

MEDIMMUNE INC /DE  
Form 10-Q  
October 25, 2005

## **UNITED STATES**

## **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 September 30, 2005**

**0-19131**

**(Commission File No.)**

## **MedImmune, Inc.**

**(Exact name of registrant as specified in its charter)**

**Delaware**

**(State or other jurisdiction of  
incorporation or organization)**

**52-1555759**

**(I. R. S. Employer  
Identification No.)**

**One MedImmune Way, Gaithersburg, MD 20878**

**(Address of principal executive offices) (Zip Code)**

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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

Indicate by check mark whether the registrant is a shell company (as defined by Rule 12b-2 of the Exchange Act). Yes No

As of October 20, 2005, 246,057,887 shares of Common Stock, par value \$0.01 per share, were outstanding.

**MEDIMMUNE, INC.**

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MedImmune, Synagis, CytoGam, Ethyol, FluMist, NeuTrexin, RespiGam and Vitaxin are registered trademarks of the Company. Numax is a trademark of the Company.

Unless otherwise indicated, this Quarterly Report is current as of September 30, 2005 and the Company undertakes no obligation to update it to reflect events or circumstances after the date of this Quarterly Report or to reflect the occurrence of unanticipated events.

**PART I FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****MEDIMMUNE, INC.****CONSOLIDATED BALANCE SHEETS**

(in millions)

	<b>September 30, 2005 (Unaudited)</b>	<b>December 31, 2004</b>
<b>ASSETS:</b>		
Cash and cash equivalents	\$7.5	\$171.3
Marketable securities	457.7	172.6
Trade receivables, net	137.3	203.3
Inventory, net	91.7	64.1
Deferred tax assets, net	54.1	50.6
Other current assets	25.0	31.9
Total Current Assets	773.3	693.8
Marketable securities	954.2	1,362.2
Property and equipment, net	354.8	310.9
Deferred tax assets, net	124.9	127.3
Intangible assets, net	363.0	13.1
Goodwill	20.0	24.8
Other assets	44.5	32.3
Total Assets	\$2,634.7	\$2,564.4
<b>LIABILITIES AND SHAREHOLDERS' EQUITY:</b>		
Accounts payable	\$64.8	\$34.7
Accrued expenses	121.1	231.8
Product royalties payable	22.3	85.9
Convertible senior notes	500.0	-
Other current liabilities	242.3	11.4
Total Current Liabilities	950.5	363.8
Convertible senior notes	-	500.0
Other long-term debt	5.4	6.2
Other liabilities	89.7	19.8
Total Liabilities	1,045.6	889.8
Commitments and Contingencies		
<b>SHAREHOLDERS' EQUITY:</b>		
Preferred stock, \$.01 par value; authorized 5.5 shares; none issued or outstanding	-	-
Common stock, \$.01 par value; authorized 420.0 shares; issued 255.5 at September 30, 2005 and 255.4 at December 31, 2004	2.6	2.6
Paid-in capital	2,693.7	2,690.0
Deferred compensation	-	(0.1)
Accumulated deficit	(804.0)	(788.5)
Accumulated other comprehensive income	2.2	11.1
	1,894.5	1,915.1
Less: Treasury stock at cost; 9.7 shares at September 30, 2005 and 6.9 shares at December 31, 2004	(305.4)	(240.5)

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Total Shareholders' Equity	1,589.1	1,674.6
Total Liabilities and Shareholders' Equity	\$2,634.7	\$2,564.4

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

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**MEDIMMUNE, INC.****CONSOLIDATED STATEMENTS OF OPERATIONS****(Unaudited)**

(in millions, except per share data)

	<b>Three months ended September 30,</b>		<b>Nine months ended September 30,</b>	
	<b>2005</b>	<b>2004</b>	<b>2005</b>	<b>2004</b>
<b>Revenues:</b>				
Product sales	\$ 146.0	\$ 92.3	\$ 739.4	\$ 666.2
Other revenue	7.6	0.4	12.5	9.1
Total revenues	153.6	92.7	751.9	675.3
<b>Costs and expenses:</b>				
Cost of sales	48.7	40.4	196.5	235.9
Research and development	119.1	84.5	267.7	202.1
Selling, general and administrative	81.1	68.0	299.5	250.6
Other operating expenses	3.8	2.4	9.3	6.3
Impairment of intangible asset	-	-	-	73.0
Acquired in-process research and development	4.7	3.8	4.7	28.5
Total expenses	257.4	199.1	777.7	796.4
Operating loss	(103.8)	(106.4)	(25.8)	(121.1)
Interest income	15.1	17.3	49.4	50.0
Interest expense	(2.3)	(2.0)	(6.2)	(6.3)
Gain (loss) on investment activities	0.4	(12.0)	(0.5)	(4.7)
Earnings (loss) before income taxes	(90.6)	(103.1)	16.9	(82.1)
Income tax provision (benefit)	(26.5)	(38.1)	11.1	(27.8)
Net earnings (loss)	\$ (64.1)	\$ (65.0)	\$ 5.8	\$ (54.3)
Basic earnings (loss) per share	\$ (0.26)	\$ (0.26)	\$ 0.02	\$ (0.22)
Shares used in calculation of basic earnings (loss) per share	245.9	248.9	247.1	248.6
Diluted earnings (loss) per share	\$ (0.26)	\$ (0.26)	\$ 0.02	\$ (0.22)
Shares used in calculation of diluted earnings (loss) per share	245.9	248.9	249.4	248.6

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



## MEDIMMUNE, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(in millions)

	<b>Nine months ended September 30,</b>	
	<b>2005</b>	<b>2004</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net earnings (loss)	\$ 5.8	\$ (54.3)
Adjustment to reconcile net earnings (loss) to net cash provided by operating activities:		
Impairment of intangible asset	-	73.0
Charges for acquired in-process research and development	4.7	28.5
Deferred taxes	11.0	(24.8)
Advances from Wyeth	-	(51.9)
Depreciation and amortization	29.1	28.6
Amortization of premium on marketable securities	11.5	10.3
Realized losses on investments	0.5	4.7
Losses on write downs of inventory	7.6	40.2
Decrease in sales allowances	(26.8)	(27.7)
Other, net	3.2	(0.9)
Other changes in assets and liabilities	(70.9)	(52.6)
Net cash used in operating activities	(24.3)	(26.9)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Decrease (increase) in marketable securities, net	98.3	(185.5)
Capital expenditures	(64.3)	(54.2)
Purchase of promotion rights from Abbott	(70.0)	-
Purchase of assets from Wyeth	-	(32.0)
Investments in strategic alliances	(12.9)	(23.1)
Net cash used in investing activities	(48.9)	(294.8)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from issuance of common stock	19.7	12.1
Share repurchases	(105.9)	(15.0)
Debt prepayments	-	(172.7)
Repayments of long-term obligations	(4.5)	(0.6)
Net cash used in financing activities	(90.7)	(176.2)
Effect of exchange rate changes on cash	0.1	-
Net decrease in cash and cash equivalents	(163.8)	(497.9)
Cash and cash equivalents at beginning of period	171.3	515.5
Cash and cash equivalents at end of period	\$ 7.5	\$ 17.6

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





**MEDIMMUNE, INC.**

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS -CONTINUED**

**(Unaudited)**

**Supplemental schedule of noncash investing activities:**

In August 2005, the Company amended its co-promotion agreement with Abbott Laboratories ( Abbott ) for sales of Synagis in the United States to, among other things, assume full selling and marketing responsibilities for Synagis beginning in July 2006. In connection with this transaction, the Company recorded an intangible asset of \$360.4 million which represents the estimated fair value of the exclusive promotion rights, determined as the aggregate value of the incremental payments to be made to Abbott as a result of the amended terms of the agreement in excess of the value of the co-promotion services to be rendered, as determined under the previous agreement. Of the \$360.4 million recorded as an intangible asset, \$70.0 million represents cash payments made during Q3 2005 and the remaining balance of \$290.4 million represents the present value of the future incremental payments that the Company deems probable, which have been recorded as liabilities in the consolidated balance sheet (see Note 3).

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

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**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 is committed to advancing science to develop better medicines that help people live healthier, longer and more satisfying lives. The Company currently focuses its efforts on using biotechnology to produce innovative products for prevention and treatment in the therapeutic areas of infectious disease, oncology and immunology. The Company's scientific expertise is largely in the areas of monoclonal antibodies and vaccines. The Company markets four products, Synagis, FluMist, Ethyol and CytoGam, and has a diverse pipeline of development-stage products.

**2. Summary of Significant Accounting Policies**

*General*

The financial information presented as of and for the three and nine months ended September 30, 2005 (Q3 2005 and YTD 2005, respectively) and for the three and nine months ended September 30, 2004 (Q3 2004 and YTD 2004, respectively) is unaudited. In the opinion of the Company's management, the financial information presented herein contains all adjustments necessary for a fair presentation of results for the interim periods presented. The Company's operations and financial results are highly seasonal. 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 for the year ended December 31, 2004 and the Company's Quarterly Reports on Form 10-Q for the quarters ended March 31, 2005 and June 30, 2005.

*New Accounting Pronouncements*

In December 2004, the Financial Accounting Standards Board (FASB) issued SFAS 123R, a revision of SFAS 123, Accounting for Stock-based Compensation. SFAS 123R requires public companies to recognize expense associated with share-based compensation arrangements, including employee stock options, using a fair value-based option pricing model, and eliminates the alternative to use the intrinsic value method of accounting for share-based payments under Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees (APB 25). SFAS 123R will be effective for the Company's fiscal year beginning January 1, 2006. Adoption of the expense provisions of the statement is expected to have a material impact on the Company's results of operations. The Company has determined that it will apply the modified prospective transition method upon adoption. Under this method, compensation expense will be reflected in the financial statements beginning January 1, 2006 with no restatement of prior periods. As such, compensation expense will be recognized for awards that are granted, modified, repurchased or cancelled on or after January 1, 2006 as well as for the portion of awards previously granted that have not vested as of January 1, 2006. Upon adoption, the Company will select an expense attribution method to use for new share-based awards that have graded-vesting features and service conditions. Currently, the Company anticipates implementing the straight-line expense attribution method, whereas the Company's current expense attribution method is the graded-vesting method, an accelerated method, described by FASB Interpretation No. 28, Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plans (FIN 28).

*Stock-based Compensation*

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Compensation costs attributable to stock option and similar plans are currently 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 APB 25. Such amount, if any, is recognized over the related vesting period.

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

	<b>Q3 2005</b>	<b>Q3 2004(1)</b>	<b>YTD 2005</b>	<b>YTD 2004(1)</b>
Net earnings (loss), as reported	\$ (64.1)	\$ (65.0)	\$ 5.8	\$ (54.3)
Add:				
Stock-based employee compensation expense included in historical results for the vesting of stock options assumed in conjunction with the Aviron 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	0.1	0.5
Deduct:				
Stock-based employee compensation expense determined under the fair value based method for all awards, net of related tax effect	(9.9)	(12.9)	(34.5)	(44.1)
Pro forma net loss	\$ (74.0)	\$ (77.8)	\$ (28.6)	\$ (97.9)
Basic earnings (loss) per share, as reported	\$ (0.26)	\$ (0.26)	\$ 0.02	\$ (0.22)
Basic earnings (loss) per share, pro forma	\$ (0.30)	\$ (0.31)	\$ (0.12)	\$ (0.39)
Diluted earnings (loss) per share, as reported	\$ (0.26)	\$ (0.26)	\$ 0.02	\$ (0.22)
Diluted earnings (loss) per share, pro forma	\$ (0.30)	\$ (0.31)	\$ (0.12)	\$ (0.39)

- (1) The pro forma net losses for Q3 2004 and YTD 2004 of \$77.8 million and \$97.9 million, respectively, have been recomputed from the pro forma net losses previously disclosed of \$79.3 million and \$99.3 million, respectively, to reflect a revised estimated tax effect and to properly reflect the Company's accounting policy for amortization of compensation costs using the graded-vesting method described by FIN 28.

As of September 30, 2005, there was approximately \$36 million of total unrecognized pro forma compensation cost, net of tax, related to nonvested stock option awards. Approximately 23% and 52% of this unrecognized compensation cost will be amortized during the remainder of 2005 (for disclosure purposes) and in 2006, respectively.

Effective January 1, 2005, the Company has estimated the fair value of stock compensation expense associated with employee stock options using the binomial model approach. The Company believes that the binomial approach provides a better measure of fair value of employee stock options because it incorporates assumptions about patterns of employee exercises in relation to such considerations as stock price appreciation, post-vesting employment termination behavior, the contractual term of the option and other factors. Historically, the Company estimated the fair value of employee stock options using the Black-Scholes option pricing model, which does not incorporate such correlation assumptions.

Based on an analysis of economic data that marketplace participants would likely use in determining an exchange price for an option, the Company's weighted-average estimate of expected volatility for YTD 2005 ranged from 28% to 32%, reflecting the implied volatility determined from the market prices of traded call options on the Company's stock. During YTD 2004, the weighted-average estimate of expected volatility using monthly observations ranged from 48% to 50%, based on the historical volatility over the expected term.

The following disclosure provides a description of the significant assumptions used during 2005 and 2004 to estimate the fair value of the Company's employee stock option awards.

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2005 - The fair value of employee stock options granted during 2005 was estimated using a binomial model that uses the weighted-average assumptions shown in the table below. The Company uses historical data to estimate option exercise and employee termination within the binomial model; separate groups of employees that have similar historical exercise behavior are considered separately for valuation purposes. The expected life of an option is derived from the output of the binomial model and represents the period of time that options granted are expected to be outstanding; the range given below results from certain groups of employees exhibiting different exercise patterns. The risk-free interest rate is based on the rate currently available for zero-coupon U.S. government issues with a term equal to the contractual life of the option.

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	<b>Q3 2005</b>		<b>Q2 2005</b>		<b>Q1 2005</b>	
Option pricing model	Binomial		Binomial		Binomial	
Expected stock price volatility	28	%	31	%	32	%
Expected dividend yield	0	%	0	%	0	%
Expected life of option-years	4.5 to 4.9		4.5 to 5.4		4.6 to 5.1	
Risk-free interest rate	4.2	%	4.2	%	4.3	%
Weighted average fair value of options granted	\$ 8.96		\$ 9.41		\$ 8.27	

2004 - The fair value of employee stock options granted during 2004 was estimated using a Black-Scholes model that uses the weighted-average assumptions shown in the table below. The expected life of an option was derived from historical stock option exercise experience. The risk-free interest rate was based on the rate currently available for zero-coupon U.S. government issues with a term equal to the expected life of the option.

	<b>Q3 2004</b>		<b>Q2 2004</b>		<b>Q1 2004</b>	
Option pricing model	Black-Scholes		Black-Scholes		Black-Scholes	
Expected stock price volatility	48	%	50	%	50	%
Expected dividend yield	0	%	0	%	0	%
Expected life of option-years	5.0		5.0		5.0	
Risk-free interest rate	3.5	%	3.9	%	2.8	%
Weighted average fair value of options granted	\$ 10.65		\$ 11.49		\$ 11.07	

#### *Product Royalties*

During the second quarter of 2005, the Company recouped approximately \$12.1 million from licensors related to overpayments under various royalty agreements. During Q3 2005, the Company recognized \$4.9 million of this royalty recoupment as a reduction to cost of goods sold after determining that related contingencies had been resolved. The remaining amount has been deferred until fully realizable and therefore is recorded in Other Current Liabilities within the consolidated balance sheet.

#### *Reclassifications*

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

### **3. Amendment of Co-Promotion Agreement with Abbott Laboratories**

In August 2005, the Company amended its co-promotion agreement with Abbott Laboratories ( Abbott ) for sales of Synagis in the United States. Under the terms of the amended agreement, Abbott will continue to provide promotional activities with respect to Synagis until June 30, 2006, at which time the Company will take full responsibility for sales and marketing in the United States. The Company will continue to pay Abbott for their co-promotion services during the 2005-2006 respiratory syncytial virus ( RSV ) season as provided for under the original agreement. The Company has agreed to make certain incremental payments over and above the previous co-promotion agreement to Abbott through December 31, 2006, including milestone-based payments and increased incentive payments contingent upon the achievement of certain sales thresholds. In addition, if Numax, the Company's second-generation anti-RSV monoclonal antibody that is currently in Phase 3 development, is not approved by the United States Food and Drug Administration before September 1, 2008, the Company would pay Abbott a portion of the proceeds from the sales of Synagis in the U.S. for up to a two-year period beginning at such time. The present value of the incremental payments that the Company deems probable have been recorded as liabilities in the consolidated balance sheet as follows: Other Current Liabilities, \$201.7



million; Other Liabilities, \$88.7 million.

In connection with this transaction, the Company recorded an intangible asset of \$360.4 million which represents the estimated fair value of the exclusive promotion rights, determined as the aggregate present value of the probable incremental payments to be made as a result of the amended terms of the agreement in excess of the value of the co-promotion services to be rendered, as determined under the original agreement. The intangible asset will be amortized ratably over future sales of Synagis over the expected period of active sales and marketing activity in the United States (see Note 6).

#### **4. Dissolution of the Collaboration with Wyeth**

During the second quarter of 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 assumed full responsibility for the manufacturing, marketing, and sale of FluMist and any subsequent related

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product. Wyeth provided bulk manufacturing materials and transferred clinical trial data, as well as provided manufacturing services, during a transition that was completed in large part by the end of 2004. In connection with the dissolution of the collaboration, the Company agreed to make certain future milestone payments related to the development of CAIV-T. The Company recorded charges for in-process research and development of \$4.7 million and \$3.8 million during Q3 2005 and Q3 2004, respectively, and \$28.5 million during YTD 2004 related to milestone payments and other payments. A permanent impairment charge of \$73.0 million was recorded during YTD 2004 to write off the remaining unamortized cost of the intangible asset recorded for the worldwide collaboration with Wyeth.

### 5. Collaborative Agreements

In February 2005, the Company amended its international distribution agreement with Abbott International ( AI ) to include the exclusive distribution of Numax outside of the United States, if and to the extent approved for marketing by the appropriate regulatory authorities. Under the amended agreement, AI pays the Company additional compensation as compared to the original agreement, and such amounts in excess of estimated fair value for product sales of Synagis are recognized as other revenue in the consolidated statement of operations.

In February 2005, the Company amended its agreement with GlaxoSmithKline ( GSK ) for the development of an HPV vaccine. Under the amended agreement, the Company, in addition to receiving milestone payments and royalties from GSK, may also receive certain milestone payments and royalties on future development and sales of an investigational HPV vaccine now in Phase 3 development by Merck & Co., Inc.

In August 2005, the Company licensed worldwide rights from GSK to develop certain anti-Staphylococcal monoclonal antibodies, the lead antibody being in Phase 2 clinical development for the prevention of serious bloodstream infections caused by Staphylococcus in low-birthweight infants. The Company will be responsible for future research and development and any resulting second-generation monoclonal antibodies as well as all future sales and marketing activities worldwide. Under the terms of the agreement, the Company agreed to provide an upfront fee, potential milestone payments and royalties on any resulting marketed products. The Company has also assumed responsibility for future milestone and royalty payment obligations to Biosynexus Inc., from which GSK originally licensed the BSYX-A110 antibody and related rights in 2002.

In September 2005, the Company entered into a collaborative agreement with VasGene Therapeutics, Inc. ( VasGene ) to develop cancer-focused monoclonal antibodies targeting a novel member of a subfamily of receptor tyrosine kinases, EphB4, as well as its ligand, EphrinB2. Under the terms of the agreement, the Company will be responsible for the clinical development and commercialization of any resulting products. VasGene will provide research and development support in exchange for an upfront fee, development and regulatory milestone payments, as well as royalties on any resulting marketed products.

The Company recorded charges totaling \$35.7 million and \$41.7 million during Q3 2005 and YTD 2005, respectively, associated with upfront fees and milestone payments under licensing agreements and research collaborations, which are included as a component of research and development expense in the consolidated statements of operations.

### 6. Intangible Assets

The Company's intangible assets are definite-lived assets stated at 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 are comprised of the following (in millions):

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	<b>September 30, 2005</b>		<b>December 31, 2004</b>	
	<b>Gross Carrying</b>	<b>Accumulated</b>	<b>Gross Carrying</b>	<b>Accumulated</b>
	<b>Amount</b>	<b>Amortization</b>	<b>Amount</b>	<b>Amortization</b>
Promotion rights acquired from Abbott	\$ 360.4	\$ (3.9)	\$ -	\$ -
Manufacturing know-how acquired from Evans	39.0	(32.5)	39.0	(25.9)
Other intangible assets	0.4	(0.4)	0.4	(0.4)
Total	\$ 399.8	\$ (36.8)	\$ 39.4	\$ (26.3)

As discussed in Note 3, the Company recorded an intangible asset of \$360.4 million during Q3 2005 in conjunction with the reacquisition of the co-promotion rights for Synagis in the United States. Amortization of the intangible asset will be computed based on future sales of Synagis over the expected period of active sales and marketing efforts in the United States,

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which is projected to continue through the first half of 2009.

Amortization of the Evans intangible asset and other intangible assets is computed on the straight-line method based on the estimated useful lives of the assets.

Amortization for the Company's intangible assets for Q3 2005 and Q3 2004 was \$6.1 million and \$2.2 million, respectively. Amortization for YTD 2005 and YTD 2004 was \$10.5 million and \$8.5 million, respectively. The estimated aggregate amortization for the remaining life of the assets is as follows (in millions):

For the three months ended December 31, 2005	\$ 40.9
For the year ended December 31, 2006	103.1
For the year ended December 31, 2007	104.9
For the year ended December 31, 2008	84.3
For the six months ended June 30, 2009	29.8
	\$ 363.0

### 7. Inventory

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

	September 30, 2005	December 31, 2004
Raw Materials	\$ 13.1	\$ 16.5
Work in Process	40.2	38.3
Finished Goods	38.4	9.3
	\$ 91.7	\$ 64.1

The Company recorded permanent inventory write-downs totaling \$14.0 million during Q3 2004, and \$7.6 million and \$40.2 million during YTD 2005 and YTD 2004, respectively, in cost of goods sold to reflect total FluMist inventories at net realizable value. No write-downs of FluMist inventories were recorded in Q3 2005. The Company recorded permanent inventory write-downs of \$3.3 million during Q3 2005 for certain Synagis lots that were determined to be nonsaleable as they are outside of normal specifications and not recoverable.

### 8. Earnings per Share

The following is a reconciliation of the numerators and denominators of the diluted EPS computation (in millions):

	Q3 2005	Q3 2004	YTD 2005	YTD 2004
Numerator:				
Net earnings (loss) for basic EPS	\$ (64.1)	\$ (65.0)	\$ 5.8	\$ (54.3)

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Adjustments for interest expense on 1% Convertible Senior Notes, net of tax (1)	-	-	-	-
Earnings (loss) for diluted EPS	\$ (64.1)	\$ (65.0)	\$ 5.8	\$ (54.3)
Denominator:				
Weighted average shares for basic EPS	245.9	248.9	247.1	248.6
Effect of dilutive securities:				
Stock options and warrants	-	-	2.3	-
1% Convertible Senior Notes (1)	-	-	-	-
Weighted average shares for diluted EPS	245.9	248.9	249.4	248.6
Basic earnings (loss) per share	\$ (0.26)	\$ (0.26)	\$ 0.02	\$ (0.22)
Diluted earnings (loss) per share	\$ (0.26)	\$ (0.26)	\$ 0.02	\$ (0.22)

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(1) EITF Issue No. 04-8, The Effect of Contingently Convertible Debt on Diluted Earnings per Share, which became effective during the fourth quarter of 2004, 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. Under the provisions of EITF 04-8, the Company's 1% Convertible Senior Notes, which represent 7.3 million potential shares of common stock, are included in the calculation of diluted earnings per share using the if-converted method whether or not the contingent requirements have been met for conversion to common stock, unless the effect is anti-dilutive. For all periods presented, these convertible senior notes were anti-dilutive.

The Company incurred a net loss for Q3 2005, Q3 2004 and YTD 2004 and, accordingly, did not assume exercise or conversion of any of the Company's outstanding stock options or warrants during the periods because to do so would be anti-dilutive. As a result, options and warrants to purchase 33.4 million and 30.7 million shares of common stock were outstanding at September 30, 2005 and 2004, respectively, but were excluded from the calculation of diluted earnings per share.

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. Options to purchase 18.5 million shares of common stock at prices ranging from \$26.35 to \$83.25 per share, were outstanding as of September 30, 2005 but were not included in the computation of diluted earnings per share for YTD 2005 because the exercise price of the options exceeded the average market price.

## 9. Income Taxes

The Company's effective tax rate was 29% for Q3 2005 compared to an effective tax rate of 37% for Q3 2004. The effective tax rate for YTD 2005 was 65% compared to an effective tax rate of 34% for YTD 2004. The effective rates for Q3 2005 and YTD 2005 were impacted by a correction to the prior accounting for the reversal of \$4.8 million of valuation allowances associated with the utilization of certain acquired income tax carryforwards. The correction was comprised of relatively small amounts related to reporting periods dating back to the acquisition of Aviron in January 2002. The correction resulted in additional tax expense of approximately \$4.8 million during Q3 2005 and a corresponding reduction to goodwill on the Company's consolidated balance sheet. The effective tax rate for Q3 2004 and YTD 2004 was impacted by approximately \$6.9 million of non-deductible charges for in-process research and development incurred during the second quarter of 2004.

## 10. Comprehensive Income

	<b>Q3 2005</b>	<b>Q3 2004</b>	<b>YTD 2005</b>	<b>YTD 2004</b>
Net earnings (loss)	\$ (64.1)	\$ (65.0)	\$ 5.8	\$ (54.3)
Change in foreign currency translations adjustment	-	0.1	(0.8)	(0.2)
Change in unrealized gain (loss) on investments, net of tax	0.9	6.5	(8.1)	(15.0)
Change in unrealized gain (loss) on cash flow hedges, net of tax	-	(0.2)	-	2.4
Comprehensive loss	\$ (63.2)	\$ (58.6)	\$ (3.1)	\$ (67.1)

Reclassification adjustments, net of tax, during Q3 2004 and YTD 2004 were \$1.0 million and \$5.4 million, respectively. Reclassification adjustments for Q3 2005 and YTD 2005 were immaterial.

**11. Shareholders Equity**

During Q3 2005, the Company repurchased approximately 1.4 million shares of common stock under the stock repurchase program at a cost of \$38.4 million, or an average cost of \$27.35 per share. During YTD 2005, the Company repurchased approximately 4.0 million shares of common stock under the stock repurchase program at a cost of \$105.9 million, or an average cost of \$26.18 per share. Through October 20, 2005, the Company has not repurchased additional treasury shares. The Company is holding repurchased shares as treasury shares and is using them for general corporate purposes, including but not limited to issuance upon exercise of outstanding stock options and acquisition-related transactions.

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## 12. Long-Term Debt

The holders of the Company's 1% convertible senior notes may require the Company to redeem the notes on July 15, 2006, as provided for under the notes indenture. If the holders exercise their right to require the Company to purchase all or a portion of their notes in July 2006, the Company will be required to purchase the notes for cash at 100% of the principal amount of the notes, plus any accrued and unpaid interest, contingent interest, if any, and liquidated damages, if any. As such, the aggregate principal amount of the notes of \$500 million has been reclassified to current liabilities within the consolidated balance sheet as of September 30, 2005.

## 13. Legal Proceedings

The Company's material legal proceedings are described in Note 17 to the consolidated financial statements included with the Company's Annual Report on Form 10-K for the year ended December 31, 2004, as updated in the Company's Quarterly Reports on Form 10-Q for the quarters ended March 31, 2005 and June 30, 2005. There have not been any material developments in the proceedings between the Company and Sun Pharmaceutical Industries Limited other than those previously disclosed. With respect to the other legal proceedings described therein, the following material developments have occurred:

In the Company's suit against Centocor, Inc., the United States Court of Appeals for the Federal Circuit issued a decision on June 1, 2005 denying the Company's appeal. The Company filed a Petition for Rehearing en banc which was denied on August 25, 2005 and the Company is exploring its various options, which could include filing a petition for certiorari with the United States Supreme Court.

In the Company's suit against Genentech, Inc., the United States Court of Appeals for the Federal Circuit issued a decision on October 18, 2005 denying the Company's appeal. The Company is exploring its various options, which could include filing a Petition for Rehearing en banc, or filing a petition for certiorari with the United States Supreme Court.

With respect to the various pending Average Wholesale Price litigation cases, as of September 30, 2005, the Company estimates the range of possible pre-tax loss from the Alabama action, the New York City action and the New York State County actions (both consolidated and unconsolidated) to be between \$0 to \$14 million, exclusive of alleged treble damages, best price related claims and other asserted state law causes of action. The Company intends to vigorously defend the claims asserted in such complaints.

In addition, on October 20, 2005, the Company became aware of a lawsuit filed by the State of Mississippi naming approximately 50 defendants, including the Company. The Complaint alleges causes of action for state Medicaid fraud, deceptive trade practices, false advertising, crimes against the sovereignty, mail fraud, restraint of trade, common law fraud, and unjust enrichment. The Mississippi case is another in a series of Average Wholesale Price litigation cases, like those currently pending against various pharmaceutical manufacturers, including the Company, and filed by various Counties in New York, New York City and the State of Alabama. The Company intends to vigorously defend the claims asserted in this new complaint.

## 14. Subsequent Event

On October 14, 2005, the Company acquired the outstanding equity interests of Collective, a privately-held early-stage biopharmaceutical company, for approximately \$44 million in cash, net of cash acquired of approximately \$9 million. Collective has three preclinical stage programs developing monoclonal antibodies that target the B-cell antigens CD19, CD20 and CD22, which are believed to play important roles in



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regulating the immune system and offer potential treatments for patients battling cancer and autoimmune diseases. Under the terms of the agreement, the Company has also agreed to pay Collective's shareholders future contingent payments of up to approximately \$105 million should the antibody programs achieve certain product development and sales milestones. The Company's wholly-owned venture capital subsidiary, MedImmune Ventures, Inc., owned approximately 10% of the outstanding equity interests of Collective prior to the acquisition. The transaction will be accounted for as a purchase of assets, and the purchase price will be allocated to assets acquired and liabilities assumed based on their relative fair values. In connection with the transaction, the Company expects to record a charge for acquired in-process research and development of approximately \$42 million to \$47 million during the fourth quarter of 2005, based on a preliminary valuation. The charge for acquired in-process research and development will not be deductible for tax purposes, causing the Company's effective tax rate for the full year 2005 to increase to approximately 94%.

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## 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 Annual Report on Form 10-K for the year ended December 31, 2004.*

### INTRODUCTION

MedImmune is committed to advancing science to develop better medicines that help people live healthier, longer and more satisfying lives. MedImmune currently focuses its efforts 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 markets four products, Synagis, FluMist, Ethyol and CytoGam, and has a diverse pipeline of development-stage products.

### OVERVIEW OF 2005

Total revenues increased 11% in YTD 2005 as compared to YTD 2004, reflecting 16% growth in sales of Synagis, offset by lower product sales of FluMist, due to the timing of revenue recognition related to the 2003/2004 influenza season. We recorded diluted net earnings of \$0.02 per share in YTD 2005 compared to diluted net loss per share of \$0.22 in YTD 2004. YTD 2004 results reflect the impact of the in-process research and development and impairment charges totaling \$101.5 million incurred for the reacquisition of the influenza vaccines franchise from Wyeth. The growth in net income in YTD 2005 is also attributable to a 26% increase in gross profit, partially offset by increased selling, general and administrative expenses, and research and development spending.

During 2005, we amended our distribution arrangement with Abbott International (AI) to include Numax, which provides us with a larger portion of the economics from our respiratory syncytial virus (RSV) franchise outside the U.S. and provides us with the opportunity to participate directly in the commercialization of Numax outside the United States. We also amended our co-promotion agreement with Abbott Laboratories (Abbott) to take full responsibility for the sales and marketing of Synagis in the U.S. starting in the 2006-2007 RSV season, which will provide us with strategic and operational advantages as we prepare for the continued growth of the pediatric infectious disease component of our business.

Our research and development efforts in YTD 2005 included completion of the Phase 3 study to bridge refrigerator-stable CAIV-T to frozen FluMist, which successfully demonstrated equivalent immunogenicity. In September 2005, we submitted a supplemental Biologics License Application with the U.S. Food and Drug Administration (FDA) for approval to use CAIV-T in preventing influenza in healthy individuals 5 to 49 years of age, and we submitted an application for our new bulk vaccine manufacturing facility in Speke, England. In addition, we continued the preparatory steps required for unblinding the Phase 3 efficacy trial results with CAIV-T in the fourth quarter of 2005. We also completed dosing patients in the first Northern Hemisphere portion for our pivotal Phase 3 study for Numax and enrolled additional patients for the Southern Hemisphere component of the study, and completed patient enrollment in our Phase 2 prostate cancer study with Vitaxin. We also filed investigational new drug applications to begin clinical studies of our antibody candidate targeting lupus and our combination RSV and parainfluenza virus type-3 (PIV-3) vaccine candidate. In October 2005, we received regulatory approval in Japan for the use of Synagis as a prevention in pediatric patients with hemodynamically significant congenital heart disease.

During the year, we also expanded our pipeline of potential product candidates through the in-licensing and acquisition of new product candidates and technologies. We licensed worldwide rights from GlaxoSmithKline ( GSK ) to develop certain anti-Staphylococcal monoclonal antibodies, the lead antibody being in Phase 2 clinical development for the prevention of serious bloodstream infections caused by Staphylococcus in low-birthweight infants. We also expanded our oncology pipeline through new collaborations with VasGene Therapeutics, Inc. ( VasGene ), Seattle Genetics and Avidia, Inc., an in-licensing agreement with Georgetown University, and the acquisition of the outstanding equity interests of Collective Therapeutics, Inc. ( Collective ). We also amended our licensing agreement for a cervical cancer vaccine with GSK to receive milestone payments and royalties for both GSK and Merck & Co, Inc. ( Merck ) products. In addition, we entered into a collaboration with Avalon Pharmaceuticals, Inc. ( Avalon ) to discover and develop small molecule therapeutic compounds in the area of inflammatory disease.

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During June 2005, we settled the dispute with Celltech R&D Ltd. related to the Adair 927 Patent, resulting in the dismissal of all pending litigation related to the patent. Under the terms of the settlement, we have no royalty obligation for sales of Synagis before July 1, 2005, which was estimated to range up to \$35 million under the original license terms. We agreed to pay Celltech a royalty (which is lower than the royalty rate called for in the original license agreement) based on Synagis sold or manufactured in the United States after July 1, 2005, but we do not expect our overall royalty obligation with respect to sales of Synagis to materially change as a result of the settlement.

The Company's cash and marketable securities at September 30, 2005 totaled \$1.4 billion as compared to \$1.7 billion as of December 31, 2004, reflecting the impact of payments of \$70 million made to Abbott in conjunction with the reacquisition of the promotion rights for Synagis in the United States, upfront fees and milestone payments under licensing agreements and research collaborations totaling \$41.7 million, as well as repurchases of approximately 4.0 million shares of our common stock at a total cost of \$106 million. The third quarter has historically been our seasonal low point in cash balances, prior to the ramp-up in collections related to Synagis and FluMist.

#### **AMENDMENT OF INTERNATIONAL DISTRIBUTION AGREEMENT WITH AI**

In February 2005, we amended our international distribution agreement with AI to include the exclusive distribution of Numax outside of the United States, if and to the extent approved for marketing by the appropriate regulatory authorities. Under the amended terms of the agreement, AI pays us additional compensation as compared to the previous agreement, and such amounts in excess of estimated fair value for product sales of Synagis are recognized as other revenue in the consolidated statement of operations.

#### **AMENDMENT OF CO-PROMOTION AGREEMENT WITH ABBOTT**

In August 2005, we amended our co-promotion agreement with Abbott for sales of Synagis in the United States. Under the terms of the amended agreement, Abbott will continue to provide promotional activities with respect to Synagis until June 30, 2006, at which time we will take full responsibility for Synagis sales and marketing in the United States. We will continue to pay Abbott for their co-promotion services during the 2005-2006 RSV season as provided for under the original agreement. We have agreed to make certain incremental payments, as compared to the original agreement, to Abbott through December 31, 2006, including milestone-based payments and increased incentive payments contingent upon the achievement of certain sales thresholds. In addition, if Numax, our second-generation anti-RSV monoclonal antibody that is currently in Phase 3 development, is not approved by the FDA before September 1, 2008, we would pay Abbott a portion of the proceeds from the sales of Synagis in the U.S. for up to a two-year period beginning at such time. The present value of the incremental payments that we deem probable have been recorded as liabilities in the consolidated balance sheet as follows: Other Current Liabilities, \$201.7 million; Other Liabilities, \$88.7 million.

In connection with this transaction, we recorded an intangible asset of \$360.4 million which represents the estimated fair value of the exclusive promotion rights, determined as the aggregate present value of the probable incremental payments to be made as a result of the amended terms of the agreement in excess of the value of the co-promotion services to be rendered, as determined under the previous agreement. The intangible asset will be amortized ratably over future sales of Synagis over the expected period of active sales and marketing in the United States, which are projected to continue through the first half of 2009.

#### **COLLABORATIVE AGREEMENTS**

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In February 2005, we amended our agreement with GSK for the development of an HPV vaccine. Under the amended agreement, we may, in addition to receiving milestone payments and royalties from GSK, also receive certain milestone payments and royalties on future development and sales of an investigational HPV vaccine now in Phase 3 development by Merck.

In August 2005, we licensed worldwide rights from GSK to develop certain anti-Staphylococcal monoclonal antibodies. We will be responsible for future research and development and any resulting second-generation monoclonal antibodies as well as all future sales and marketing activities worldwide. Under the terms of the agreement, we agreed to provide an upfront fee, potential milestone payments and royalties on any resulting marketed products. We have also assumed responsibility for future milestone and royalty payment obligations to Biosynexus, Inc., from which GSK originally licensed the BSYX-A110 antibody and related rights in 2002.

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In September 2005, we entered into a collaborative agreement with VasGene to develop cancer-focused monoclonal antibodies. Under the terms of the agreement, we will be responsible for the clinical development and commercialization of any resulting products. VasGene will provide research and development support and receive an upfront fee, development and regulatory milestone payments, as well as royalties on any resulting marketed products.

We recorded charges totaling \$35.7 million and \$41.7 million during Q3 2005 and YTD 2005, respectively, associated with upfront fees and milestone payments under licensing agreements and research collaborations, which are included as a component of research and development expense in the consolidated statements of operations.

#### **ACQUISITION OF COLLECTIVE THERAPEUTICS, INC.**

On October 14, 2005, we acquired the outstanding equity interests of Collective, a privately held early-stage biopharmaceutical company, for approximately \$44 million in cash, net of cash acquired of approximately \$9 million. Collective has three preclinical stage programs developing monoclonal antibodies that target the B-cell antigens CD19, CD20 and CD22, which are believed to play important roles in regulating the immune system and offer potential treatments for patients battling cancer and autoimmune diseases. Under the terms of the agreement, we have also agreed to pay Collective's shareholders future contingent payments of up to approximately \$105 million should the antibody programs achieve certain product development and sales milestones. Our wholly-owned venture capital subsidiary, MedImmune Ventures, Inc., owned approximately 10% of the outstanding equity interests of Collective prior to the acquisition. The transaction will be accounted for as a purchase of assets, and the purchase price will be allocated to assets acquired and liabilities assumed based on their relative fair values. In connection with the transaction, we expect to record a charge for acquired in-process research and development of approximately \$42 million to \$47 million during the fourth quarter of 2005, based on a preliminary valuation. The charge for acquired in-process research and development will not be deductible for tax purposes, causing the Company's effective tax rate for the full year 2005 to increase to approximately 94%.

#### **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. For additional information regarding our critical accounting estimates, please refer to Part II, Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations of the Company's Annual Report on Form 10-K for the year ended December 31, 2004. 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.

**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 becomes available and is used for commercial sale.

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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 a specification waiver from regulatory agencies, and becomes available and is 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 demand and 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 as soon as a need for such a write-down is determined. Such write-downs in

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inventory are permanent in nature, and will not be reversed in future periods.

The valuation of FluMist inventories requires 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.

The annual FluMist production cycle begins in October of the year prior to the influenza season in which the product will be available for consumption. For example, the production cycle for the 2005/2006 season began in October 2004. The production cycle begins by preparing the master viral working seeds and readying the manufacturing facilities for the bulk monovalent production. The next part of the process includes 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. Raw materials, semi-processed raw materials, work-in-process inventory and semi-finished goods may be carried over to succeeding production seasons under certain conditions. Each season's finished FluMist product has an approved shelf life up to six months.

For all FluMist inventory components on hand as of September 30, 2005, 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 anticipated distribution costs; utilization of semi-finished goods inventory for the succeeding production season; 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, 2005 at net realizable value was consistent with the methodology used for our valuations since product approval in June 2003.

The valuation of inventory as of September 30, 2005 is based on sales volume and price estimates for the 2005/2006 season that are largely based on our actual experience for the 2004/2005 season. During the first three quarters of 2005, we revised our estimate of production costs for the 2005/2006 season based on anticipated reductions in our plant and manufacturing costs, which decreased the per unit cost to produce FluMist. Sales estimates for the 2005/2006 season incorporated into the inventory valuations performed as of September 30, 2005 were consistent with the first and second quarters of 2005. 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 as of September 30, 2005. No write-downs of FluMist inventory were recorded in Q3 2005 due to lower manufacturing costs and semi-finished goods inventory determined to be useable for the next production season.

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

	<b>Gross Inventory</b>	<b>Reserves</b>	<b>Net Inventory</b>
<b><i>FluMist Details</i></b>			
As of December 31, 2004	\$ 50.7	\$ (35.7)	\$ 15.0
Raw materials, net	(4.3)	1.7	(2.6)
Cost of goods sold recognized on 2004/2005 inventory	(3.2)	3.1	(0.1)
Cost of goods sold recognized on 2005/2006 inventory	(13.3)	3.5	(9.8)
Production, net	45.9	(7.6)	38.3
Disposals and scrap	(20.2)	19.1	(1.1)
As of September 30, 2005	\$ 55.6	\$ (15.9)	\$ 39.7



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Because finished FluMist product has an approved shelf life up to six months, no finished product for a particular flu season may be sold in a subsequent season. Thus, if our actual sales fall below our projections, we will be required to write off any remaining finished goods 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. During Q3 2005, we recorded permanent inventory write-downs of \$3.3 million for certain Synagis lots that were determined to be nonsaleable as they are outside of normal specifications and not recoverable.

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## NEW ACCOUNTING STANDARDS

Issued in December 2004, Statement of Financial Accounting Standards ( SFAS ) No.123R requires public companies to recognize expense associated with share-based compensation arrangements, including employee stock options, using a fair value-based option pricing model, and eliminates the alternative to use the intrinsic value method of accounting for share-based payments. SFAS 123R will be effective for our fiscal year beginning January 1, 2006. Adoption of the expense provisions of the statement is expected to have a material impact on our results of operations. We have determined that we will apply the modified prospective transition method upon adoption. Under this method, compensation expense will be reflected in the financial statements beginning January 1, 2006 with no restatement of prior periods. As such, compensation expense will be recognized for awards that are granted, modified, repurchased or cancelled on or after January 1, 2006 as well as for the portion of awards previously granted that have not vested as of January 1, 2006. Upon the adoption of SFAS 123R, we will select an expense attribution method to use for new share-based awards that have graded-vesting features and service conditions. Currently, we anticipate implementing the straight-line expense attribution method, whereas our current expense attribution method is the graded-vesting method, an accelerated method, described by FIN 28.

In anticipation of the adoption of SFAS 123R, we are currently evaluating alternative stock-based compensation programs, including potential changes in the quantity or type of instruments used in share-based payment programs and changes in the terms of share-based payment arrangements. Any potential changes to our compensation strategy would likely affect comparability to our prior period footnote disclosures of pro forma net earnings and earnings per share.

The actual pro forma expense for disclosure purposes in 2005 is dependent on a number of factors that we cannot predict, including the number of stock options granted, our common stock price, expected future volatility, and other variables utilized in estimating the fair value of stock options at the time of grant. However, we expect that our pro forma after tax expense for disclosure purposes for stock-based compensation for the full twelve months in 2005 will approximate \$40 million to \$50 million. Prior to adoption of FAS 123R in the first quarter of 2006, the Company's financial statements will not be impacted by the pro forma compensation expense disclosures.

The pro forma stock-based compensation expense disclosure for 2005 is expected to be lower than 2004 due to a lower number of stock options estimated to be granted in 2005, the diminishing impact of accelerated amortization of compensation expense for prior period options (which were assigned higher fair values) under the graded vesting method, and an anticipated reduction in the estimated fair value of new stock option grants.

The estimated fair value of new stock option grants beginning in 2005 is expected to be lower than 2004 for the following reasons:

**Binomial Model** Effective January 1, 2005, we have estimated the fair value of stock compensation expense associated with employee stock options using the binomial model approach. We believe the binomial approach provides a better measure of fair value of employee stock options because it incorporates assumptions about patterns of employee exercises in relation to such considerations as stock price appreciation, post-vesting employment termination behavior, the contractual term of the option and other factors. Historically, we estimated the fair value of employee stock options using the Black-Scholes option pricing model, which does not incorporate such correlation assumptions.

**Shorter Expected Life** The expected life of an option represents the period of time that options granted are expected to be outstanding. During YTD 2005, the expected life of an option, as derived from the output of the binomial model, ranged from 4.5 years to 5.4 years. For YTD 2004, the expected life of an option was 5 years, estimated based on historical stock option exercise experience.

**Lower Expected Stock Price Volatility** Based on an analysis of economic data that marketplace participants would likely use in determining an exchange price for an option, our weighted-average estimate of expected volatility for YTD 2005 ranged from 28% to 32%, reflecting the implied volatility determined from the market prices of traded call options on our stock. During YTD 2004, the weighted-average estimate of expected volatility ranged from 48% to 50%, based on the historical volatility over the expected life, using monthly

observations.

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**RESULTS OF OPERATIONS****Q3 2005 compared to Q3 2004****Revenues Product Sales**

(in millions)	Q3 2005	Q3 2004	Change	
<b>Synagis</b>				
Domestic	\$ 42.8	\$ 42.0	2	%
International	58.2	18.9	208	%
	101.0	60.9	66	%
<b>Ethylol</b>				
Domestic	23.5	20.5	15	%
International	1.2	1.0	15	%
	24.7	21.5	15	%
<b>FluMist</b>	10.4	-	N/A	
<b>Other Products</b>	9.9	9.9	-	%
<b>Total Product Sales</b>	\$ 146.0	\$ 92.3	58	%

**Synagis** - Synagis accounted for approximately 69% and 66% of our product sales in Q3 2005 and Q3 2004, respectively. In Q3 2005, domestic sales of Synagis increased 2% to \$42.8 million from Q3 2004 sales of \$42.0 million.

We record Synagis international product sales based on a portion of AI's sales price to customers, as defined in our distribution agreement. Our reported international sales of Synagis increased 208% to \$58.2 million for Q3 2005 as compared to \$18.9 million in Q3 2004. The increase is primarily attributable to the early stocking of inventories by AI for the 2004/2005 RSV season during the second quarter of 2004, a heavier than expected inventory stocking pattern in the current quarter along with strong growth in end-user demand. We expect that the stocking pattern of inventories by AI for the balance of the 2005/2006 RSV season will moderate.

**Ethylol** - Ethylol accounted for approximately 17% and 23% of our product sales in Q3 2005 and Q3 2004, respectively. Domestic sales of Ethylol increased 15% to \$23.5 million in Q3 2005, compared to \$20.5 million in Q3 2004. Of the overall increase, approximately 12 percentage points resulted from an increase in domestic sales volume. As of September 30, 2005, estimated wholesaler and distributor inventories are in line with demand, and demand remained flat for Q3 2005 versus Q3 2004. International sales of Ethylol increased 15% to \$1.2 million versus the prior year quarter.

**FluMist** - Our Q3 2005 product sales of FluMist amounted to \$10.4 million. Due to the seasonal nature of influenza, the majority of FluMist sales are expected to occur between September and January. Our results for Q3 2005 reflect early shipments of FluMist; we expect the majority of FluMist sales for 2005 to occur in the fourth quarter. Results for Q3 2004 reflect the impact of a delay by the FDA for final lot release until October 2004 for FluMist inventory for the 2004/2005 influenza season.

**Other Products** - Sales of other products in Q3 2005, which include sales of CytoGam, NeuTrexin, and by-products that result from the CytoGam manufacturing process, were \$9.9 million in both Q3 2005 and Q3 2004.

**Revenues - Other Revenues**

Other revenues for Q3 2005 include \$7.2 million of incremental revenue recognized under the amended international distribution agreement with AI, which represents amounts received in excess of estimated fair value for product sales of Synagis. Such excess amounts have been determined using projected reimbursements for the Synagis season, and are recorded in other revenue, as such excess payments are deemed consideration from AI for the rights to distribute Numax outside of the United States.

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### **Cost of Sales**

Cost of sales was \$48.7 million for Q3 2005 compared to \$40.4 million in Q3 2004. Gross margins on product sales for Q3 2005 were 67%, up eleven percentage points from gross margins of 56% for Q3 2004. Gross margins for all products, excluding FluMist, were 72% and 69% in Q3 2005 and Q3 2004, respectively, primarily reflecting the favorable impact of higher international Synagis sales during Q3 2005 on margins, as well as the \$4.9 million recoupment of past royalty overpayments that was recognized as a reduction to cost of sales during Q3 2005. Gross margins for FluMist reduced overall gross margins by five percentage points and 13 percentage points in Q3 2005 and Q3 2004, respectively. The lower negative impact of FluMist on gross margins for Q3 2005 was due primarily to reduced production costs and the anticipated ability to utilize certain semi-finished inventory components for the next production season (see Critical Accounting Estimates - Inventory).

### **Research and Development Expenses**

Research and development expenses increased 41% to \$119.1 million in Q3 2005, compared to \$84.5 million in Q3 2004. The increase in our drug discovery and development expenses is related to a large number of ongoing clinical and preclinical studies, particularly for Numax and CAIV-T which we advanced into Phase 3 in late 2004, costs associated with the expansion of infrastructure to support these studies, and upfront licensing fees and milestone payments related to various in-licensing agreements and collaborations. Q3 2005 expenses include upfront licensing fees and milestones totaling \$35.7 million in connection with in-licensing agreements and collaborations, as compared to \$1.0 million in the prior year period. During Q3 2005 and Q3 2004, research and development expenses also include approximately \$0.5 million and \$11.8 million, respectively, in connection with the technology transfer and transition activities associated with reacquisition of the influenza vaccines franchise from Wyeth.

### **Selling, General and Administrative Expenses**

Selling, general and administrative ( SG&A ) expenses increased 19% to \$81.1 million in Q3 2005 compared to \$68.0 million in Q3 2004. The increase is largely attributable to the continuing expansion of the pediatric commercial organization and new marketing and medical education programs related to Synagis and FluMist, as well as amortization expense of \$3.9 million recognized during Q3 2005 associated with the intangible asset for U.S. co-promotion rights for Synagis acquired and recorded during Q3 2005.

### **Acquired IPR&D**

In connection with the achievement of certain CAIV-T related milestones, we recorded charges for acquired IPR&D of \$4.7 million and \$3.8 million during Q3 2005 and Q3 2004, respectively, in conjunction with our reacquisition of the influenza vaccines franchise from Wyeth. In September 2005, we submitted a supplemental Biologics License Application with the FDA for approval to use CAIV-T in preventing influenza in healthy individuals 5 to 49 years of age, which triggered the milestone payment to Wyeth. The charges for acquired IPR&D represent the relative fair value of purchased in-process technologies and research and development projects at the acquisition date, including the impact of subsequent milestone payments, primarily CAIV-T, calculated utilizing the income approach. We may incur additional charges for acquired in-process research and development in the future associated with the transaction with Wyeth, if the development of CAIV-T progresses and certain developmental milestones are achieved.

### **Gain (Loss) on Investment Activities**

We recorded a gain on investment activities of \$0.4 million during Q3 2005, compared to a loss of \$12.0 million during Q3 2004. The Q3 2004 loss consisted 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, partially offset by \$1.7 million realized gains on the sale of common stock and other investments.

**Taxes**

We recorded an income tax benefit of \$26.5 million for Q3 2005, resulting in an effective tax rate of 29%. We recorded an income tax benefit of \$38.1 million for Q3 2004, resulting in an effective rate of 37% for the period. During Q3 2005, we made a correction to the prior accounting for the reversal of approximately \$4.8 million of valuation allowances associated with the utilization of certain acquired income tax carryforwards. The correction was comprised of relatively small amounts related to reporting periods dating back to the acquisition of Aviron in January 2002. The correction resulted in tax expense

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of approximately \$4.8 million during Q3 2005 and a corresponding reduction to goodwill on the consolidated balance sheet. The correction reduced the amount of benefit available from income taxes in Q3 2005, thereby reducing the effective rate.

### Net Loss

The reported net loss for Q3 2005 was \$64.1 million, or \$0.26 per share, compared to net loss for Q3 2004 of \$65.0 million or \$0.26 per share. Shares used in computing net loss per share in Q3 2005 were 245.9, while shares used in computing net loss per share for Q3 2004 were 248.9 million.

### YTD 2005 compared to YTD 2004

#### Revenues Product Sales

(in millions)	YTD 2005	YTD 2004	Change	
<b>Synagis</b>				
Domestic	\$ 525.8	\$ 471.8	11	%
International	97.7	66.9	46	%
	623.5	538.7	16	%
<b>Ethyol</b>				
Domestic	66.1	67.9	(3)	%
International	3.9	3.0	30	%
	70.0	70.9	(1)	%
<b>FluMist</b>	13.2	27.1	(51)	%
<b>Other Products</b>	32.7	29.5	11	%
<b>Total Product Sales</b>	\$ 739.4	\$ 666.2	11	%

**Synagis** - Synagis accounted for approximately 84% and 81% of our product sales for YTD 2005 and YTD 2004, respectively. We achieved an 11% increase in domestic Synagis sales to \$525.8 million for YTD 2005, up from \$471.8 million in YTD 2004. The growth over the prior year period resulted from higher unit sales volumes, as the impact of price increases was largely offset by higher sales allowances. Our reported international sales of Synagis increased to \$97.7 million in YTD 2005 compared to \$66.9 million in YTD 2004, primarily due to continued demand growth and a heavier than expected inventory stocking pattern for the 2005/2006 season. We expect that the growth rate for reported international sales of Synagis will moderate for the full year 2005.

**Ethyol** - Ethyol accounted for approximately 9% and 11% of our product sales for YTD 2005 and YTD 2004, respectively. Worldwide Ethyol sales declined 1% to \$70.0 million in YTD 2005, as compared to \$70.9 million in YTD 2004, primarily driven by a 3% decline in domestic sales due to lower unit sales volumes for YTD 2005. However, sales in Q3 2005 increased 15% over the prior year period. International sales resulted in modest growth from \$3.0 million in YTD 2004 to \$3.9 million in YTD 2005.



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**FluMist** FluMist accounted for approximately 2% and 4% of our product sales for YTD 2005 and YTD 2004, respectively. Sales of FluMist were \$13.2 million in YTD 2005, as compared to \$27.1 million in YTD 2004, a decrease primarily due to the timing of revenue recognition for product shipped during 2003. YTD 2005 sales are comprised of 0.3 million doses sold during the first quarter of 2005 as the 2004/2005 influenza season came to an end and 0.8 million doses shipped during Q3 2005 related to the 2005/2006 influenza season. Our YTD 2004 sales of FluMist of \$27.1 million consisted of transfer price for product shipped to Wyeth during 2003 for the 2003/2004 influenza season. During 2003, we shipped 4.1 million doses of FluMist to Wyeth, our former collaboration partner, who was contractually responsible for distributing the product to third parties. At December 31, 2003, we concluded that the variables associated with FluMist product revenues were not determinable, largely due to low sales volume and the lack of returns history and comparable rebate redemption rates for the new product. As a result, product revenues associated with the doses that were shipped to Wyeth in 2003 were not recognized until the first quarter of 2004.

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**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 \$32.7 million in YTD 2005 as compared to \$29.5 million for YTD 2004. The increase is primarily due to a 12% increase in sales of CytoGam. We are in the process of transferring CytoGam manufacturing responsibilities to different contract manufacturers, a process which is expected to be completed during the second half of 2006. Until the transfer is complete and the new manufacturing sites are approved by the FDA, we expect supply to be limited and that sales will be affected.

#### **Revenues Other Revenues**

Other revenues increased to \$12.5 million for YTD 2005 compared to \$9.1 million for YTD 2004. Other revenues in YTD 2005 include \$9.7 million of incremental revenue recognized under the amended terms of our international distribution agreement with AI, which represents amounts received in excess of estimated fair value for product sales of Synagis. 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.

#### **Cost of Sales**

Cost of sales for YTD 2005 decreased 17% to \$196.5 million from \$235.9 million for YTD 2004. Gross margins on product sales were 73% for YTD 2005, up eight percentage points from gross margins of 65% for YTD 2004. Gross margins for all products, excluding FluMist, were 75% and 74% in YTD 2005 and YTD 2004, respectively, reflecting the \$4.9 million recoupment of past royalty overpayments that was recognized as a reduction to cost of sales during Q3 2005. Gross margins for FluMist reduced gross margins in YTD 2005 and YTD 2004 by two percentage points and nine percentage points, respectively. The lower impact of FluMist on gross margins for YTD 2005 was due primarily to lower manufacturing cost estimates for the 2005/2006 influenza season and the ability to utilize certain semi-finished inventory components for the next production season (see Critical Accounting Estimates - Inventory).

#### **Research and Development Expenses**

Research and development expenses of \$267.7 million in YTD 2005 increased 32% from \$202.1 million in YTD 2004. The increase is due largely to direct costs associated with ongoing and additional clinical and preclinical trials for product candidates, increases in headcount and related expenses in support of increased research and development activities and upfront licensing fees and milestone payments related to in-licensing agreements and research collaborations. Upfront fees and milestones incurred in connection with research collaborations and in-licensing agreements were \$41.7 million in YTD 2005 versus \$3.9 million in YTD 2004. Also included in research and development expenses in YTD 2005 and YTD 2004 are \$1.9 million and \$22.5 million, respectively, in costs for technology transfer and transition activities associated with our assumption of research and development activities related to the influenza vaccines franchise. Research and development expenses in YTD 2005 were 36% of product sales versus 30% of product sales in YTD 2004, reflecting the continuing investment to bring new products to market as part of our long-range plan.

#### **Selling, General and Administrative Expenses**

SG&A expenses increased 20% to \$299.5 million in YTD 2005 compared to \$250.6 million in YTD 2004. The increase is largely attributable to increased co-promotion expense, corresponding to the increase in domestic Synagis sales, and the expansion of the pediatric commercial

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organization. Also included in SG&A expense in YTD 2005 is amortization expense of \$3.9 million associated with the intangible asset for U.S. co-promotion rights for Synagis that was acquired and recorded during Q3 2005. As a percentage of product sales, SG&A expense increased to 41% of product sales for YTD 2005 compared to 38% of products sales in YTD 2004.

### **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 collaboration with Wyeth.

### **Acquired IPR&D**

We recorded charges for acquired IPR&D of \$4.7 million and \$28.5 million in YTD 2005 and YTD 2004, respectively, in conjunction with our reacquisition of the influenza vaccines franchise from Wyeth. The charges represent the relative fair

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value of purchased in-process technologies and research and development projects, primarily CAIV-T at the acquisition date, including the impact of subsequent milestone payments, calculated utilizing the income approach.

### Loss on Investment Activities

We recorded a net loss on investment activities of \$0.5 million during YTD 2005, compared to a net loss of \$4.7 million during YTD 2004. The YTD 2004 net 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 \$9.0 million.

### Taxes

We recorded income tax expense of \$11.1 million for YTD 2005, resulting in an effective tax rate of 65%. Comparatively, we recorded income tax benefit of \$27.8 million for YTD 2004, which resulted in an effective tax rate of 34%, excluding the impact of approximately \$6.9 million of non-deductible charges for IPR&D incurred during the second quarter of 2004. During Q3 2005, we made a correction to the prior accounting for the reversal of approximately \$4.8 million of valuation allowances associated with the utilization of certain acquired income tax carryforwards. The correction increased income tax expense by approximately \$4.8 million in Q3 2005, which had the impact of increasing the effective tax rate for YTD 2005.

In connection with the acquisition of all of the outstanding equity interests of Collective during October 2005, we anticipate that we will record a charge for acquired in-process research and development of approximately \$42 million to \$47 million during the fourth quarter of 2005, based on a preliminary valuation. The charge for acquired in-process research and development will not be deductible for tax purposes, causing the effective tax rate for the full year 2005 to increase to approximately 94%.

### Net Earnings

We reported net earnings for YTD 2005 of \$5.8 million, or \$0.02 per share compared to net loss for YTD 2004 of \$54.3 million, or \$0.22 per share.

Shares used in computing basic and diluted earnings per share for YTD 2005 were 247.1 million and 249.4 million, respectively, while shares used for computing loss per share for YTD 2004 were 248.6 million.

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

### LIQUIDITY AND CAPITAL RESOURCES

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**Sources and uses of cash** - Cash and marketable securities were \$1.4 billion as of September 30, 2005 as compared to \$1.7 billion as of December 31, 2004, a decrease of 17%. The third quarter has historically been our seasonal low point in cash balances, prior to the ramp-up in collections related to Synagis and FluMist. The decrease in cash is primarily due to share repurchases, payments made to Abbott in Q3 2005 in conjunction with the reacquisition of the co-promotion rights for Synagis in the United States, as well as upfront fees and milestones paid related to in-licensing agreements and research collaborations. Working capital decreased to \$(177.2) million at September 30, 2005 from \$330.0 million as of December 31, 2004, primarily due to the reclassification of our convertible senior notes to current liabilities, as the holders may require us to purchase the notes for cash in July 2006, as provided for in the indenture.

### *Operating Activities*

Net cash used in operating activities was \$24.3 million in YTD 2005 as compared to of \$26.9 million in YTD 2004.

### *Investing Activities*

Cash used for investing activities during YTD 2005 amounted to \$48.9 million, as compared to \$294.8 million during YTD 2004. Cash used for investing activities in YTD 2005 included net reductions to our investment portfolio of \$98.3 million; incremental payments to Abbott of \$70 million in conjunction with the amendment of the U.S. co-promotion agreement for Synagis; capital expenditures totaling \$64.3 million, primarily for the construction of our new pilot lab in Gaithersburg, Maryland and the expansion of our influenza vaccine manufacturing facilities in Speke, England; and minority interest investments in strategic partners totaling \$12.9 million through our venture capital subsidiary. We expect our capital expenditures for the full year to approximate \$100 million.

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### *Financing Activities*

Financing activities used \$90.7 million in cash for YTD 2005, as compared to \$176.2 million used in YTD 2004. The decrease is principally due to the use of \$172.7 million in cash during the first quarter of 2004 to repurchase and retire the balance of the 5¼% convertible subordinated notes. During YTD 2005, we used \$105.9 million in cash to repurchase shares of our common stock as authorized under our share repurchase program, as compared to \$15.0 million used for repurchases during YTD 2004. Approximately \$19.7 million was received upon the exercise of employee stock options and through the employee stock purchase plan in YTD 2005, as compared to \$12.1 million received in YTD 2004.

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. We expend cash to finance our 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. We currently anticipate that the holders of our 1% convertible senior notes will require us to redeem the notes for cash in July 2006 as provided for under the indenture. We believe that our cash and marketable securities on hand will be adequate to service the cash requirement. Also, the BBB rating on our outstanding indebtedness, considered to be investment grade, will contribute to our ability to access capital markets, should we desire or need to do so. In February 2005, our Board of Directors approved an additional \$100 million in funding for our venture capital subsidiary, bringing the total amount allocated to \$200 million. We may raise additional capital in the future to take advantage of favorable conditions in the market or in connection with our development activities.

During the second quarter of 2005, we recouped approximately \$12.1 million from licensors related to overpayments under various royalty agreements. During Q3 2005, we recognized \$4.9 million of this royalty recoupment as a reduction to cost of goods sold after determining that related contingencies had been resolved. The remaining amount has been deferred until fully realizable and therefore is recorded in Other Current Liabilities within the consolidated balance sheet.

Our Board of Directors has authorized the repurchase of up to \$500 million of the Company's common stock during the period from July 2003 through June 2006 in the open market or in privately negotiated transactions, pursuant to terms management deems appropriate and at such times it may designate. During YTD 2005, we repurchased approximately 4.0 million shares of common stock under the stock repurchase program at a cost of \$105.9 million, or an average cost of \$26.18 per share. As of October 20, 2005, approximately \$134.3 million remained available under the authorization for additional repurchases of stock. We are holding repurchased shares as treasury shares and are using 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, 2005 continue to be the exposures to loss resulting from changes in interest rates, foreign currency exchange rates, and equity prices. Our market risks at September 30, 2005 have not changed significantly from those discussed in our Annual Report on Form 10-K for the year ended December 31, 2004. 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 for the year ended December 31, 2004.

### **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

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( CEO ), and Senior Vice President and Chief Financial Officer ( CFO ), 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 September 30, 2005, the Company carried out an evaluation, under the supervision and with the participation of the Company's management, including the Company's CEO and CFO, 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

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Company's CEO and its CFO 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 CEO and its CFO, have determined that there was no change in the Company's internal control over financial reporting that occurred during Q3 2005 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 13 of Part I, Item 1 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 for the year ended December 31, 2004 as updated in the Company's Quarterly Reports on Form 10-Q for the quarters ended March 31, 2005 and June 30, 2005.

#### **ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

##### **(c) Issuer purchases of equity securities(1)**

<b>Period</b>	<b>Total Number of Shares Purchased</b>	<b>Average Price Paid per Share</b>	<b>Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs</b>	<b>Approximate Dollar Value that May Yet Be Purchased Under the Plans or Programs</b>
July 1, 2005 through July 31, 2005	500,000	\$ 27.30	500,000	\$ 159,038,000
August 1, 2005 through August 31, 2005	805,000	\$ 27.40	805,000	\$ 136,978,000
September 1, 2005 through September 30, 2005	100,000	\$ 27.17	100,000	\$ 134,261,000

(1) The Company's Board of Directors has authorized the repurchase of up to \$500 million of the Company's common stock on the open market or in privately negotiated transactions during the period from July 2003 through June 2006.

#### **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**



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### (a) Exhibits:

- 10.1 (1) Co-Promotion Agreement, dated as of November 26, 1997, by and between MedImmune, Inc. and Abbott Laboratories, incorporated by reference to Exhibit 10.76 to the Company's Annual Report on Form 10-K for the year ended December 31, 1997, as amended by that certain Third Amendment to the Co-Promotion Agreement, dated as of August 26, 2005 (filed herewith).
- 10.2+ Employment agreement, dated as of October 1, 2005, by and between Wayne T. Hockmeyer, Ph.D. and the Company.
- 31.1 Certification of CEO pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 Certification of CFO pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

+ Management contract or compensatory plan or arrangement.

(1) Confidential treatment has been granted by the SEC for certain portions of this agreement and the copy incorporated by reference omits the information subject to the confidentiality grant. Confidential treatment has been requested for certain portions of the amendment filed herewith. The copy of the amendment filed as an exhibit omits the information subject to the confidentiality request.

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**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 thereunto duly authorized.

**MEDIMMUNE, INC.**

(Registrant)

Date: October 25, 2005

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

Date: October 25, 2005

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

Date: October 25, 2005

/s/ Mark E. Spring  
Mark E. Spring  
Vice President, Finance and Controller  
Principal Accounting Officer