR&D charges may cause the company s year-to-date effective tax rate to fluctuate.

CRITICAL ACCOUNTING ESTIMATES

The preparation of consolidated financial statements requires management 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 consider an accounting estimate to be critical if the accounting estimate requires us to make assumptions about matters that were highly uncertain at the time the accounting estimate was made and if changes in the estimate that are reasonably likely to occur from period to period, or use of different estimates that we reasonably could have used in the current period, would have a material impact on our financial condition or results of operations. We believe the following critical accounting estimates have the greatest impact on the preparation of our consolidated financial statements. Management has discussed the development of and selection of these critical accounting estimates with the Audit Committee of our Board of Directors. In addition, there are other items within our financial statements that require estimation, but are not deemed critical as defined above. Changes in estimates used in these and other items could have a material impact on our financial statements.

In-Process Research and Development (IPR&D) When we enter into significant agreements for access to late-stage technology or product candidates, we generally perform a valuation of the transaction to determine the fair value of the acquired in-process technologies at the acquisition date, calculated as the sum of probability-adjusted commercial scenarios, or income approach. This method is usually based upon management s estimates of the probability of FDA and/or other regulatory body approval and commercial success for the product candidate, which can include the estimated impact of key factors, including the size of the indicated population, price, volume, timing of regulatory approval and any potential failure to commercialize the product.

During Q3 2004 and YTD 2004, we recorded charges of $3.8 million and $28.5 million, respectively, for acquired IPR&D in conjunction with our reacquisition of FluMist rights from Wyeth in May 2004. The charge represents the relative fair value, as of the purchase date, of the acquired in-process technologies and certain IPR&D projects, primarily CAIV-T, calculated utilizing the income approach. CAIV-T, a development stage, refrigerator-stable version of FluMist, is not expected to have the logistical and distribution issues associated with the frozen formulation. The Company does not believe that there will be any alternative future use for the in-process technologies that were expensed as of the reacquisition date. In valuing the purchased in-process technologies, the Company estimated cash inflows based on extensive market research performed on the U.S. marketplace and cash outflows for product costs, milestones and royalties to be paid over a 10-year period assuming approval and U.S. launch in the 2007/2008 timeframe using probability-of-success-adjusted scenarios and a discount rate of 11.3%. Based on current information, management believes that the projections underlying the analysis are reasonable; however, the actual cash inflows or outflows cannot be predicted with certainty. To achieve these projections, the Company is required to complete certain Phase 3 clinical trials over the next several years. The estimated total cost of these worldwide Phase 3 clinical trials, which is dependent upon several factors including the ultimate design of the trials, the number of patients to be enrolled, and the number of sites needed to complete enrollment, is estimated to range between $100 million and $150 million.

As with all biotechnology products, the probability of commercial success for any one research and development project is highly uncertain. If we fail to successfully complete the clinical trials or if CAIV-T is not approved by the FDA as a safe and effective vaccine for our targeted populations, the launch may be delayed or terminated, resulting in a diminished or no return on any milestone payments made to Wyeth and development costs incurred prior to that date. In addition, as of September 30, 2004, none of the existing manufacturing facilities involved in the production of CAIV-T have been licensed to manufacture CAIV-T by any regulatory agency, nor has CAIV-T 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 CAIV-T, we will not achieve the currently anticipated return on any investment we have made or will make in CAIV-T.

During Q1 2002, we recorded a charge of $1,179.3 million for acquired IPR&D in conjunction with the Acquisition. MedImmune Vaccines then leading product candidate, FluMist, was considered to be a late-stage product candidate, and as such, we used the methodology described above to value the amount of the purchased IPR&D at the transaction date. FluMist was approved in June 2003 and launched in September 2003.

As a result of multiple factors, which were unforeseen at the time of the Acquisition, FluMist did not achieve the level of initial commercial success that we had projected for the first season. After a thorough analysis of the product subsequent to the first season, we are focusing on changing the formulation from frozen to refrigerator-stable (see discussion above) and expanding the label to 6 months through 64 years of age. As such, and despite the anticipated U.S. shortage of injectable vaccine for the 2004/2005 influenza season that we believe may favorably impact our results for the fourth quarter of 2004, we do not presently believe that the FluMist product will be a meaningful contributor to revenue growth before 2007, when the Company hopes to launch CAIV-T. Had we known at the time of the Acquisition that we would have a more narrow indication (the June 2003 approval was for healthy people from 5 years to 49 years of age) than expected or that our sales volumes would be much lower than expected, the value of the purchased IPR&D would likely have been approximately half of the original valuation.

Inventory We capitalize inventory costs associated with 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 permanently write down 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 inventory previously written down became available and was used for commercial sale.

We capitalize inventory costs associated with marketed products based on management s judgment of probable future commercial use and net realizable value. We could be required to permanently write down previously capitalized costs related to commercial inventory due to quality issues or other potential factors. Conversely, our gross margins may be favorably impacted if some or all of the inventory previously written down was recovered through further processing or receipt of specification waiver from regulatory agencies, and became available and was used for commercial sale.

We are required to state all inventory at lower of cost or market. In assessing the ultimate realization of inventories, we are required to make judgments as to multiple factors affecting our inventories and compare these with current or committed inventory levels. In the highly regulated industry in which we operate, raw materials, work-in-process and finished goods inventories have expiration dates that must be factored into our judgments about the recoverability of inventory costs. Additionally, if our estimate of a product s pricing is such that we may not fully recover the cost of inventory, we must consider that in our judgments as well. In the context of reflecting inventory at the lower of cost or market, we will record permanent inventory write-downs (inventory reserves) as soon as a need for such a write-down is determined. Such write-downs in inventory are permanent in nature, and will not be reversed in future periods.

The valuation of FluMist inventories continues to require a significant amount of judgment for multiple reasons. Specifically, the manufacturing process is complex, in part due to the required annual update of the formulation for recommended influenza strains, and there can be no guarantee that we will be able to continue to successfully manufacture the product. Prior to approval in June 2003, all FluMist inventories were considered pre-approval and pre-launch inventories. Subsequent to approval, all FluMist inventories were considered to be inventory available for commercial sale.

The annual FluMist production cycle begins in October of the year prior to the influenza season in which the product will be consumed. For example, the production cycle for the 2004/2005 season began in October 2003. The production cycle begins by preparing the master viral working seeds and readying the manufacturing facilities for the bulk monovalent production, blending three monovalent strains into a trivalent vaccine, filling into intranasal sprayers, packaging sprayers into multi-dose packs and distributing the frozen product. Our raw materials have expiration dates (dates by which they must be used in the production process) that range from 24 months to 60 months. Our semi-processed raw materials and work-in-process inventory have multiple components, each having different expiration dates that range from nine to 24 months. Each season s finished FluMist product has an approved shelf life of up to nine months.

For all inventory components on hand as of September 30, 2004, we reviewed the following assumptions to determine the amount of any necessary reserves: expected production levels and estimated cost per dose; sales volume projections that are subject to variability; the expected price to be received for the product; and current information about the influenza strains recommended by the Centers for Disease Control and Prevention for each season s vaccine. The methodology used to calculate adjustments required to value our FluMist inventories as of September 30, 2004 at net realizable value was consistent with the methodology used for the valuations as of December 31, 2003, March 31, 2004 and June 30, 2004.

The December 31, 2003 valuation of FluMist inventories considered the disappointing sales results of our initial launch of FluMist, which became available in late 2003, and the Company s revised sales estimates of FluMist for both the 2003/2004 and 2004/2005 flu seasons. As a result, we revised our sales volume estimates and decreased the estimated price expected to be received per dose for the 2004/2005 flu season. In addition, we decreased our estimated production levels based on our anticipated decrease in sales volumes, which increased the per unit cost to produce FluMist. Using these assumptions, we compared the amount of expected FluMist sales with the expected production cost to estimate the net realizable value of FluMist inventories to be produced throughout the season. Sales and production estimates for the 2004/2005 season incorporated into the inventory valuations performed as of December 31, 2003, March 31, 2004 and June 30, 2004 were generally consistent. The valuation as of September 30, 2004 uses management s estimates of sales and production levels that have been recently adjusted to take into account anticipated increased demand due to the shortage of injectable influenza vaccine in the U.S. for the 2004/2005 season. Our current sales projections range from one million to two million doses, and we have used the midpoint of that range for purposes of our inventory valuation.

The table below summarizes the activity within the components of FluMist inventories (in millions):

	Gross Inventory	Reserves	Net Inventory
FluMist Details			
As of December 31, 2003	$ 122.1	($85.8)	$ 36.3
Q1 raw materials	3.5	(0.2)	3.3
Q1 cost of good sold recognized on 2003/2004 inventory	(34.2)	5.0	(29.2)
Q1 production, net	15.0	(13.3)	1.7
Q1 disposal of finished goods	(50.3)	49.6	(0.7)
Q2 raw materials	0.5	0.5	1.0

	Gross Inventory	Reserves	Net Inventory
Q2 production, net	16.3	(14.6)	1.7
Q2 production scrapped	(8.4)	7.3	(1.1)
Q2 disposal of finished goods	(10.3)	10.3	--
Q3 raw materials	0.4	0.1	0.5
Q3 production, net	16.0	(11.6)	4.4
Q3 production scrapped	(1.0)	1.0	--
Q3 disposal of finished goods	--	--	--
As of September 30, 2004	$ 69.6	($51.7)	$ 17.9

Because finished FluMist product has an approved shelf life of up to nine months, all finished product produced for a particular flu season must be sold within that season. Thus, if our actual sales fall below our projections, we will be required to write off any remaining (unreserved) inventory balance at the end of the flu season.

For our other products, we periodically assess our inventory balances to determine whether net realizable value is below recorded cost. Factors we consider include expected sales volume, production capacity and expiration dates. No significant inventory adjustments were recorded for our other products during YTD 2004.

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 a reduction to gross product sales. The timing of actual discounts, returns and chargebacks taken, and rebates paid to government purchasers can lag the sale of the product by up to several months. As such, a significant amount of judgment is required when estimating the impact of sales allowances on gross sales for a reporting period. The assumptions used in developing our estimates of sales reserves include the following key factors:

- historical trends for discounts, returns, rebate claims, or other claims;
- our current contracts with customers and current discount programs;
- actual performance of customers against contractual volume targets tied to discounts;
- proportion of gross sales ultimately used by Medicaid patients;
- state Medicaid policies and our reimbursement practices; and
- accuracy of reporting by our customers of end-user product sales by state.

We update these factors for any known changes in facts or circumstances as soon as the changes are known. If our historical trends are not indicative of the future, or our actual sales are materially different from the projected amounts, or if our assessments prove to be materially different than actual occurrence, our results could be affected. The estimation process for determining liabilities for sales allowances inherently results in adjustments each year. Additionally, because of the varying lags and the seasonal nature of our largest product, Synagis, our sales discounts, returns, chargebacks and rebates fluctuate throughout the year. If our estimate of the percentage of gross sales to be recorded for sales allowances for Synagis were to increase by 1%, our revenues for the 2003/2004 Synagis sales season (which runs from July 2003 to June 2004) would have been reduced by approximately $9 million. A decrease of 1% in the sales allowances for Synagis during the same period would have increased our revenues by a similar approximation of $9 million. During Q3 2004 and YTD 2004, we reduced our total sales allowances by approximately $0.9 million and $7.0 million, respectively, primarily to reflect the actual performance of customers against contractual volume targets that differed from our estimates, changes in historical trends for returns and a change in the estimated impact of recent refinements to our reimbursement practices for rebates due to government purchasers.

Reserves for discounts, returns, chargebacks and rebates that were accrued and not yet paid as of September 30, 2004 and December 31, 2003 were $25.6 million and $51.4 million, respectively. On our accompanying balance sheets, reserves for discounts, returns, and chargebacks are recorded as a reduction to trade receivables and reserves for government reimbursements are recorded as accrued expenses.

COMPLIANCE WITH SARBANES-OXLEY REQUIREMENTS

Section 404 of the Sarbanes-Oxley Act of 2002 requires management to perform an evaluation of its internal control over financial reporting and have our independent auditors attest to such evaluation. Along with many other companies whose fiscal year ends on December 31, we must implement these requirements for the first time in connection with the preparation of the annual report for the year ending December 31, 2004. We have been actively preparing for the implementation of this requirement by, among other things, establishing an ongoing program to document, evaluate and test the systems and processes necessary for compliance. While we anticipate that we will be able to comply on a timely basis with these requirements, unforeseen delays may occur which could prevent us from achieving timely compliance. If we fail to complete our evaluation on a timely basis and in a satisfactory manner, or if our external auditors are unable to attest on a timely basis to the adequacy of the Company's internal control, we may be subject to additional scrutiny surrounding our internal control over financial reporting.

RESULTS OF OPERATIONS
Q3 2004 compared to Q3 2003

Revenues Product Sales

(in millions)	Q3 2004	Q3 2003	Growth
Synagis	$ 60.9	$ 48.6	25%
Ethyol	21.5	20.6	4%
FluMist	--	--	N/A
Other Products	9.9	13.1	(24%)
	$ 92.3	$ 82.3	12%

Product sales grew 12% in Q3 2004 to $92.3 million as compared to $82.3 million in Q3 2003, primarily due to increased sales of Synagis. Due to the seasonal nature of Synagis sales, less than 10% of the respective overall seasonal sales (July 1 through June 30) typically occur in the third quarter. With a relatively low level of sales for the quarter, as compared to other calendar quarters, the underlying growth trends in product sales can be significantly impacted by the timing of product shipments and modest fluctuations in wholesaler inventory levels. Of the overall 12% increase in product sales, approximately ten percentage points were attributed equally to an increase in international sales and domestic price increases. The remaining two growth points were due to to reductions in sales allowances.

Synagis Synagis accounted for approximately 66% and 59% of our product sales in Q3 2004 and Q3 2003, respectively. In Q3 2004, domestic sales of Synagis increased 19% to $42.0 million from Q3 2003 sales of $35.4 million. Of the overall 19% increase, approximately seven percentage points are due to the 5.5% price increase effective for the 2004/2005 season, another seven percentage points are due to a positive true-up to sales allowances reflecting favorable experience for the 2003/2004 season, and the remaining five growth points are due to an increase in unit volume.

We record Synagis international product sales based on Abbott International s (AI s) sales price to customers, as defined in our distribution agreement. Our reported international Synagis sales increased 43% to $18.9 million for Q3 2004 as compared to $13.2 million in Q3 2003. Of the overall 43% increase, approximately 22 percentage points are attributable to a 15% increase in the product transfer price for the 2004/2005 season and 21 growth points are due to an increase in sales volume. We believe that international sales for the quarter were favorably impacted by the early stocking of inventories for the 2004/2005 season.

Ethyol Ethyol accounted for approximately 23% and 25% of our product sales in Q3 2004 and Q3 2003, respectively. Worldwide Ethyol sales grew 4% to $21.5 million in Q3 2004, compared to $20.6 million in Q3 2003. This growth was primarily driven by a domestic price increase. Domestic sales volumes for Q3 2004 and Q3 2003 were relatively flat, which we believe is due to the depletion of wholesaler inventories during Q3 2004, a reduction in the census of head and neck cancer patients, and the impact, which we believe is temporary, of a relatively new form of radiation treatment. International sales declined over the prior period, primarily due to a 68% decline in unit sales volume to our international distribution partner, Schering-Plough Corporation (Schering). 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 2004, which include sales of CytoGam, NeuTrexin, and by-products that result from the CytoGam manufacturing process, decreased $3.2 million from Q3 2003. The decrease was driven by a $1.9 million decrease in CytoGam sales. We believe this decrease is not the result of a decrease in end-user demand for the product in Q3 2004, but rather reflects a decision by our wholesalers to reduce inventory levels. Within Q3 2004, wholesaler levels decreased to accommodate end-user demand, whereas within Q3 2003, wholesaler inventory levels nearly doubled. During 2003, the Company determined that RespiGam, which has been replaced in the marketplace by our second-generation RSV product, Synagis, would no longer be manufactured and thus expects to have no further sales of RespiGam for the remainder of 2004 and thereafter.

Revenues Other Revenues

Other revenues decreased to $0.3 million for Q3 2004 compared to $17.1 million in Q3 2003. During Q3 2003, we recognized $7.3 million of supply goal payments from Wyeth for the reimbursement of manufacturing costs for the 2003/2004 influenza season, and an additional $5.0 million in milestone revenues from Wyeth associated with the inclusion of FluMist in the American Academy of Pediatrics *Influenza Vaccine Implementation Information for 2003/2004*.

Cost of Sales

Cost of sales was $40.4 million for Q3 2004 compared to $30.5 million in Q3 2003. Gross margins on product sales for Q3 2004 were 56%, down seven percentage points from Q3 2003, primarily due to the permanent write downs of FluMist inventory during Q3 2004. See our discussion of FluMist inventory valuation adjustments in the Critical Accounting Estimates section of Management s Discussion and Analysis. The unfavorable impact of FluMist costs was partially offset by the favorable contribution of Synagis, which accounted for 66% of product sales during Q3 2004, versus 59% of product sales during the prior year period. Excluding the negative contribution of FluMist, gross margins on product sales were 69% and 64% for Q3 2004 and Q3 2003, respectively. The favorable comparison to prior year is largely due to the impact of unplanned scrap costs in Q3 2003 for Synagis as well as lower sales allowances in Q3 2004 that favorably impacted Synagis sales. We expect that gross margins may vary significantly from quarter to quarter, based on changes in the product mix due to the seasonality of Synagis.

Research and Development Expenses

Research and development expenses, as reported in the accompanying statement of operations, include both our normal ongoing expenses of drug discovery and development efforts and costs incurred in the technology transfer and transition activities associated with reacquisition of the influenza vaccines franchise from Wyeth. Total research and development expenses of $84.3 million in Q3 2004 increased 57% from $53.7 million in Q3 2003.

Of the $84.3 million incurred in Q3 2004, approximately $72.5 million related to the ongoing expenses of our internal drug discovery efforts and approximately $11.8 million related to the impact of the reacquisition of the influenza vaccines franchise from Wyeth. Our drug discovery and development costs in Q3 2004 are associated with preclinical and clinical trials for product candidates, as well as headcount and related expenses in support of increased research and development activities. During Q3 2004, we progressed with two ongoing Phase 2 trials for Vitaxin targeting melanoma and prostate cancer, while we discontinued two trials for Vitaxin targeting rheumatoid arthritis and psoriasis based on preliminary data suggesting lack of clinical benefit in these inflammatory diseases. We are conducting a Phase 1 / 2 trial with Numax, our second generation RSV monoclonal antibody product candidate. We are conducting a bridging study between the current frozen FluMist product and the liquid CAIV-T formulation, and began enrolling patients in October for a Phase 3 trial that will compare CAIV-T to the traditional injectible flu vaccine in children from 6 months to 59 months of age. Also during Q3 2004, we began a Phase 1 clinical trial with an anti-interleukin-9 (IL-9) monoclonal antibody to evaluate the molecule as a potential treatment for symptomatic, moderate to severe persistent asthma. The costs incurred in Q3 2004 for technology transfer and transition activities associated with our reacquisition of the influenza vaccines franchise are largely the result of payments to Wyeth for collection and analysis of data from five late-stage CAIV-T studies conducted by Wyeth over the last several years, including assistance in documenting study reports, closing and locking databases for clinical trials and transition of clinical study results to our clinical databases. Payments to Wyeth also relate to the maintenance of the CAIV-T development facility and production of CAIV-T clinical trial material, as well as assistance with internal technology transfer of manufacturing operations for CAIV-T. We expect research and development expenses to continue to increase in future periods as we work toward our goal of moving several product candidates into clinical development and ultimately to market as part of our five-year plan.

Selling, General and Administrative Expenses

Selling, general and administrative (SG&A) expenses, as reported in the accompanying statement of operations, increased 31% to $68.1 million in Q3 2004 compared to $52.0 million in Q3 2003. The increase is due primarily to increases in programs associated with the reacquisition of the influenza vaccines franchise from Wyeth, including the expansion of our pediatric sales force, as well as the creation of new marketing and medical education programs and materials.

Other Operating Expenses

Other operating expenses were $2.5 million in Q3 2004 compared to $1.9 million in Q3 2003. Other operating expenses primarily include excess capacity charges associated with the plasma production section of the Frederick Manufacturing Center located in Frederick, Maryland.

Acquired IPR&D

We recorded a charge of $3.8 million for acquired IPR&D during Q3 2004 in conjunction with our reacquisition of the influenza vaccines franchise from Wyeth. The charge represents the relative fair value on the purchase date of purchased in-process technologies and research and development projects, primarily CAIV-T, calculated utilizing the income approach. See further discussion of IPR&D in the Critical Accounting Estimates section of Management s Discussion and Analysis.

Interest Income and Expense

We earned interest income of $17.2 million for Q3 2004, compared to $14.5 million in Q3 2003, primarily due to higher average rates. Interest expense for Q3 2004, net of amounts capitalized, was $2.0 million, down from $3.0 million in Q3 2003. This decrease is largely due to the retirement of the 5¼% Notes in March 2004, partially offset by a decrease in capitalized interest, as the new R&D facility and corporate headquarters were completed in March 2004.

(Loss) Gain on Investment Activities

We recorded a loss on investment activities of $11.9 million during Q3 2004, compared to a gain of $1.2 million during Q3 2003. The Q3 2004 loss consists primarily of impairment write-downs of $13.7 million due to the decline in fair value of certain of our investments in private companies below their cost basis that were determined to be other-than-temporary. During Q3 2004 and Q3 2003, we recognized gains on the sale of common stock and other investments of $1.7 million and $1.4 million, respectively.

Taxes

We recorded a benefit for income taxes of $38.1 million and $9.6 million for Q3 2004 and Q3 2003, respectively, resulting in an effective rate of 37% for both periods. See further discussion of Income Taxes in the Dissolution of the Collaboration with Wyeth section of Management s Discussion and Analysis.

Net (Loss) Earnings

The reported net loss for Q3 2004 was $65.0 million, or $0.26 per share, compared to a net loss for Q3 2003 of $16.4 million or $0.07 per share.

Shares used in computing net loss per share for Q3 2004 were 248.9 million. Shares used in computing net loss per share for Q3 2003 were 249.4 million. The decrease in share count is primarily attributable to our share repurchase program which was implemented in July 2003.

YTD 2004 compared to YTD 2003

Revenues Product Sales

(in millions)	**YTD 2004**	**YTD 2003**	**Growth**
Synagis	$ 538.7	$ 490.8	10%
FluMist	27.1	--	N/A
Ethyol	70.9	71.5	(1%)
Other Products	29.5	31.7	(7%)
	$ 666.2	$ 594.0	12%

For YTD 2004, product sales grew 12% to $666.2 million as compared to $594.0 million in YTD 2003, primarily due to a 10% increase in sales of Synagis to $538.7 million. Of the overall 12% increase in product sales, approximately six percentage points were due to an increase in domestic sales volumes, including 2003/2004 seasonal sales of FluMist in YTD 2004, and domestic price increases accounted for five growth points. International sales added four growth points, but were largely negated by higher sales allowances that reduced sales by three percentage points.

Synagis Synagis accounted for approximately 81% and 83% of our product sales for YTD 2004 and YTD 2003, respectively. We achieved a 5% increase in domestic Synagis sales to $471.8 million for YTD 2004, up from $451.0 million in YTD 2003. The five percentage points of growth resulted from price increases, as the three percentage point impact of higher sales volumes was offset by higher sales allowances during Q3 2004. The comparison of sales allowances was impacted by a favorable adjustment in the YTD 2003 period of $14.3 million reflecting a

refinement in our methodology for estimating reserves for rebates due to government purchasers. Our reported international sales of Synagis increased to $66.9 million in YTD 2004 compared to $39.8 million in YTD 2003, largely due to a 56% increase in units sold to AI. We believe this growth is due to a combination of increased product demand by end users and early stocking of inventories for the 2004/2005 Synagis season by AI. Also contributing to sales growth was an increase in the sales price caused by a change in the mix of countries to which we sell Synagis internationally that favorably impacted the average sales price, and the favorable currency translation impact of a weakened U.S. dollar. We record Synagis international product sales based on AI s sales price to customers, as defined in our agreement with them.

FluMist Our YTD 2004 sales of FluMist amounted to $27.1 million and include transfer price revenues for product shipped to Wyeth for the entire 2003/2004 season. During the second half of 2003, we shipped 4.1 million doses of FluMist to Wyeth, who was contractually responsible for distributing the product to third parties. We determined the product transfer price to be fixed or determinable during Q1 2004, and recorded $25.9 million of FluMist product revenues at that time. Our Q2 2004 product sales of FluMist amounted to $1.2 million, representing the final agreed-upon reconciliation of sales discounts and returns with Wyeth as part of the dissolution of our collaboration.

Ethyol Ethyol accounted for approximately 11% and 12% of our product sales for YTD 2004 and YTD 2003, respectively. Worldwide Ethyol sales declined 1% to $70.9 million in YTD 2004, as compared to $71.5 million in YTD 2003, primarily driven by a 37% decline in our international sales. YTD 2004 domestic sales of Ethyol remained consistent with those of YTD 2003, as the seven percentage point growth from price increases was largely negated by the higher sales allowances and lower sales volumes. We believe that the lower domestic sales volumes for YTD 2004 as compared to YTD 2003 are largely due to the depletion of wholesaler inventories from December 31, 2003 levels to accommodate end-user demand. In the YTD 2003 period, we experienced an increase in wholesaler inventories from December 31, 2002 levels.

Other Products Sales of other products include sales of CytoGam, RespiGam, NeuTrexin, and by-products that result from the CytoGam manufacturing process and amounted to $29.5 million in YTD 2004 as compared to $31.7 million for YTD 2003. The slight decrease is primarily due to the decline in sales of RespiGam, which has been replaced in the marketplace by our second-generation RSV product, Synagis, and is no longer manufactured or actively marketed.

Revenues Other Revenues

Other revenues of $9.0 million for YTD 2004 are lower than YTD 2003 other revenues of $52.5 million largely due to decreased revenues under collaborative agreements. Other revenues in YTD 2004 are largely comprised of contractual payments received from Wyeth prior to dissolution of our collaboration, including royalties related to the 2003/2004 influenza season and corporate funding for clinical development and sales and marketing programs. During YTD 2003, we recognized $25.0 million of milestone revenue from Wyeth, associated with the approval of FluMist and the inclusion of FluMist in the American Academy of Pediatrics *Influenza Vaccine Implementation Information for 2003/2004*, as well as $7.3 million in supply goal payments from Wyeth for reimbursement of certain manufacturing costs for the 2003/2004 influenza season. Also during YTD 2003, we recognized $7.5 million of milestone revenue for achieving in excess of $100 million in end-user sales of Synagis outside the U.S. during a single RSV season.

Cost of Sales

Cost of sales for YTD 2004 increased 50% to $235.9 million from $157.5 million for YTD 2003. Gross margins on product sales were 65% for YTD 2004, down eight percentage points from gross margins of 73% for YTD 2003. The decrease in margins is largely due to cost of sales for the 2003/2004 seasonal sales of FluMist and the permanent write downs of 2004/2005 FluMist inventory produced in YTD 2004. Excluding the negative contribution of FluMist, gross margins on product sales were 74% for both YTD 2004 and YTD 2003.

Research and Development Expenses

Research and development expenses of $202.0 million in YTD 2004 increased 75% from $115.1 million in YTD 2003. The increase is due largely to direct costs associated with ongoing and additional clinical and preclinical trials for product candidates, as well as increases in headcount and related expenses in support of increased research and development activities. Also included in research and development expenses in YTD 2004 are $22.5 million in costs for technology transfer and transition activities associated with our assumption of research and development activities related to the influenza vaccines franchise that are expected to be complete by the end of 2004.

Selling, General, and Administrative Expenses

Selling, general and administrative (SG&A) expenses increased 16% to $250.7 million in YTD 2004 compared to $216.1 million in YTD 2003. The increase is largely attributable to increases in legal costs associated with the ongoing litigation described in Note 12 of Part I, Item 1, "Consolidated Financial Statements," outside consulting, and increases in marketing programs for Synagis and co-promotion expense, reflective of the increase in YTD 2004 Synagis sales. In addition, we incurred increased marketing expenses due to our assumption of sales and marketing responsibility for FluMist from Wyeth during Q2 2004. Among other related expenses, our infectious disease sales and marketing organization was expanded to sell and promote FluMist during 2004. As a percentage of product sales, SG&A expense increased to 38% of product sales for YTD 2004 compared to 36% of products sales in YTD 2003. Absent the amounts incurred during 2004 for Wyeth-related transition activities and the favorable impact in YTD 2003 of an adjustment to the bad debt provision, SG&A expense as a percentage of product sales remained flat at 37%.

Other Operating Expenses

Other operating expenses, which reflect manufacturing start-up costs and other manufacturing related costs, decreased to $6.4 million in YTD 2004 from $24.8 million in YTD 2003. 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. Other operating expenses in both periods also include excess capacity charges associated with the plasma production portion of the Frederick Manufacturing Center.

Impairment of Intangible Asset

As a result of entering into agreements to dissolve the collaboration with Wyeth during April 2004, we recorded a permanent impairment loss of $73.0 million that represented the remaining unamortized cost originally recorded for the original collaboration with Wyeth.

Acquired IPR&D

We recorded a charge of $28.5 million for acquired IPR&D for YTD 2004 in conjunction with our reacquisition of the influenza vaccines franchise from Wyeth. The charge represents the relative fair value of purchased in-process technologies at the acquisition date, calculated utilizing the income approach, of certain IPR&D projects, primarily CAIV-T. See further discussion of IPR&D in the Critical Accounting Estimates section of Management s Discussion and Analysis.

Interest Income and Expense

We earned interest income of $50.0 million for YTD 2004, compared to $41.8 million in YTD 2003, reflecting higher average investment balances and higher average rates. Interest expense for YTD 2004, net of amounts capitalized, was $6.3 million, down from $6.4 million in YTD 2003. The amount of interest expense capitalized declined in YTD 2004 versus the prior period, due to the completion of several large construction projects in 2004, including the new R&D facility and corporate headquarters in Maryland.

(Loss) Gain on Investment Activities

We incurred a $4.7 million loss on investment activities for YTD 2004, compared to a gain of $0.8 million in YTD 2003. The YTD 2004 loss consists of impairment write-downs of $13.7 million due to the decline in fair value of certain of our investments in private companies below their cost basis that were determined to be other-than-temporary, partially offset by realized gains on sales of common stock and other investments totaling $8.9 million. During YTD 2003, we recognized gains on the sale of common stock of $1.4 million, partially offset by investment losses to record our portion of our minority investees operating results as required by the equity method of accounting.

Taxes

We recorded an income tax benefit of $27.8 million for YTD 2004, resulting in an effective tax rate of 34%. Comparatively, we recorded income tax expense of $62.6 million for YTD 2003, which resulted in an effective tax rate of 37%.

The year-over-year change in our estimated effective tax rate is due to approximately $6.9 million of non-deductible charges for IPR&D during the second quarter of 2004. All remaining IPR&D charges during 2004 are expected to be deductible for tax purposes. Our effective tax rate in both years is impacted by the availability of the estimated credits available for research and development activities, including credits earned for Orphan Drug status of certain research and development activities, relative to our earnings growth. These credits will vary from year to year depending on the activities of the Company.

Net (Loss) Earnings

We reported a net loss for YTD 2004 of $54.3 million, or $0.22 per share compared to net earnings for YTD 2003 of $106.6 million or $0.42 per share.

Shares used in computing loss per share for YTD 2004 were 248.6 million, while shares used for computing basic and diluted earnings per share for YTD 2003 were 251.0 million and 254.7 million, respectively. The decrease in share count is primarily attributable to our stock repurchase program that we implemented in July 2003.

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

LIQUIDITY AND CAPITAL RESOURCES

Sources and uses of cash Cash and marketable securities were $1,582.4 million at September 30, 2004 as compared to $1,900.1 million at December 31, 2003, a decrease of 17%. The decrease in cash is primarily due to the combined impact of the March 31, 2004 retirement of the 5¼% Notes and payments made to Wyeth in conjunction with our reacquisition of the influenza vaccines franchise. Working capital decreased to $232.1 million at September 30, 2004 from $712.0 million at December 31, 2003, also due to the retirement of the 5¼% Notes and the payments made to Wyeth, a decrease in trade accounts receivable caused by the seasonal nature of Synagis, as well as a shift in our fixed income portfolio mix to longer-term maturities.

Operating Activities
Net cash used in operating activities was $26.9 million in YTD 2004 as compared to cash provided by operating activities of $97.5 million in YTD 2003. The change versus prior period is primarily the result of the decrease in net earnings in 2004, excluding the noncash charge for the impairment of an intangible asset, and the final settlement of advances from Wyeth, and payments made for the reacquisition of the influenza vaccines franchise. Additionally, cash paid for accrued expenses and product royalties payable increased year over year, reflecting the increase in net sales.

Investing Activities
Cash used for investing activities during YTD 2004 amounted to $294.8 million, as compared to $164.1 million in the first nine months of 2003. Cash used for investing activities in YTD 2004 included net additions to our investment portfolio of $185.5 million; capital expenditures totaling $54.2 million, primarily for the construction of our new R&D facility and corporate headquarters and the expansion of our FluMist manufacturing facilities in Speke, England; $32.0 million paid to Wyeth for certain in-process technologies and IPR&D projects, primarily CAIV-T, and the distribution facility in Louisville; and minority interest investments in strategic partners totaling $23.1 million through our venture capital subsidiary.

Financing Activities
Financing activities used $176.2 million in cash for YTD 2004, as compared to $287.9 million generated in the comparable period of 2003. Approximately $12.1 million was received upon the exercise of employee stock options in YTD 2004, as compared to $36.0 million received in YTD 2003, reflecting decreased stock option exercises by employees. Additionally, we used $172.7 million in cash to repurchase and retire the balance of the 5¼% Notes, and an additional $15.0 million to repurchase shares of our common stock as authorized under our share repurchase program. During the YTD 2003 period, we received net cash proceeds of $489.5 million in connection with the issuance of the 1% Notes, which was partially offset by treasury stock repurchases of $218.9 million.

Our primary source of liquidity is operating cash flow. Management continues to believe that such internally generated cash flow as well as its existing funds will be adequate to service its existing debt and other cash requirements. The Company expends cash to finance its research and development and clinical trial programs; to obtain access to new technologies through collaborative research and development agreements with strategic partners, through our venture capital subsidiary, or through other means; to fund capital projects; and to finance the production of inventories. During Q2 2004, we received a BBB rating on our outstanding indebtedness by Standard & Poor s. This rating is considered to be

investment grade and we believe the rating will contribute to our ability to access capital markets, should we desire or need to do so. We may raise additional capital in the future to take advantage of favorable conditions in the market or in connection with our development activities.

In 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 and at such times as management deems appropriate. During Q3 2004, we repurchased approximately 0.7 million shares at a cost of $15.0 million, or an average cost of $22.50 per share. Through October 20, 2004, we have repurchased an additional 0.1 million shares at an average cost of $24.49 per share. We will hold repurchased shares as treasury shares and intend to use them for general corporate purposes, including but not limited to acquisition-related transactions and for issuance upon exercise of outstanding stock options.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We believe our primary market risks as of September 30, 2004 continue to be the exposures to loss resulting from changes in interest rates, foreign currency exchange rates, and equity prices.

During Q3 2004, we determined that declines in fair value below the cost basis of certain of our investments in nonmarketable securities were other than temporary, based primarily on the financial condition and prospects of the investee companies, and we recorded impairment losses of $13.7 million in the Consolidated Statement of Operations to write-down the cost basis of the investments to fair value. We expect the volatility in the fair value of our minority investments to continue and, thus, the value assigned to the investments could change significantly from period to period.

Our market risks at September 30, 2004 have not changed significantly from those discussed in our Form 10-K, as amended for the year ended December 31, 2003. For other information regarding the Company s market risk exposure, please refer to Part II, Item 7A, Quantitative and Qualitative Disclosures About Market Risk of the Company s Annual Report on Form 10-K, as amended, for the year ended December 31, 2003.

ITEM 4. CONTROLS AND PROCEDURES

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

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

In addition, the management of the Company, with the participation of the Company s Chief Executive Officer, President and Vice Chairman and Senior Vice President and Chief Financial Officer, have determined that there was no change in the Company s internal control over financial reporting that occurred during Q3 2004 that has materially affected, or is reasonably likely to materially affect, the Company s internal control over financial reporting.

PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Information with respect to legal proceedings is included in Note 12 of Part I, Item 1 Consolidated Financial Statements, and is incorporated herein by reference and should be read in conjunction with the related disclosure previously reported in the Company s Annual Report on Form 10-K, as amended, for the year ended December 31, 2003.

Item 2. CHANGES IN SECURITIES, USE OF PROCEEDS, AND ISSUER REPURCHASES OF SECURITIES

Issuer purchases of equity securities[1]

Period	Total Shares Purchased	Average Number of Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Approximate Dollar Value that May Yet Be Purchased Under the Plans or Programs
July 1, 2004 through July 31, 2004	--	--	--	$270,198,000
August 1, 2004 through August 31, 2004	667,300	$22.50	667,300	$255,181,000
September 1, 2004 through September 30, 2004	--	--	--	$255,181,000

[1]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 on the
open market or in privately negotiated transactions.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES NONE

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

ITEM 5. OTHER INFORMATION NONE

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits:

31.1	Certification pursuant to 18 USC Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification pursuant to 18 USC Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32	Certification pursuant to 18 USC Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, furnished as permitted by Item 601(b)(32)(ii) of Regulation S-K. This Exhibit 32 is not filed for purposes of Section 18 of the Securities Exchange Act of 1934, and is not and should not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934.

(b)Reports on Form 8-K:

Report Date	Report Date Event Reported
July 22, 2004	MedImmune reports 2004 Second Quarter and Six Month Results.
August 31, 2004	MedImmune adopts amendments to its Global Standards of Business Conduct and Ethics

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

MEDIMMUNE, INC.
(Registrant)

Date: October 21, 2004

/s/: DAVID M. MOTT

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

Date: October 21, 2004

/s/: LOTA S. ZOTH

Lota S. Zoth
Senior Vice President and Chief Financial Officer