

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

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

**FORM 10-Q**

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

For the quarterly period ended June 30, 2004

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

Delaware  
(State or other jurisdiction of  
incorporation or organization)

0-19131  
(Commission File No.)

52-1555759  
(I.R.S. Employer Identification No.)

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

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

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. Yes  No

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

As of July 30, 2004, 249,249,949 shares of Common Stock, par value \$0.01 per share, were outstanding.

**MEDIMMUNE, INC.**  
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Trademark information: Synagis® (palivizumab), CytoGam® (cytomegalovirus immune globulin intravenous (human)), RespiGam® (respiratory syncytial virus immune globulin intravenous (human)), and Vitaxin® are registered trademarks of MedImmune, Inc. Numax™ is a trademark of MedImmune, Inc. Ethyol® (amifostine) and NeuTrexin® (trimetrexate glucuronate for injection) are registered trademarks of MedImmune Oncology, Inc. FluMist™ (Influenza Virus Vaccine Live, Intranasal) is a trademark of MedImmune Vaccines, Inc.

Unless otherwise indicated, this quarterly report is as of June 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)

	June 30, 2004	December 31, 2003
	(Unaudited)	
<b>ASSETS:</b>		
Cash and cash equivalents	\$ 193,427	\$ 515,502
Marketable securities	224,091	272,765
Trade receivables, net	19,236	161,229
Inventory, net	68,361	91,703
Deferred tax assets	39,320	29,322
Other current assets	15,945	32,233
	<hr/>	<hr/>
Total Current Assets	560,380	1,102,754
Marketable securities	1,357,368	1,111,882
Property and equipment, net	294,307	273,597
Deferred tax assets, net	144,190	151,280
Intangible assets, net	17,453	96,694
Goodwill	13,614	13,614
Other assets	40,451	44,849
	<hr/>	<hr/>
Total Assets	\$ 2,427,763	\$ 2,794,670
	<hr/>	<hr/>

**LIABILITIES AND SHAREHOLDERS' EQUITY:**

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	<b>June 30,</b>	<b>December 31,</b>
Accounts payable	\$ 19,035	\$ 22,116
Accrued expenses	114,148	217,915
Product royalties payable	48,028	81,808
Advances from Wyeth	--	51,910
Taxes payable	120	120
Other current liabilities	11,267	16,846
	<hr/>	<hr/>
Total Current Liabilities	192,598	390,715
Long-term debt	506,664	681,223
Obligations to Evans	21,902	21,627
Other liabilities	1,693	1,887
	<hr/>	<hr/>
Total Liabilities	722,857	1,095,452
	<hr/>	<hr/>
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 and outstanding 249,023 at June 30, 2004 and 248,036 at December 31, 2003	2,552	2,543
Paid-in capital	2,686,286	2,673,059
Deferred compensation	(543)	(1,379)
Accumulated deficit	(762,668)	(772,936)
Accumulated other comprehensive income	8,496	27,733
	<hr/>	<hr/>
	1,934,123	1,929,020
Less: Treasury stock at cost; 6,223 shares at June 30, 2004 and 6,239 shares at December 31, 2003	(229,217)	(229,802)
	<hr/>	<hr/>
Total Shareholders' Equity	1,704,906	1,699,218
	<hr/>	<hr/>
Total Liabilities and Shareholders' Equity	\$ 2,427,763	\$ 2,794,670
	<hr/>	<hr/>

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

**MEDIMMUNE, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

(Unaudited)  
(in thousands, except per share data)

	<b>For the three months ended June 30,</b>		<b>For the six months ended June 30,</b>	
	<b>2004</b>	<b>2003</b>	<b>2004</b>	<b>2003</b>
Revenues:				
Product sales	\$ 90,744	\$ 80,596	\$ 573,953	\$ 511,705
Other revenue	2,932	31,935	8,724	35,446
	<hr/>	<hr/>	<hr/>	<hr/>
Total revenues	93,676	112,531	582,677	547,151
	<hr/>	<hr/>	<hr/>	<hr/>
Costs and expenses:				
Cost of sales	37,328	23,663	195,521	127,003
Research and development	67,921	29,824	117,685	61,495
Selling, general and administrative	58,860	48,841	182,592	164,085
Other operating expenses	2,041	1,415	3,859	22,871

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	For the		For the	
Impairment of intangible asset	72,957	--	72,957	--
Acquired in-process research and development	24,713	--	24,713	--
<b>Total expenses</b>	<b>263,820</b>	<b>103,743</b>	<b>597,327</b>	<b>375,454</b>
Operating (loss) earnings	(170,144)	8,788	(14,650)	171,697
Interest income	16,545	14,310	32,745	27,300
Interest expense	(2,096)	(1,604)	(4,262)	(3,403)
Gain (loss) on investment activities	464	(139)	7,171	(396)
(Loss) earnings before income taxes	(155,231)	21,355	21,004	195,198
(Benefit) provision for income taxes	(54,918)	7,901	10,289	72,223
<b>Net (loss) earnings</b>	<b>(\$100,313)</b>	<b>\$ 13,454</b>	<b>\$ 10,715</b>	<b>\$ 122,975</b>
<b>Basic (loss) earnings per share</b>	<b>(\$ 0.40)</b>	<b>\$ 0.05</b>	<b>\$ 0.04</b>	<b>\$ 0.49</b>
Shares used in calculation of basic (loss) earnings per share	248,722	252,106	248,455	251,836
<b>Diluted (loss) earnings per share</b>	<b>(\$ 0.40)</b>	<b>\$ 0.05</b>	<b>\$ 0.04</b>	<b>\$ 0.48</b>
Shares used in calculation of diluted (loss) earnings per share	248,722	258,200	249,812	257,390

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

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

	For the six months ended June 30,	
	2004	2003
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net earnings	\$ 10,715	\$ 122,975
Adjustments:		
Impairment of intangible asset	72,957	--
Deferred taxes	10,726	67,041
Deferred revenue	(221)	(4,580)
Advances from Wyeth	(51,910)	--
Depreciation and amortization	19,846	18,497
Amortization of premium on marketable securities	7,571	7,381
Amortization of deferred compensation	631	2,666
Amortization of premium on convertible subordinated notes	(391)	(933)
Amortization of bond issuance costs	1,779	--
Realized (gains) losses on investments	(7,172)	396
Gain on early redemption of convertible notes	(1,010)	--
Losses on write downs of inventory	26,517	20,519
Decrease in sales allowances	(20,392)	(27,461)
Decrease in restructuring liability for cash employee termination costs	--	(251)
Other	(335)	1,042
Other changes in assets and liabilities	34,557	(12,709)

	<b>For the</b>	
	<u>          </u>	<u>          </u>
Net cash provided by operating activities	103,868	194,583
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Increase in marketable securities	(210,760)	(183,567)
Capital expenditures	(34,465)	(43,573)
Investments in strategic alliances	(17,500)	(11,780)
Net cash used in investing activities	<u>(262,725)</u>	<u>(238,920)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from issuance of common stock	9,907	20,272
Debt repayments	(172,677)	--
Repayments on long-term obligations	(443)	(415)
Net cash (used in) provided by financing activities	<u>(163,213)</u>	<u>19,857</u>
Effect of exchange rate changes on cash	(5)	(53)
Net decrease in cash and cash equivalents	(322,075)	(24,533)
Cash and cash equivalents at beginning of period	<u>515,502</u>	<u>130,056</u>
Cash and cash equivalents at end of period	<u>\$ 193,427</u>	<u>\$ 105,523</u>

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 is focused on developing vaccines and antibodies that address significant medical needs in the areas of infectious diseases, autoimmune disease and cancer.

**2. Summary of Significant Accounting Policies**

*General*

The financial information presented as of and for the three months and six months ended June 30, 2004 (Q2 2004 and YTD 2004, respectively) and as of and for the three months and six months ended June 30, 2003 (Q2 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/A 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 otherwise considered unmarketable, the Company measures the amount of the permanent write down as the difference between the historical cost of the expired, excess or unmarketable inventory and its market value.

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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 production costs, 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 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 to stock-based employee compensation (in millions, except per share data):

	<b>Q2 2004</b>	<b>Q2 2003</b>	<b>YTD 2004</b>	<b>YTD 2003</b>
Net (loss) earnings, as reported	(\$100.3)	\$ 13.5	\$ 10.7	\$ 123.0
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	0.2	0.6	0.3	1.7
Deduct: stock-based employee compensation expense determined under the fair value based method for all awards, net of related tax effect	(15.5)	(24.8)	(25.3)	(49.0)
Pro forma net (loss) earnings	(\$115.6)	(\$10.7)	(\$14.3)	\$ 75.7
Basic (loss) earnings per share, as reported	(\$0.40)	\$0.05	\$0.04	\$0.49
Basic (loss) earnings per share, pro forma	(\$0.46)	(\$0.04)	(\$0.06)	\$0.30
Diluted (loss) earnings per share, as reported	(\$0.40)	\$0.05	\$0.04	\$0.48
Diluted (loss) earnings per share, pro forma	(\$0.46)	(\$0.04)	(\$0.06)	\$0.30

### *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, CAIV-T and all related technology. As a result of the dissolution, MedImmune reacquired the influenza vaccines franchise, and will assume full responsibility for the manufacturing, marketing, and sale of FluMist and any subsequent related product. Wyeth will provide bulk manufacturing materials and will transfer clinical trial data, as well as provide manufacturing services, during a transition that the companies expect to complete in large part by the fourth quarter of 2004.

Through June 30, 2004, the Company has made cash payments totaling \$50.7 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 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. This transaction was accounted for as a purchase of assets, and the initial purchase price was allocated to each of the components based on their relative fair values as determined by an independent valuation. Additional payments due, but not yet paid as of June 30, 2004, totaling approximately \$12.4 million were accrued for technology transfer and transition activities, including a milestone payment. The Company is also obligated to make additional payments under the agreements for milestones and sales related royalties, should certain conditions be met.

In connection with the transaction, the Company recorded a charge to in-process research and development of \$24.7 million during Q2 2004 as well as a permanent impairment charge of \$73.0 million 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 June 30, 2004 are comprised of the following (in millions):

Contract manufacturing agreement with Evans	\$ 39.0
Other intangible assets	0.4
	<hr/>
	39.4
Less accumulated amortization	(21.9)
	<hr/>
	\$ 17.5
	<hr/>

Amortization of intangible assets is computed on the straight-line method based on the estimated useful lives of the assets. Amortization expense for Q2 2004 and YTD 2004 was \$1.9 million and \$6.3 million, respectively. As of June 30, 2004, FluMist inventory includes approximately \$0.5 million of amortization costs associated with the contract manufacturing agreement with Evans Vaccines Limited, a wholly owned subsidiary of Chiron Corporation ( Evans ). The estimated aggregate amortization for the Evans agreement for the remainder of 2004 through 2006 is as follows: 2004, \$4.4 million; 2005, \$8.7 million; and 2006, \$4.4 million.

As a result of signing agreements to dissolve the collaboration with Wyeth for the nasal flu vaccine FluMist (Influenza Virus Vaccine Live, Intranasal) and all related technology and to reacquire rights to an investigational second-generation liquid formulation, Cold Adapted Influenza Vaccine-Trivalent (CAIV-T) from Wyeth in May 2004, we recorded a permanent impairment loss of \$73.0 million to write off the remaining unamortized cost of the intangible asset recorded for our worldwide collaboration with Wyeth.

### 5. Inventory

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

	June 30, 2004	December 31, 2003
	<hr/>	<hr/>
Raw Materials	\$13.2	\$ 11.6
Work in Process	41.3	39.3
Finished Goods	13.9	40.8
	<hr/>	<hr/>
	\$68.4	\$91.7

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June 30,

December 31,

The Company recorded permanent inventory write downs totaling \$14.6 million and \$28.1 million in cost of goods sold to reflect total FluMist inventories at net realizable value during Q2 2004 and the first half of 2004, respectively. During Q2 2003, the Company disposed of \$10.3 million of fully-reserved finished goods inventory related to the 2002/2003 flu season. During Q1 2003, prior to regulatory approval, the Company recorded permanent inventory write downs totaling \$19.6 million to other operating expenses to reflect total FluMist inventories at net realizable value.

### 6. Earnings per Share

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

	Q2 2004	Q2 2003	YTD 2004	YTD 2003
Denominator:				
Weighted average shares outstanding	248.7	252.1	248.5	251.8
Effect of dilutive securities: stock options, warrants, and convertible notes	--	6.1	1.3	5.6
Denominator for diluted EPS	248.7	258.2	249.8	257.4

The Company incurred a net loss for Q2 2004 and, accordingly, did not assume exercise or conversion of any of the Company's outstanding stock options, warrants, or convertible notes because to do so would be anti-dilutive. 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. As a result, options to purchase 21.5 million shares of the Company's common stock with exercise prices ranging from \$23.84 to \$83.25 per share were outstanding during Q1 2004, but were excluded from the computation of diluted earnings per share. Additionally, options to purchase 14.3 million shares of the Company's common stock with exercise prices ranging from \$35.41 to \$83.25 were outstanding during Q2 2003, but were excluded from the computation of diluted earnings per share. During Q1 2003, options to purchase 15.0 million shares of the Company's common stock with exercise prices ranging from \$30.16 to \$83.25 were outstanding, but were excluded from the computation of diluted earnings per share. The Company's 1% Convertible Senior Notes (the 1% Notes) are considered contingent convertible securities for all periods presented, meaning they are eligible for conversion to common stock only if certain requirements are met. The 1% Notes, which were excluded from the diluted earnings per share calculations, represent 7.3 million potential shares of common stock issuable upon conversion.

### 7. Income Taxes

Our effective tax rate for Q2 2004 was a 35% benefit, as compared to our 2003 effective rate of approximately 37%, reflecting \$6.9 million of acquired in-process research and development charges incurred during the quarter 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 quarterly effective rate to differ from the projected annual effective rate. Additional IPR&D charged during 2004 are all 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

	Q2 2004	Q2 2003	YTD 2004	YTD 2003
Net (loss) earnings	(\$100.3)	\$13.5	\$10.7	\$123.0
Change in foreign currency translation adjustment	(0.1)	0.2	(0.3)	1.0
Change in unrealized (loss) gain on investments, net of tax	(25.8)	9.6	(14.6)	13.3
Reclassification adjustment for realized gains on securities included in net (loss) earnings	--	--	6.9	--



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	Q2	Q2	YTD	YTD
Reclassification adjustment for realized losses on cash flow hedges included in net (loss) earnings	--	--	3.1	--
Change in unrealized gain (loss) on cash flow hedges, net of tax	--	--	(0.5)	(0.2)
	(\$126.2)	\$23.3	(\$8.5)	\$137.1
Comprehensive (loss) income	(\$126.2)	\$23.3	(\$8.5)	\$137.1

### 9. Recent 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.

### 10. 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 5¼% 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.

### 11. 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.

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. 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. 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.

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 defendants. 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 defendants. Suffolk, Westchester and Rockland (collectively, the Counties ) allege that the defendants manipulated the average wholesale price ( AWP ) causing the Counties to pay artificially inflated prices for covered drugs. In addition, the Counties 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 three 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 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. The Company is continuing to evaluate its position and intends to vigorously enforce its patents as appropriate.

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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 half of 2004, we continued to progress towards our short and long-term business goals. We saw 12% growth in our product sales for YTD 2004 as compared to YTD 2003, reflecting growth in Synagis sales and our recognition of FluMist product sales revenues related to the 2003/2004 flu season. From an operating results perspective, we earned \$0.04 per diluted share in YTD 2004 compared to diluted earnings per share of \$0.48 in YTD 2003, primarily reflecting charges incurred in 2004 for the reacquisition of the influenza vaccines franchise from Wyeth, including associated technology transfer and transition expenses. Our YTD 2003 earnings also included milestone payments of \$20.0 million for FDA approval of FluMist and \$7.5 million upon achieving \$100 million in international end-user Synagis sales.

Our efforts in the first half of 2004 included the determination of the future of our influenza vaccines franchise, including FluMist, a frozen formulation which is commercially available, and a second-generation liquid formulation, Cold Adapted Influenza Vaccine-Trivalent (CAIV-T) which is in phase 3 clinical development. 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 rights to this technology, and 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 also continued development of our pipeline of product candidates during the first half of 2004. Four Phase 2 trials are currently being conducted with Vitaxin in the following indications: rheumatoid arthritis, melanoma, prostate cancer and psoriasis. We are currently underway in a Phase 1 and 2 program with Numax, and 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 also filed a supplemental biologics license application for liquid Synagis, for which we received approval on July 23, 2004.

The Company's cash and marketable securities at June 30, 2004 were \$1.8 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, the Company 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 will assume full responsibility for the manufacturing, marketing, and sale of FluMist and any subsequent related product. As part of the dissolution, the Company acquired Wyeth's distribution facility in Louisville, Kentucky. Wyeth will provide bulk manufacturing materials and will transfer clinical trial data, as well as provide manufacturing services, during a transition that the companies expect to complete in large part by the fourth quarter of 2004. Through June 30, 2004, the Company has made payments totaling \$50.7 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 certain milestones for achieving certain goals for transition activities. Additional payments due, but not yet paid as of June 30, 2004, totaling approximately \$12.4 million were accrued for technology transfer and transition activities, including a milestone payment.

The notable impacts of the transaction, as well as anticipated effects for the last half 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 purchase of MedImmune Vaccines 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 Q2 2004 to write off the remaining unamortized cost of the intangible asset recorded for the collaboration.

**Acquired In-Process Research and Development-** We recorded an in-process research and development (IPR&D) charge of \$24.7 million during Q2 2004, representing the relative fair value of purchased in-process technologies at the acquisition date. Our calculation of relative fair value was determined by an independent valuation. A portion of the charges that occurred in Q2 2004 relate to milestone payments from us to Wyeth as they achieve certain contractual deliverables. Additional milestone payments, estimated to be approximately \$5 million, are projected to occur in the last half 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 Q2 2004 was a benefit of 35%, as compared to our 2003 effective rate of approximately 37%, reflecting the impact of the portion of IPR&D incurred during the 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 quarterly effective rate 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. 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 Q2 2004, we recorded a charge of \$24.7 million for acquired IPR&D in conjunction with our reacquisition of FluMist rights from Wyeth in May 2004. The charge represents the relative fair value of the in-process technologies acquired at the reacquisition date, calculated utilizing the income approach, of certain IPR&D projects, primarily CAIV-T. 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, we cannot predict the actual cash inflows or outflows 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 \$50 million and \$100 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 safe and effective 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 June 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.

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During Q1 2002, we recorded a charge of \$1,179.3 million for acquired IPR&D in conjunction with the Acquisition. Aviron's 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, 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, the refrigerator-stable version. Had we known at the time of the Acquisition that we would have a more narrow indication (the June 2003 approval was for 5 years to 49 years of age only) 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 and or receipt of specification waiver from regulatory agencies, and became available and was used for commercial sale.

We are required to state all of our inventory at lower of cost or market. In assessing the ultimate realization of inventories, we are required to make judgments as to multiple factors affecting our inventories and compare these with current or committed inventory levels. In the highly regulated industry in which we operate, raw materials, work-in-process and finished goods inventories have expiration dates that must be factored into our judgments about the recoverability of inventory costs. Additionally, if 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. 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 securing 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 nine months.

For all inventory components on hand as of June 30, 2004, we reviewed the following assumptions to determine the amount of any necessary reserves: expected production levels and estimated cost per dose; the expected sales volume; 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. Our review indicated no material changes had occurred to our evaluation performed as of December 31, 2003 and March 31, 2004. We therefore used the same methodology to calculate any additional adjustments required to value our FluMist inventories as of June 30, 2004 at net realizable value. This resulted in additional reserves of \$14.6 million for inventories, which were produced during Q2 2004.

As of December 31, 2003, we evaluated our inventories based upon the factors above. In our analysis, we considered the disappointing results of our 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 estimated price per dose to produce FluMist. Using these assumptions, we compared the expected amount to be received from FluMist sales to the expected cost to produce it to estimate the net realizable value of FluMist inventories to be produced throughout the season.

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

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	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
Q2 production	16.3	(14.6)	1.7
Q2 production scrapped	(8.4)	7.3	(1.1)
Q2 disposal of finished goods	(10.3)	10.3	--
As of June 30, 2004	\$ 54.2	(\$41.2)	\$ 13.0

Approximately \$1.1 million of net inventory was scrapped during Q2 2004 due to naturally occurring complications in the manufacturing process, which have since been resolved. Additionally, because finished FluMist product has an approved nine-month shelf life, 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. The write off could be as large as the current net finished goods inventory balance.

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.

#### 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:

- o historical trends for discounts, returns, rebate claims, or other claims
- o our current contracts with customers and current discount programs
- o actual performance of customers against contractual volume targets that drive discount levels
- o proportion of gross sales ultimately used by Medicaid patients
- o state Medicaid policies and our reimbursement practices
- o 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, our largest product, were to increase by 1%, our revenues for the 2003/2004 Synagis sales season (which runs from July 2003 to June 2004) would be reduced by approximately \$9 million. A decrease of 1% in the sales allowances for Synagis during the same period would increase our revenues by a similar approximation of \$9 million. During the second quarter of 2004, we reduced our total sales allowances by approximately \$6.1 million, 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 June 30, 2004 and December 31, 2003 were \$33.8 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.

**RESULTS OF OPERATIONS****Q2 2004 compared to Q2 2003****Revenues Product Sales**

<i>(in millions)</i>	<b>Q2 2004</b>	<b>Q2 2003</b>	<b>Growth</b>
Synagis	\$56.1	\$50.9	10%
Ethylol	25.0	24.1	4%
FluMist	1.2	--	N/A
Other Products	8.4	5.6	52%
	<hr/> \$90.7 <hr/>	<hr/> \$80.6 <hr/>	13%

Product sales grew 13% in Q2 2004 to \$90.7 million as compared to \$80.6 million in Q2 2003, primarily due to increased sales of Synagis. 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 inventory fluctuations. Of the overall 13% increase in product sales, approximately half, or six percentage points, were due to an increase in worldwide sales volumes. Four of the growth points were due to price increases and the remaining three growth points were due to reductions in sales allowances.

**Synagis** Synagis accounted for approximately 63% of our product sales in both reporting periods. Due to the seasonal nature of Synagis sales, only five to six percent of the respective overall seasonal sales (July 1 through June 30) typically occur in the second quarter. In Q2 2004, domestic sales of Synagis fell 13% to \$39.7 million from Q2 2003 sales of \$45.7 million primarily due to a decrease in unit volume, which we believe is partially due to our distributors reducing their inventories more significantly in Q2 2004 than in Q2 2003. This decrease was partially offset by the impact of a price increase and a reduction in our estimate of 2003/2004 sales allowances.

We record Synagis international product sales based on Abbott International's (AI's) sales price to customers, as defined in our agreement. Our reported international Synagis sales more than tripled to \$16.4 million for Q2 2004 as compared to \$5.2 million in Q2 2003. International sales for the quarter were favorably impacted by the early stocking of inventories for the 2004/2005 season. Also, our portion of AI's end user sales to customers reflected in Q2 2004 increased compared to Q2 2003, due to higher sales volumes and an increase in the average of AI's sales price caused by a change in the mix of countries to which we sell Synagis. The comparison to last year's international sales was also impacted by the favorable currency translation of a weaker U.S. dollar.

**FluMist** 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.

**Ethylol** Ethylol accounted for approximately 28% and 30% of our product sales in Q2 2004 and Q2 2003, respectively. Worldwide Ethylol sales grew 4% to \$25.0 million in Q2 2004, compared to \$24.1 million in Q2 2003. This growth was driven by the combined impact of a domestic price increase and a three percent increase in domestic unit sales, which was partially offset by an increase in our estimate of sales allowances. Sales to our international partner, Schering-Plough Corporation (Schering), in Q2 2004 decreased slightly from Q2 2003. We record Ethylol international product sales based on a percentage of Schering's end-user sales, as defined in our agreement.

**Other Products** Sales of other products in Q2 2004, which include sales of CytoGam, NeuTrexin, and by-products that result from the CytoGam manufacturing process, increased \$2.9 million from Q2 2003. The increase was driven by a \$4.3 million increase in CytoGam sales. We believe this increase is not entirely the result of an increase in demand for the product in Q2 2004, but is the result of last year's decision by our wholesalers to reduce inventory levels rather than purchase product from us during Q2 2003, which caused Q2 2003 sales to be lower. The increase in CytoGam sales is offset by decreases in sales of our other products, primarily RespiGam, which has been replaced in the marketplace by our second-generation RSV product, Synagis. During 2003, the Company determined that RespiGam 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 \$2.9 million for Q2 2004 compared to \$31.9 million in Q2 2003. During Q2 2003, we recorded \$20.0 million of milestone revenue from Wyeth, associated with the approval of FluMist. Also during Q2 2003, we recognized \$7.5 million of milestone revenue from AI 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 Q2 2004 increased 58% to \$37.3 million from \$23.7 million in Q2 2003. As a result, gross margins on product sales for Q2 2004 were 59%, down 12 percentage points from Q2 2003, primarily due to the permanent write downs of FluMist inventory produced in Q2 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 impact of higher CytoGam and Ethyol margins. Ethyol margins were improved due to a decrease in the domestic royalties owed to ALZA on sales of the product.

### **Research and Development Expenses**

Research and development expenses, as reported in the accompanying statement of operations, include both our normal on going expenses of drug discovery 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 \$67.9 million in Q2 2004 increased 128% from \$29.8 million in Q2 2003.

Of the \$67.9 million incurred in Q2 2004, approximately \$57.1 million related to the ongoing expenses of our internal drug discovery efforts and approximately \$10.8 million related to the impact of the reacquisition of the influenza vaccines franchise from Wyeth. Our drug discovery costs in Q2 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 Q2 2004, we progressed with four ongoing Phase 2 trials for Vitaxin targeting rheumatoid arthritis, melanoma, prostate cancer and psoriasis. We are also currently conducting a combined Phase 1 and 2 program with Numax, our second generation RSV monoclonal antibody product candidate. Additionally, we are continued our substantial clinical development efforts for FluMist and CAIV-T, including the administration and preparation for several new clinical trials in 2004. The costs incurred in Q2 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 related 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 continue our transition activities for FluMist and CAIV-T and 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 21% to \$58.9 million in Q2 2004 compared to \$48.8 million in Q2 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. Also included in SG&A expenses in Q2 2004 is \$0.8 million for other Wyeth-related transition activities that are expected to be complete by the end of 2004.

### **Other Operating Expenses**

Other operating expenses were \$2.0 million in Q2 2004 compared to \$1.4 million in Q2 2003. Other operating expenses primarily include excess capacity charges associated with the plasma production section of the Frederick Manufacturing Center.

### **Impairment of Intangible Asset**

As a result of entering into agreements to dissolve the collaboration with Wyeth during May 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 \$24.7 million for acquired IPR&D during Q2 2004 in conjunction with our reacquisition of the influenza vaccines franchise from Wyeth in April 2004. The charge represents the 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 \$16.5 million for Q2 2004, compared to \$14.3 million in Q2 2003, reflecting higher average cash balances available for investment. Interest expense for Q2 2004, net of amounts capitalized, was \$2.1 million, up from \$1.6 million in Q2 2003. This increase is largely due to a reduction in capitalized interest, as the Company's corporate headquarters was completed in Q1 2004. Further, we experienced a reduction in the rate at which interest was both expensed and capitalized due to the combined impact of the issuance of the 1% Notes in July 2003 and the retirement of the 5¼% Notes in March 2004.

### Gain (Loss) on Investment Activities

We earned \$0.5 million on investment activities during Q2 2004, primarily for gains on sales of portfolio securities, while we incurred \$0.1 million in losses for Q2 2003. Both amounts include our portion of our minority investees' operating results as required by the equity method of accounting.

### Taxes

We recorded a benefit for income taxes of \$54.9 million for Q2 2004, resulting in an effective rate of 35%. Comparatively, we recorded income tax expense of \$7.9 million for Q2 2003, resulting in an effective rate of 37%. The variance in the estimated effective tax rate between 2004 and 2003 is primarily due to the \$6.9 million of IPR&D charges incurred during the Q2 2004, which are not deductible for tax purposes. See further discussion of Income Taxes in the Dissolution of the Collaboration with Wyeth section of Management's Discussion and Analysis.

### Net (Loss) Earnings

Net loss for Q2 2004 was \$100.3 million, or \$0.40 per share, compared to net earnings for Q2 2003 of \$13.5 million or \$0.05 per share basic and diluted.

Shares used in computing net loss per share for Q2 2004 were 248.7 million. Shares used in computing basic earnings per share for Q2 2003 were 252.1 million, while shares used for computing diluted earnings per share were 258.2 million. The decrease in share count is primarily attributable to our purchase of treasury stock beginning in July 2003.

### YTD 2004 compared to YTD 2003

#### Revenues - Product Sales

	YTD 2004	YTD 2003	Growth
<i>(in millions)</i>			
Synagis	\$477.8	\$442.2	8%
FluMist	27.1	--	N/A
Ethyol			