

MEDIMMUNE INC /DE  
Form 10-Q  
November 01, 2006

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D. C. 20549

**FORM 10-Q**

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

**For the quarterly period ended September 30, 2006**

**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)

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 a large accelerated filer, an accelerated filer or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer

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 24, 2006, 239,207,356 shares of Common Stock, par value \$0.01 per share, were outstanding.



**MEDIMMUNE, INC.**

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

Unless otherwise indicated, this Quarterly Report is current as of September 30, 2006 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,<br/>2006<br/>(Unaudited)<br/>(In millions)</b> | <b>December 31,<br/>2005</b> |
|---|---|------------------------------|
| <b>ASSETS:</b>  |   |                              |
| Cash and cash equivalents   | \$ 284.2  | \$ 153.4                     |
| Marketable securities   | 438.6   | 457.1                        |
| Trade receivables, net  | 115.3   | 281.0                        |
| Inventory, net  | 102.4   | 69.4                         |
| Deferred tax assets, net  | 58.7  | 58.0                         |
| Other current assets  | 30.5  | 18.4                         |
| Total Current Assets  | 1,029.7   | 1,037.3                      |
| Marketable securities   | 749.8   | 861.4                        |
| Property and equipment, net   | 457.0   | 381.4                        |
| Deferred tax assets, net  | 333.6   | 128.6                        |
| Intangible assets, net  | 269.1   | 323.5                        |
| Other assets  | 84.5  | 47.8                         |
| Total Assets  | \$ 2,923.7  | \$ 2,780.0                   |
| <b>LIABILITIES AND SHAREHOLDERS' EQUITY:</b>  |   |                              |
| Accounts payable  | \$ 38.5   | \$ 37.0                      |
| Accrued expenses  | 157.9   | 242.1                        |
| Product royalties payable   | 24.6  | 93.0                         |
| Convertible senior notes  |   | 500.0                        |
| Other current liabilities   | 261.5   | 276.4                        |
| Total Current Liabilities   | 482.5   | 1,148.5                      |
| Long-term debt  | 1,164.8   | 5.2                          |
| Other liabilities   | 0.6   | 55.8                         |
| Total Liabilities   | 1,647.9   | 1,209.5                      |
| <b>Commitments and Contingencies</b>  |   |                              |
| <b>SHAREHOLDERS' EQUITY:</b>  |   |                              |
| Preferred stock, \$.01 par value; 5.5 million shares authorized; none issued or outstanding   |   |                              |
| Common stock, \$.01 par value; 420.0 million shares authorized; 255.5 million shares issued at September 30, 2006 and December 31, 2005 | 2.6   | 2.6                          |
| Paid-in capital   | 2,697.8   | 2,688.5                      |
| Accumulated deficit   | (935.0)   | (842.5)                      |
| Accumulated other comprehensive loss  | (5.0)   | (11.0)                       |
|   | 1,760.4   | 1,837.6                      |
| Less: Treasury stock at cost; 16.2 million shares at September 30, 2006 and 8.5 million shares at December 31, 2005                     | (484.6)   | (267.1)                      |
| Total Shareholders' Equity  | 1,275.8   | 1,570.5                      |
| Total Liabilities and Shareholders' Equity  | \$ 2,923.7  | \$ 2,780.0                   |

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)

|   | Three months ended<br>September 30, |            | Nine months ended<br>September 30, |          |
|---|-------------------------------------|------------|------------------------------------|----------|
|   | 2006                                | 2005       | 2006                               | 2005     |
| <b>Revenues:</b>  |                                     |            |                                    |          |
| Product sales   | \$ 158.6                            | \$ 146.0   | \$ 716.4                           | \$ 739.4 |
| Other revenue   | 18.6                                | 7.6        | 31.7                               | 12.5     |
| Total revenues  | 177.2                               | 153.6      | 748.1                              | 751.9    |
| <b>Costs and expenses:</b>                                      |                                     |            |                                    |          |
| Cost of sales   | 53.5                                | 48.7       | 190.6                              | 196.5    |
| Research and development  | 162.0                               | 119.1      | 343.6                              | 267.7    |
| Selling, general and administrative                             | 88.2                                | 81.1       | 382.1                              | 299.5    |
| Other operating expenses  | 2.2                                 | 3.8        | 13.7                               | 9.3      |
| Acquired in-process research and development                    |                                     | 4.7        |                                    | 4.7      |
| Total expenses  | 305.9                               | 257.4      | 930.0                              | 777.7    |
| Operating loss  | (128.7 )                            | (103.8 )   | (181.9 )                           | (25.8 )  |
| Interest income   | 19.3                                | 15.1       | 50.2                               | 49.4     |
| Interest expense  | (6.3 )                              | (2.3 )     | (12.0 )                            | (6.2 )   |
| Gain (loss) on investment activities                            | (8.2 )                              | 0.4        | (8.1 )                             | (0.5 )   |
| Earnings (loss) before income taxes                             | (123.9 )                            | (90.6 )    | (151.8 )                           | 16.9     |
| Income tax provision (benefit)                                  | (68.1 )                             | (26.5 )    | (79.8 )                            | 11.1     |
| Net earnings (loss)   | \$ (55.8 )                          | \$ (64.1 ) | \$ (72.0 )                         | \$ 5.8   |
| Basic earnings (loss) per share                                 | \$ (0.23 )                          | \$ (0.26 ) | \$ (0.29 )                         | \$ 0.02  |
| Shares used in calculation of basic earnings (loss) per share   | 239.3                               | 245.9      | 244.3                              | 247.1    |
| Diluted earnings (loss) per share                               | \$ (0.23 )                          | \$ (0.26 ) | \$ (0.29 )                         | \$ 0.02  |
| Shares used in calculation of diluted earnings (loss) per share | 239.3                               | 245.9      | 244.3                              | 249.4    |

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

**MEDIMMUNE, INC.**

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

(Unaudited)

(in millions)

|  | Nine months ended<br>September 30, |          |
|--|------------------------------------|----------|
|  | 2006                               | 2005     |
| <b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>                                       |                                    |          |
| Net earnings (loss)  | \$ (72.0 )                         | \$ 5.8   |
| Adjustment to reconcile net earnings to net cash provided by operating activities: |                                    |          |
| Share-based compensation expense   | 24.2                               |          |
| Charge for acquired in-process research and development                            |                                    | 4.7      |
| Deferred taxes   | (65.3 )                            | 8.6      |
| Depreciation and amortization  | 79.2                               | 29.1     |
| Amortization of premium on marketable securities                                   | 8.2                                | 11.5     |
| Realized losses on investments   | 8.1                                | 0.5      |
| Losses on write downs of inventory   | 9.8                                | 7.6      |
| Decrease in sales allowances   | (29.6 )                            | (26.8 )  |
| Other, net   | 5.6                                | 3.2      |
| Other changes in assets and liabilities  | (91.4 )                            | (68.5 )  |
| Net cash used in operating activities  | (123.2 )                           | (24.3 )  |
| <b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>                                       |                                    |          |
| Decrease in marketable securities, net   | 124.9                              | 98.3     |
| Capital expenditures   | (105.7 )                           | (64.3 )  |
| Minority interest investments, net   | (29.5 )                            | (12.9 )  |
| Purchase of promotion rights from Abbott   |                                    | (70.0 )  |
| Net cash used in investing activities  | (10.3 )                            | (48.9 )  |
| <b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>                                       |                                    |          |
| Proceeds from issuance of common stock   | 51.5                               | 19.7     |
| Excess tax benefits from share-based payment arrangements                          | 3.1                                |          |
| Share repurchases  | (289.6 )                           | (105.9 ) |
| Repayments on long-term obligations  | (0.7 )                             | (4.5 )   |
| Redemption of 1% Convertible Senior Notes  | (489.6 )                           |          |
| Proceeds from issuance of long-term debt, net of issuance costs                    | 1,129.2                            |          |
| Purchase of call options on convertible senior notes                               | (316.5 )                           |          |
| Proceeds from issuance of warrants   | 177.0                              |          |
| Net cash provided by (used in) financing activities                                | 264.4                              | (90.7 )  |
| Effect of exchange rate changes on cash  | (0.1 )                             | 0.1      |
| Net increase (decrease) in cash and cash equivalents                               | 130.8                              | (163.8 ) |
| Cash and cash equivalents at beginning of period                                   | 153.4                              | 171.3    |
| Cash and cash equivalents at end of period   | \$ 284.2                           | \$ 7.5   |

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



**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 as of the acquisition date of the future incremental payments that the Company deems probable, which were recorded as liabilities in the consolidated balance sheet.

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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, cancer and inflammatory disease. 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, 2006 (Q3 2006 and YTD 2006, respectively) and as of and for the three and nine months ended September 30, 2005 (Q3 2005 and YTD 2005, respectively) is unaudited. In the opinion of the Company's management, the financial information presented herein contains all adjustments necessary for a fair statement 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, 2005 and the Company's Quarterly Reports on Form 10-Q for the quarters ended March 31, 2006 and June 30, 2006. The December 31, 2005 consolidated balance sheet data was derived from audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the United States of America.

*Seasonality*

The Company's largest revenue-generating product, Synagis, is used to prevent respiratory syncytial virus (RSV) disease in high-risk infants. RSV is most prevalent in the winter months in the Northern Hemisphere. Because of the seasonal nature of RSV, limited sales, if any, of Synagis are expected in the second and third quarters of any calendar year, causing financial results to vary significantly from quarter to quarter.

FluMist is a nasally delivered live, attenuated vaccine used to help prevent influenza in healthy individuals from 5 to 49 years of age. As influenza is most prevalent in the fall and winter months in the Northern Hemisphere, the majority of FluMist sales are expected to occur during the second half of any calendar year, causing financial results to vary significantly from quarter to quarter.

*Intangible Assets*

Management assesses intangible assets for impairment on a periodic basis. The intangible asset associated with the reacquisition of the U.S. co-promotion rights for Synagis is amortized based on total future projected domestic sales of Synagis through the first half of 2009. These projections are evaluated in conjunction with the annual long-range planning process. Should the total of incremental payments, a portion of which are variable based on actual sales, made to Abbott in connection with the reacquisition of the U.S. co-promotion rights for Synagis ultimately be less than the amount of the associated liability recorded, the amount of the intangible asset will be adjusted accordingly.

*Product Sales*

The Company recognizes revenue on product sales when persuasive evidence of an arrangement exists, delivery has occurred, the sales price is fixed or determinable, and collectibility is probable. These criteria are generally met upon shipment of product or receipt of product by customers, depending on the contractual terms of the arrangement.

In certain of the Company's international distribution agreements, a portion of the compensation received by the Company from its partner is variable based, in part, on the end-user sales price. When all of the other revenue criteria have been met, the Company recognizes revenue to the extent that the customer has an obligation to pay, the customer has limited or no control over the end-user sales price and, accordingly, any subsequent adjustments to the recorded revenue are not expected to be significant.



Subsequent adjustments to recorded revenue that result from variances between amounts previously invoiced and the total sales price received are recorded as an adjustment to product sales in the quarter in which they become known.

#### *Sales Allowances*

Product sales are recorded net of allowances for estimated chargebacks, returns, discounts, and government rebates. Both in the U.S. and elsewhere, sales of pharmaceutical products depend on the availability of reimbursement to the consumer from third-party payers, such as government and private insurance plans. The Company estimates the portion of its sales that will be covered by government insurance and records allowances at a level that management believes is sufficient to cover estimated requirements for reimbursements.

#### *Contract Revenues*

The Company uses the milestone payment method of accounting for contract revenues, recognizing revenue when all milestones to be received under contractual arrangements are determined to be substantive, at-risk and the culmination of an earnings process. Substantive milestones are payments that are conditioned upon an event requiring substantive effort, when the amount of the milestone is reasonable relative to the time, effort and risk involved in achieving the milestone and when the milestones are reasonable relative to each other and the amount of any upfront payment. If all of these criteria are not met, then the Company will use the contingency-adjusted performance model.

Incremental revenue recognized under the amended terms of the Company's international distribution agreement with Abbott International ( AI ), which represents amounts received in excess of the estimated fair value for product sales of Synagis, are recorded as other revenues in the Company's consolidated statement of operations.

#### *Miscellaneous Revenues*

Other revenues may also include licensing fees, grant income, royalty income, corporate funding, and reimbursement of expenses under research and other collaborative agreements. These revenues are recognized when the payments are received or when collection is assured, and only when no further performance obligations exist.

#### *Government Contract*

Revenues from the Company's cost plus fixed-fee government contract are recognized as the costs are incurred, and fees are recognized on a pro rata basis of costs incurred to date to total estimated costs. Reimbursement of certain direct and indirect costs is recorded utilizing provisional rates, which are subject to periodic review, audit and adjustment to reflect actual rates.

#### *Other Operating Expenses*

Other operating expenses include manufacturing start-up costs and other manufacturing related costs associated with pre-approval products, as well as excess capacity charges associated with the plasma production portion of the Frederick Manufacturing Center.

#### *Stock-based Compensation*

In December 2004, the Financial Accounting Standards Board ( FASB ) issued SFAS 123R, a revision of SFAS 123, Share-based Payments. 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 is effective for the Company's fiscal year beginning January 1, 2006. Adoption of the expense provisions of the statement has had and is expected to continue to have a material impact on the Company's results of operations. The Company adopted SFAS 123R using the modified prospective transition method. Under this method, compensation expense has been reflected in the financial statements beginning January 1, 2006 with no restatement of prior periods. As such, compensation expense is 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 had not vested as of January 1, 2006. The Company has implemented the straight-line expense attribution method, whereas the Company's previous expense attribution method was 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 ).

The following table illustrates the effect on net earnings and earnings per share if the Company had applied the fair value recognition provisions to share-based employee compensation in Q3 2005 and YTD 2005 (in millions, except per share data):



|  | Q3<br>2005 | YTD<br>2005 |
|--|------------|-------------|
| Net earnings (loss), as reported   | \$ (64.1 ) | \$ 5.8      |
| Add:   |            |             |
| share-based employee compensation expense included in historical results for the vesting of stock options assumed in conjunction with the Company's acquisition of Aviron in January 2002, 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         |
| Deduct:  |            |             |
| share-based employee compensation expense determined under the fair value based method for all awards, net of related tax effect   | (9.9 )     | (34.5 )     |
| Pro forma net earnings (loss)  | \$ (74.0 ) | \$ (28.6 )  |
| Basic earnings (loss) per share, as reported   | \$ (0.26 ) | \$ 0.02     |
| Basic earnings (loss) per share, pro forma   | \$ (0.30 ) | \$ (0.12 )  |
| Diluted earnings (loss) per share, as reported   | \$ (0.26 ) | \$ 0.02     |
| Diluted earnings (loss) per share, pro forma   | \$ (0.30 ) | \$ (0.12 )  |

#### *New Accounting Standards*

In July 2006, the FASB issued FASB Interpretation Number 48, Accounting for Uncertainty in Income Taxes, an Interpretation of FASB Statement No. 109 (FIN48). FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return, and provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. The Company is currently assessing the impact of the interpretation on its financial statements and will adopt the provisions of this interpretation beginning in the first quarter of 2007.

### 3. Collaborative Agreements

In August 2006, the Company entered into a collaborative agreement with Infinity Pharmaceuticals, Inc. (Infinity) to jointly develop and commercialize novel small molecule cancer drugs targeting Heat Shock Protein 90 (Hsp90) and the Hedgehog cell-signaling pathway. Under the terms of the agreement, the Company will make upfront payments to Infinity totaling \$70.0 million, which were recorded as research and development expense in Q3 2006, and agreed to potential development and sales-related milestone payments of up to \$430.0 million.

The Company recorded charges totaling \$71.7 million and \$72.9 million in Q3 2006 and YTD 2006, respectively, and \$35.2 million and \$40.6 million during Q3 2005 and YTD 2005, respectively, associated with upfront fees and milestone payments under licensing agreements and research collaborations. Such amounts are included as a component of research and development expense in the accompanying statements of operations.

### 4. Intangible Assets

Intangible assets are comprised of the following (in millions):

|  | September 30, 2006<br>Gross Carrying<br>Amount | Accumulated<br>Amortization | December 31, 2005<br>Gross Carrying<br>Amount | Accumulated<br>Amortization |
|--|--|-----------------------------|---|-----------------------------|
| Promotion rights reacquired from Abbott    | \$ 360.4                                       | \$ (91.3 )                  | \$ 360.4                                      | \$ (41.3 )                  |
| Manufacturing know-how acquired from Evans | 39.0   | (39.0 )                     | 39.0  | (34.6 )                     |
| Other intangible assets                    | 0.4  | (0.4 )                      | 0.4   | (0.4 )                      |
| Total                                      | \$ 399.8                                       | \$ (130.7 )                 | \$ 399.8                                      | \$ (76.3 )                  |

The Company recorded an intangible asset of \$360.4 million during the third quarter of 2005 in conjunction with the reacquisition of the co-promotion rights for Synagis in the United States. Amortization of the intangible asset is computed based on projected future sales of

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Synagis over the expected period of active sales and marketing efforts in the United States, which is projected to continue through the first half of 2009.

Amortization for the Company's intangible assets for Q3 2006 and Q3 2005 was \$4.6 million and \$6.1 million, respectively. Amortization for YTD 2006 and YTD 2005 was \$54.4 million and \$10.5 million, respectively. The estimated aggregate amortization for the remaining life of the assets is as follows (in millions):

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|  |          |
|--|----------|
| For the three months ended December 31, 2006 | \$ 41.0  |
| For the year ended December 31, 2007         | 104.5    |
| For the year ended December 31, 2008         | 90.7     |
| For the year ended December 31, 2009         | 32.9     |
|  | \$ 269.1 |

## 5. Inventory

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

|                 | September 30,<br>2006 | December 31,<br>2005 |
|-----------------|-----------------------|----------------------|
| Raw Materials   | \$ 13.6               | \$ 11.1              |
| Work-in-Process | 23.9                  | 42.4                 |
| Finished Goods  | 64.9                  | 15.9                 |
|                 | \$ 102.4              | \$ 69.4              |

The Company recorded permanent inventory write-downs totaling \$0.9 million during Q3 2006 and \$9.8 million and \$7.6 million during YTD 2006 and YTD 2005, respectively, in cost of sales to reflect total FluMist inventories at net realizable value. No permanent inventory write-downs were recorded during Q3 2005.

## 6. Credit Facility

On April 25, 2006, the Company entered into a \$600.0 million credit facility with a three-year term. The credit facility provides for revolving borrowings and letters of credit collateralized by the Company's marketable securities, which become restricted to the extent the credit facility is utilized. Borrowings bear interest at a variable rate based on prime or LIBOR rates, and the Company is obligated for a commitment fee associated with the unused portion of the credit facility. The credit facility contains covenants restricting the ability of the Company and its subsidiaries to incur indebtedness, grant liens, merge or liquidate, or make certain investments. As of September 30, 2006, there were no outstanding borrowings under the credit facility. As of September 30, 2006, there was \$4.4 million of restricted collateral under the credit facility related to outstanding letters of credit, which is included in other long-term assets in the accompanying balance sheet.

## 7. 1% Convertible Senior Notes Due 2023

On July 10, 2006, most of the holders of the Company's 1% convertible senior notes exercised their put options requiring the Company to redeem the notes for cash at 100% of the principal amount of the notes, plus accrued and unpaid interest. On July 17, 2006, the Company paid \$492.1 million to redeem the notes, including \$489.6 million in aggregate principal amount and \$2.5 million in accrued and unpaid interest. The remaining \$10.4 million aggregate principal amount was not redeemed and is classified as long-term debt in the accompanying balance sheet, as holders of the notes are not able to exercise a put option requiring redemption until July 2009.

## 8. Long-term Debt

During June 2006, the Company issued in a private placement \$575 million aggregate principal amount of convertible senior notes due 2011 (2011 Notes) and \$575 million aggregate principal amount of convertible senior notes due 2013 (2013 Notes) (collectively referred to as the Notes). The 2011 Notes and 2013 Notes bear interest at 1.375% per annum and 1.625% per annum, respectively, in each case payable semi-annually in arrears on January 15 and July 15 of each year.

The Notes are senior unsecured obligations of the Company, and are convertible into cash and, if applicable, shares of our common stock based on an initial conversion rate, subject to adjustment, of 29.9679 shares per \$1,000 principal amount of Notes (which represents an initial conversion price of approximately \$33.37 per share). Upon conversion, a holder would receive cash up to the principal amount of the note and the Company's common stock in respect of such note's conversion value in excess of such principal amount. The Notes are convertible only in the following circumstances: (1) if the closing sale price of the Company's common stock exceeds 130% of the conversion price during a period as defined in the indenture; (2) if the average trading price per \$1,000 principal amount of the Notes is less than or equal to 97% of the average conversion value of the Notes during a period as defined in the indenture; (3) upon the occurrence of specified corporate





transactions; and (4) at any time during the 30 day period immediately preceding the maturity date. Upon a change in control or termination of trading, holders of the Notes may require the Company to repurchase all or a portion of their Notes for cash at a repurchase price equal to 100% of the principal amount, plus any accrued and unpaid interest. During September 2006, the Company filed a registration statement to cover resales of the Notes.

In connection with the issuance of the Notes, the Company entered into separate convertible note hedge transactions and separate warrant transactions with respect to the Company's common stock to reduce the potential dilution upon conversion of the Notes (collectively referred to as the "Call Spread Transactions") (see Note 15). As a result of the Call Spread Transactions, the Company does not anticipate experiencing an increase in the total shares outstanding from the conversion of the Notes unless the price of its common stock appreciates above \$47.67 per share, effectively increasing the conversion premium to the Company to \$47.67. The Company purchased call options to cover approximately 34.5 million shares of the Company's common stock (subject to adjustment in certain circumstances), which is the number of shares underlying the Notes. In addition, the Company sold warrants permitting the purchasers to acquire up to approximately 34.5 million shares of the Company's common stock (subject to adjustment in certain circumstances).

Other long-term debt includes the remaining \$10.4 million aggregate principal amount of the 1% convertible senior notes as of September 30, 2006 and collateralized loans totaling \$4.4 million and \$5.2 million as of September 30, 2006 and December 31, 2005, respectively.

## 9. Government Contract

During the second quarter of 2006, the Company was awarded a five-year contract from the U.S. Department of Health and Human Services to develop cell-based seasonal and pandemic vaccines using our proprietary live, attenuated, intranasal influenza vaccine technology. The contract is cost-reimbursable plus a fixed fee and is initially anticipated to generate revenue of approximately \$170.0 million. The Company recognized \$3.5 million and \$5.8 million of revenues under the contract in Q3 2006 and YTD 2006, respectively, which is included in other revenue in the accompanying statements of operations. As of September 30, 2006, approximately \$5.8 million is due from the government, which is included in other current assets in the accompanying balance sheet.

## 10. Share-based Compensation

As of September 30, 2006, the Company has a number of share-based compensation plans as described below. The pre-tax compensation cost that has been recognized for those plans is as follows (in millions):

|                                     | Q3<br>2006 | YTD<br>2006 |
|-------------------------------------|------------|-------------|
| Cost of sales                       | \$ 0.3     | \$ 0.7      |
| Research and development            | 2.4        | 7.6         |
| Selling, general and administrative | 4.9        | 15.9        |
|                                     | \$ 7.6     | \$ 24.2     |
| Capitalized in inventory            | 0.4        | 1.5         |
| Share-based compensation cost       | \$ 8.0     | \$ 25.7     |

The total income tax benefit recognized in the statements of operations for the deductible portion of share-based compensation was \$1.6 million in Q3 2006 and \$5.0 million in YTD 2006.

The Company grants stock option incentive awards under certain of the following plans. The 2004 Stock Incentive Plan (the "2004 Plan") is used prospectively as the primary plan for employee awards.

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| Plan                             | Description   | Shares Authorized for Option Grants (in millions) |
|----------------------------------|---|---|
| 1991 Plan                        | Provides option incentives to employees, consultants and advisors of the Company  | 33.0  |
| 1999 Plan                        | Provides option incentives to employees, consultants and advisors of the Company  | 23.3  |
| 2003 Non-Employee Directors Plan | Provides option incentives to non-employee directors  | 1.4   |
| 2004 Plan                        | Provides option, stock appreciation rights, restricted stock, stock units and/or stock incentive awards to employees, non-employee directors, consultants and advisors of the Company | 21.0  |

The following compensation plans, for which there are options outstanding but no future grants are intended to be made, were acquired by the Company in connection with its acquisitions of U.S. Bioscience, Inc. and Aviron ( Acquired Plans ):

| Plan                                   | Description  |
|--|--|
| Non-Executive Plan                     | Provided option incentives to employees who were not officers or directors of U.S. Bioscience, Inc., consultants and advisors of the company   |
| Non-Employee Directors Plan            | Provided option incentives to elected non-employee directors of U.S. Bioscience, Inc.  |
| 1996 Equity Incentive Plan             | Provided incentive and nonstatutory stock options to employees and consultants of Aviron   |
| 1999 Non-Officer Equity Incentive Plan | Provided nonstatutory stock options, stock bonuses, rights to purchase restricted stock, and stock appreciation rights to consultants and employees who were not officers or directors of Aviron |

Options under all plans normally vest over a three to five year period and have a maximum term of 10 years. The Company has reserved a total of approximately 17.0 million shares of common stock for issuance under these plans as of September 30, 2006. Related stock option activity is as follows (shares in millions):

|                             | 1991, 1999 and 2004 Plans |                     | Non-Employee Directors Plans |                     | Acquired Plans |                     |
|-----------------------------|---------------------------|---------------------|------------------------------|---------------------|----------------|---------------------|
|                             | Shares                    | Price per share (1) | Shares                       | Price per share (1) | Shares         | Price per share (1) |
| Outstanding, Dec. 31, 2002  | 24.1                      | \$ 33.45            | 0.9                          | \$ 29.53            | 3.6            | \$ 28.17            |
| Granted                     | 5.4                       | 30.18               | 0.2                          | 35.87               |                |                     |
| Exercised                   | (2.0 )                    | 11.61               | (0.1 )                       | 2.02                | (0.7 )         | 21.30               |
| Canceled                    | (1.4 )                    | 41.33               |                              |                     | (0.3 )         | 33.98               |
| Outstanding, Dec .31, 2003  | 26.1                      | 34.00               | 1.0                          | 30.52               | 2.6            | 29.82               |
| Granted                     | 4.9                       | 23.93               | 0.2                          | 23.17               |                |                     |
| Exercised                   | (1.0 )                    | 9.21                | (0.2 )                       | 1.31                | (0.2 )         | 20.86               |
| Canceled                    | (2.5 )                    | 35.51               |                              |                     | (0.3 )         | 32.63               |
| Outstanding, Dec. 31, 2004  | 27.5                      | 33.12               | 1.0                          | 33.12               | 2.1            | 30.48               |
| Granted                     | 5.0                       | 25.78               | 0.2                          | 26.71               |                |                     |
| Exercised                   | (1.6 )                    | 17.16               |                              |                     | (0.4 )         | 21.32               |
| Canceled                    | (2.4 )                    | 33.31               |                              |                     | (0.3 )         | 36.78               |
| Outstanding, Dec. 31, 2005  | 28.5                      | 32.58               | 1.2                          | 31.88               | 1.4            | 32.06               |
| Granted                     | 4.0                       | 35.75               | 0.2                          | 27.12               |                |                     |
| Exercised                   | (1.9 )                    | 22.63               | (0.1 )                       | 6.11                | (0.2 )         | 25.36               |
| Canceled                    | (2.6 )                    | 40.80               |                              |                     | (0.1 )         | 40.76               |
| Outstanding, Sept. 30, 2006 | 28.0                      | \$ 32.91            | 1.3                          | \$ 32.60            | 1.1            | \$ 33.02            |

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(1) Price per share is the weighted average exercise price.

The following disclosure provides a description of the significant assumptions used during the first three quarters of 2006, as well as full years 2005, 2004 and 2003 to estimate the fair value of the Company's employee stock option awards.

YTD 2006 and Full Year 2005 - The fair value of employee stock options granted since January 1, 2005 were estimated using a binomial lattice-based valuation model that uses the weighted-average assumptions shown in the table below. The

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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. 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 the first three quarters of 2006 and full year 2005 reflects the implied volatility determined from the market prices of traded call options on the Company's stock. 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.

|  | Q1 2006    | Q2 2006    | Q3 2006    | Full Year 2005 |
|--|------------|------------|------------|----------------|
| Option pricing model                           | Binomial   | Binomial   | Binomial   | Binomial       |
| Expected stock price volatility                | 31         | % 31       | % 32       | % 32           |
| Expected dividend yield                        | 0          | % 0        | % 0        | % 0            |
| Expected life of option-years                  | 4.3 to 4.8 | 4.5 to 5.4 | 4.4 to 4.8 | 4.3 to 5.4     |
| Risk-free interest rate                        | 4.6        | % 4.9      | % 5.0      | % 4.3          |
| Weighted average fair value of options granted | \$ 12.46   | \$ 10.84   | \$ 9.76    | \$ 8.94        |

2004 and 2003 - The fair value of employee stock options granted during 2004 and 2003 was estimated using a Black-Scholes model that used 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 then currently available for zero-coupon U.S. government issues with a term equal to the expected life of the option.

|  | 2004          | 2003          |
|--|---------------|---------------|
| Option pricing model                           | Black-Scholes | Black-Scholes |
| Expected stock price volatility                | 49            | % 51          |
| Expected dividend yield                        | 0             | % 0           |
| Expected life of option-years                  | 5.0           | 5.0           |
| Risk-free interest rate                        | 3.4           | % 3.3         |
| Weighted average fair value of options granted | \$ 11.20      | \$ 16.55      |

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Additional information related to the plans as of September 30, 2006 is as follows (shares in millions):

| Range of exercise prices | Options Outstanding |  |                          | Options Exercisable |                          |
|--------------------------|---------------------|--|--------------------------|---------------------|--------------------------|
|                          | Options Outstanding | Wtd Avg Remaining contractual life (yrs) | Wtd. Avg. Exercise Price | Options Exercisable | Wtd. Avg. Exercise Price |
| \$ 0.01 \$10.00          | 1.4                 | 1.2                                      | \$ 6.71                  | 1.4                 | \$ 6.71                  |
| \$10.01 \$20.00          | 1.6                 | 2.5                                      | \$ 18.24                 | 1.6                 | \$ 18.24                 |
| \$20.01 \$30.00          | 12.8                | 7.1                                      | \$ 25.65                 | 8.0                 | \$ 26.03                 |
| \$30.01 \$40.00          | 8.1                 | 7.2                                      | \$ 36.22                 | 4.1                 | \$ 36.68                 |
| \$40.01 \$50.00          | 3.1                 | 4.9                                      | \$ 42.59                 | 3.1                 | \$ 42.59                 |
| \$50.01 \$60.00          | 0.4                 | 3.5                                      | \$ 56.81                 | 0.4                 | \$ 56.81                 |
| \$60.01 \$70.00          | 2.7                 | 3.4                                      | \$ 60.94                 | 2.7                 | \$ 60.94                 |
| \$70.01 \$80.00          | 0.3                 | 3.9                                      | \$ 72.25                 | 0.3                 | \$ 72.25                 |
|                          | 30.4                | 6.0                                      | \$ 32.91                 | 21.6                | \$ 34.12                 |

The total intrinsic value of options exercised during YTD 2006 and the years ended December 31, 2005, 2004 and 2003 was \$24.6 million, \$24.5 million, \$15.5 million and \$49.3 million, respectively. The total intrinsic value of options outstanding and options exercisable at September 30, 2006 was \$96.8 million and \$76.4 million, respectively. The weighted average remaining contractual life of options exercisable at September 30, 2006 was 4.9 years.

A summary of the status of the Company's nonvested shares as of September 30, 2006 and changes during YTD 2006 is presented below (shares in millions):

| Nonvested Shares              | 1991, 1999 and 2004 Plans |                                 | Non-Employee Directors Plans |                                 |
|-------------------------------|---------------------------|---------------------------------|------------------------------|---------------------------------|
|                               | Shares                    | Wtd. Avg. Grant-Date Fair Value | Shares                       | Wtd. Avg. Grant-Date Fair Value |
| Nonvested, December 31, 2005  | 8.1                       | \$ 10.99                        | 0.5                          | \$ 11.91                        |
| Granted                       | 4.0                       | 12.19                           | 0.2                          | 10.35                           |
| Vested                        | (3.1 )                    | 12.16                           | (0.2 )                       | 13.15                           |
| Forfeited                     | (0.7 )                    | 11.16                           |                              |                                 |
| Nonvested, September 30, 2006 | 8.3                       | 11.12                           | 0.5                          | 10.86                           |

As of September 30, 2006, there was approximately \$52.3 million of total unrecognized compensation related to nonvested employee stock option awards. Such cost is expected to be recognized as follows: \$6.6 million in the fourth quarter of 2006, \$19.9 million in 2007, \$13.9 million in 2008, \$10.3 million in 2009 and \$1.6 million in 2010.

The total fair value of shares vested during YTD 2006 and the year ended December 31, 2005 was \$39.9 million and \$70.1 million, respectively.

A summary of the stock options vested and expected to vest as of September 30, 2006 is presented below (shares and intrinsic value in millions):

|                              | Shares | Wtd Avg Ex. Price | Wtd Avg remaining contractual life (yrs) | Aggregate Intrinsic Value |
|------------------------------|--------|-------------------|--|---------------------------|
| 1991, 1999 and 2004 Plans    | 26.3   | \$ 33.09          | 5.9                                      | \$ 85.4                   |
| Non-Employee Directors Plans | 1.3    | 32.60             | 6.5                                      | 4.2                       |
| Acquired Plans               | 1.1    | 33.02             | 3.6                                      | 3.2                       |



In June 2001, the Company introduced an employee stock purchase plan under which 3.0 million shares of common stock were reserved for issuance. Eligible employees may purchase a limited number of shares of the Company's common stock at 85% of the market value at plan-defined dates. Employees purchased 0.1 million shares, 0.3 million shares, 0.2 million shares and 0.2 million shares, for \$3.3 million, \$5.6 million, \$4.6 million and \$4.8 million, during YTD 2006, 2005, 2004 and 2003, respectively, under the plan. Expense recognized in Q3 2006 and YTD 2006, determined using the Black-Scholes model, was \$0.6 million and \$1.6 million, respectively.

## 11. Income Taxes

The Company's effective tax rate was 55% for Q3 2006 compared to an effective tax rate of 29% for Q3 2005. The Company's effective tax rate was 53% for YTD 2006 compared to an effective tax rate of 65% for YTD 2005.

## 12. Earnings per Share

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

|   | Q3<br>2006 | Q3<br>2005 | YTD<br>2006 | YTD<br>2005 |
|---|------------|------------|-------------|-------------|
| <b>Numerator:</b>   |            |            |             |             |
| Net (loss) earnings for basic EPS   | \$ (55.8 ) | \$ (64.1 ) | \$ (72.0 )  | \$ 5.8      |
| Adjustments for interest expense on convertible senior notes,<br>net of tax (1) |            |            |             |             |
| Earnings (loss) for diluted EPS   | \$ (55.8 ) | \$ (64.1 ) | \$ (72.0 )  | \$ 5.8      |
| <b>Denominator:</b>   |            |            |             |             |
| Weighted average shares for basic EPS   | 239.3      | 245.9      | 244.3       | 247.1       |
| <b>Effect of dilutive securities:</b>   |            |            |             |             |
| Stock options and warrants  |            |            |             | 2.3         |
| Convertible senior notes (1)  |            |            |             |             |
| Weighted average shares for diluted EPS   | 239.3      | 245.9      | 244.3       | 249.4       |
| Basic earnings (loss) per share   | \$ (0.23 ) | \$ (0.26 ) | \$ (0.29 )  | \$ 0.02     |
| Diluted earnings (loss) per share   | \$ (0.23 ) | \$ (0.26 ) | \$ (0.29 )  | \$ 0.02     |

(1) The Company's \$500 million 1% convertible senior notes, which represent 7.3 million potential shares of common stock, are included in the calculation of diluted earnings per share for the period of time they are outstanding 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. The \$1.15 billion convertible senior notes are included in the calculation of diluted earnings per share whether or not the contingent requirements have been met for conversion using the treasury stock method if the conversion price of \$33.37 is less than the average market price of the Company's common stock for the period, because upon conversion, the par value is settled in cash and only the conversion premium is settled in shares of the Company's common stock. The Company's convertible senior notes were anti-dilutive for all periods presented.

The Company incurred a net loss for Q3 2006, Q3 2005 and YTD 2006, 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 64.9 million shares (including warrants to acquire 34.5 million shares issued in June 2006) and 33.4 million shares of common stock were outstanding at September 30, 2006 and 2005, 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.



**13. Investments in Equity Securities**

During Q3 2006, the Company recorded an other-than-temporary impairment loss of \$8.1 million for one of its minority interest investments based on the duration and magnitude of the decline in the fair value as well as the financial condition and near-term prospects of the investee company.

**14. Comprehensive Income**

|   | <b>Q3<br/>2006</b> | <b>Q3<br/>2005</b> | <b>YTD<br/>2006</b> | <b>YTD<br/>2005</b> |
|---|--------------------|--------------------|---------------------|---------------------|
| Net earnings (loss)   | \$ (55.8 )         | \$ (64.1 )         | \$ (72.0 )          | \$ 5.8 )            |
| Change in foreign currency translations adjustment          | (0.2 )             |                    | 0.1                 | (0.8 )              |
| Change in unrealized gain (loss) on investments, net of tax | 9.1                | 0.9                | 5.9                 | (8.1 )              |
| Comprehensive loss  | \$ (46.9 )         | \$ (63.2 )         | \$ (66.0 )          | \$ (3.1 )           |

**15. Shareholders' Equity**

In connection with the issuance of the Notes (see Note 8) in June 2006, the Company entered into the Call Spread Transactions. The Call Spread Transactions have the effect of reducing the potential dilution upon conversion of the Notes. As a result of the Call Spread Transactions, the Company does not anticipate experiencing an increase in the number of shares outstanding from the conversion of the Notes unless the price of its common stock appreciates above \$47.67 per share, effectively increasing the conversion premium to the Company to \$47.67. The Call Spread Transactions do not affect the rights of noteholders under the Notes. The Company purchased call options in private transactions to cover approximately 34.5 million shares of the Company's common stock at a strike price of \$33.37 per share (subject to adjustment in certain circumstances) for \$316.5 million (\$201.0 net of tax benefit). The call options generally allow the Company to receive shares of the Company's common stock from counterparties equal to the number of shares of common stock payable to the holders of the Notes upon conversion. These call options will terminate the earlier of the maturity dates of the related senior convertible notes or the first day all of the related senior convertible notes are no longer outstanding due to conversion or otherwise. As of September 30, 2006, the estimated fair value of the call options was \$340.7 million. The Company also sold warrants permitting the purchasers to acquire up to approximately 34.5 million shares of the Company's common stock at an exercise price of \$47.67 per share (subject to adjustments in certain circumstances) in private transactions for a total proceeds of approximately \$177.0 million. The warrants may be settled over specified periods beginning in July 2011 and July 2013. The warrants provide for net share settlement. In no event shall the Company be required to deliver a number of shares in connection with the transaction in excess of twice the aggregate number of warrants. As of September 30, 2006, the estimated fair value of the warrants was \$203.7 million. The Company has analyzed the Call Spread Transactions under Emerging Issues Task Force Issue No. 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled In, a Company's Own Stock," and determined that they meet the criteria for classification as equity transactions. As a result, in the second quarter of 2006 the Company recorded the purchase of the call options as a reduction in additional paid-in capital and the proceeds of the warrants as an addition to paid-in capital, and the Company will not recognize subsequent changes in fair value of the agreements.

In May 2006, the Board of Directors authorized a new stock repurchase program for up to \$500 million of the Company's common stock in the open market or in privately negotiated transactions. The previous stock repurchase program, which was approved in July 2003 for \$500 million, was fully utilized as of June 2006. During Q3 2006, the Company repurchased approximately 0.3 million shares of common stock at a cost of \$7.7 million, or an average cost of \$25.73 per share. During YTD 2006, the Company repurchased approximately 10.0 million shares of common stock at a cost of \$289.6 million, or an average cost of \$28.95 per share. 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.

**16. Legal Proceedings**

The Company's material legal proceedings are described in Note 18 to the consolidated financial statements included with the Company's Annual Report on Form 10-K for the year ended December 31, 2005 and in the update to that note provided in the Company's Quarterly Report on Form 10-Q for the quarters ended March 31, 2006 and June 30, 2006. With respect to the legal proceedings described therein, no material developments have occurred except as follows:

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*Various Patent Litigation Matters*

With respect to the Company's lawsuit against Genentech, Inc., Celltech R&D Limited and City of Hope National Medical Center, in April 2004, the United States District Court for the Central District of California dismissed the claims remaining in that case at the time for lack of subject matter jurisdiction. The Company appealed the dismissal to the United States Court of Appeals for the Federal Circuit, and in October 2005, that court issued a decision, affirming the District Court decision which had dismissed all claims. The Company subsequently filed a Petition for Certiorari with the United States Supreme Court as to the subject matter jurisdiction issue which was granted in February 2006. The Supreme Court heard oral arguments with respect to this matter on October 4, 2006 and a decision is pending.

With respect to the Company's lawsuit against Centocor, Inc., the Trustees of Columbia University in the City of New York and the Board of Trustees of the Leland Stanford Junior University, in June 2004, the United States District Court for the District of Maryland dismissed the claims remaining in that case at the time for lack of subject matter jurisdiction. The Company appealed the dismissal to the United States Court of Appeals for the Federal Circuit, and in June 2005, that court issued a decision, affirming the District Court decision which had dismissed all claims. The Company subsequently filed a Petition for Certiorari with the United States Supreme Court as to the subject matter jurisdiction issue and is awaiting a decision on that petition. The Company believes the Supreme Court will not make a decision on its petition until the Genentech matter described above is resolved.

In January 2006, Genentech filed an action against the Company alleging that the Company's Synagis product infringed two United States patents relating to certain lyophilized products. The suit was filed in the United States District Court for the Eastern District of Texas and seeks unspecified money damages, but the Company was never served with the complaint. The Company has been advised that Genentech has withdrawn the complaint with respect to this matter.

*Litigation Regarding Generic Version of Ethyol*

With respect to the litigation between Sun Pharmaceutical Industries Limited and the Company related to a generic version of Ethyol (amifostine), Sun filed a motion seeking summary judgment and a hearing was held with respect to this motion on October 24, 2006. A decision by the court is pending.

*Average Wholesale Price Cases*

The status of the various lawsuits by various states and counties alleging manipulation of average wholesale price by several defendants, including the Company, did not change materially during Q3 2006. As of September 30, 2006, the Company estimates the range of potential pre-tax loss from the Alabama action, the Mississippi action, the New York City action and the New York State County actions (both consolidated and unconsolidated) to range from \$0 to \$15 million, exclusive of alleged treble damages, best price related claims and other asserted state law causes of action.

**17. Subsequent Event**

On October 24, 2006, Amgen, Inc. acquired the outstanding equity interests of Avidia, Inc., a privately held biopharmaceutical company. The Company's wholly-owned venture capital subsidiary, MedImmune Ventures, Inc., owned approximately 11% of the outstanding equity interests of Avidia. In connection with the transaction, the Company will record a pre-tax gain of approximately \$30 million during the fourth quarter of 2006 and could recognize additional gains up to \$6 million in the future upon the achievement of certain contingent milestone events.

## 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 section in Part I, Item 1 of our Annual Report on Form 10-K for the year ended December 31, 2005 and the Risk Factors section in Part II, Item 1A of this Quarterly Report on Form 10-Q.*

### INTRODUCTION

MedImmune is committed to advancing science to develop better medicines that help people live healthier, longer and more satisfying lives. We currently focus our efforts on using biotechnology to produce innovative products for prevention and treatment in the therapeutic areas of infectious disease, cancer and inflammatory disease. Our scientific expertise is largely in the areas of monoclonal antibodies and vaccines. We market four products: Synagis, FluMist, Ethyol and CytoGam, and have a diverse pipeline of development-stage products.

### OVERVIEW

We recorded a net loss of \$0.29 per diluted share in YTD 2006 compared to net earnings per diluted share of \$0.02 in YTD 2005. The decline in earnings in YTD 2006 is primarily attributable to increased research and development spending, amortization of the intangible asset resulting from the acquisition of Synagis promotion rights, higher selling, general and administrative expenses associated with the expansion of the pediatric sales force, and share-based compensation expense.

During the first three quarters of 2006, we continued to advance our research and development pipeline as follows:

- We submitted a supplemental Biologics License Application to the U.S. Food and Drug Administration ( FDA ) in July 2006 for approval to use CAIV-T in preventing influenza in children down to one year of age who do not have a history of wheezing or asthma;
- We replied to the complete response letter received from the FDA to our supplemental biologics license application for the potential approval to switch formulations from frozen FluMist to CAIV-T;
- The FDA approved our reverse genetics technology, which is a more timely, reliable, and safer process for producing seasonal and pandemic influenza vaccines;
- Dosing was completed for a Phase 1 study with a vaccine candidate against an H5N1 influenza virus under a Cooperative Research and Development Agreement ( CRADA ) with the National Institutes of Health ( NIH );
- A CRADA was signed with the NIH for the development of vaccine candidates targeting RSV, parainfluenza virus types 1, 2 and 3, and other respiratory viruses;
- We continued with three ongoing studies for Numax, with the expectation of announcing preliminary results from the pivotal Phase 3 trial directly comparing Numax to Synagis during the fourth quarter of 2006;
- Dosing began in a Phase 1 study for lupus patients with a monoclonal antibody targeting interferon alpha;
- We filed an investigational new drug application with the FDA to begin clinical studies in the U.S. with MT103 for the treatment of patients with B-cell-derived non-Hodgkins lymphoma not eligible for curative therapy.

In connection with the ongoing management of our product development programs, we made the decision to stop our Phase 3 efforts with Abegrin in metastatic melanoma. After reviewing the 24-month survival data from our Phase 2 study, we determined that the significant drop in survival benefit previously seen at 12 months would require a significantly larger study to show a clinically meaningful benefit.

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In August 2006, we entered into a collaborative agreement with Infinity Pharmaceuticals, Inc. to jointly develop and commercialize novel small molecule cancer drugs targeting Heat Shock Protein 90 ( Hsp90 ) and the Hedgehog cell-signaling pathway. Under the terms of the agreement, we will make upfront payments to Infinity of \$70.0 million, which were recognized as research and development expense in Q3 2006 and agreed to potential development and sales-related milestone payments of up to \$430.0 million.

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During YTD 2006, we earned and recorded \$11.9 million in sales royalties and milestone revenues upon approval of Merck & Co., Inc.'s human papillomavirus (HPV) vaccine to prevent cervical cancer by the FDA and European Union and achievement of certain sales-related goals, and related to GlaxoSmithKline's European filing for its cervical cancer vaccine. Sales royalties related to Merck's and GSK's HPV vaccines are based on graduated royalty rate structures up to certain annual sales levels.

During the second quarter of 2006, we were awarded a \$170.0 million, five-year contract from the U.S. Department of Health and Human Services to develop cell-based seasonal and pandemic vaccines using our proprietary live, attenuated, intranasal influenza vaccine technology. Work on the contract commenced during the second quarter, resulting in the recognition of approximately \$5.8 million of revenues for YTD 2006.

During Q3 2006, we began the expansion of our biologics manufacturing facility in Frederick, Maryland at an estimated construction cost of \$250.0 million.

On October 24, 2006, Amgen, Inc. acquired the outstanding equity interests of Avidia, Inc., a privately held biopharmaceutical company. The Company's wholly-owned venture capital subsidiary, MedImmune Ventures, Inc., owned approximately 11% of the outstanding equity interests of Avidia. In connection with the transaction, we will record a pre-tax gain of approximately \$30 million during the fourth quarter of 2006 and could recognize additional gains up to \$6 million in the future upon the achievement of certain contingent milestone events.

In May 2006, the Board of Directors authorized a new stock repurchase program for up to \$500.0 million of our common stock in the open market or in privately negotiated transactions. The original stock repurchase program, which was approved in July 2003 for \$500.0 million, was fully utilized as of June 2006.

During June 2006, we issued \$1.15 billion in convertible senior notes (the Notes) for total proceeds of \$1.13 billion, net of debt issuance costs. In connection with the issuance of the Notes, we entered into separate convertible note hedge transactions and separate warrant transactions with respect to our common stock (collectively referred to as the Call Spread Transactions). The Call Spread Transactions have the effect of reducing the potential dilution upon conversion of the Notes. As a result of the Call Spread Transactions, we do not anticipate experiencing dilution from the issuance of the Notes unless the price of our common stock appreciates above \$47.67 per share, effectively increasing the conversion premium to \$47.67. We purchased call options to cover approximately 34.5 million shares of our common stock at a strike price of \$33.37 per share for \$316.5 million, and sold warrants to acquire approximately 34.5 million shares of our common stock at a strike price of \$47.67 per share for aggregate proceeds of approximately \$177.0 million. Concurrently with the sale of the Notes, we used \$148.0 million of the net proceeds to repurchase approximately 5.4 million shares of our common stock in privately negotiated transactions. The Notes were issued in part to redeem our \$500.0 million of 1% convertible senior notes that were called by most of the bondholders in July 2006. We intend to use the balance of the proceeds for general corporate purposes, including potential acquisitions, in-licensing and collaboration opportunities, and additional share repurchases, pursuant to the company's remaining authority under our \$500.0 million share buyback program authorized in May 2006.

Our cash and marketable securities at September 30, 2006 and December 31, 2005 totaled \$1.5 billion, reflecting the net proceeds from the June 2006 convertible debt financing and related transactions, offset by the redemption of the majority of our 1% convertible senior notes in July 2006 and repurchases of approximately 10.0 million of our common stock at a total cost of \$289.6 million. Also, the third quarter is typically the seasonal low point for cash balances prior to the beginning of the Synagis and FluMist seasons.

### 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 our Annual Report on Form 10-K for the year ended December 31, 2005. 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. The following discussion updates the critical accounting estimates information included in the Form 10-K for the year ended December 31, 2005.

**Inventory** - We may capitalize inventory costs associated with 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 any 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. There are no inventory amounts related to pre-approval or pre-launch products as of September 30, 2006.

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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, certain 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 as well as sales volumes and production capacity 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 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 2006/2007 season began in October 2005. 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, 2006, 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, 2006 at net realizable value was consistent with the methodology used for previous valuations, since product approval in June 2003.

The valuation of inventory as of September 30, 2006 is based on sales volume and price estimates for the 2006/2007 season that are largely based on our actual experience for previous seasons and our expectations for the current season. Sales estimates for the 2006/2007 season incorporated into the inventory valuations performed as of March 31, 2006 were lower than the estimate used for valuation at December 31, 2005, resulting in a permanent write-down of \$7.2 million in the first quarter of 2006. Sales estimates for the 2006/2007 season incorporated into the inventory valuations performed as of June 30, 2006 were slightly higher than the estimate used for valuation at March 31, 2006, resulting in a reduction of cost of goods sold of \$2.9 million during the second quarter of 2006 to reflect the higher net realizable value. There were no changes in sales estimates for the 2006/2007 season for purposes of the inventory valuation performed as of September 30, 2006.

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

|  | Gross<br>Inventory | Reserves   | Net Inventory |
|--|--------------------|------------|---------------|
| <b>FluMist Details</b>                               |                    |            |               |
| As of December 31, 2005                              | \$ 56.4            | \$ (37.8 ) | \$ 18.6       |
| Raw materials, net                                   | (4.4 )             | 1.1        | (3.3 )        |
| Cost of goods sold recognized on 2005/2006 inventory | (1.9 )             | 0.6        | (1.3 )        |
| Cost of goods sold recognized on 2006/2007 inventory | (16.9 )            | 3.5        | (13.4 )       |
| Production, net                                      | 33.6               | (5.8 )     | 27.8          |
| Disposals and scrap                                  | (33.8 )            | 32.9       | (0.9 )        |
| As of September 30, 2006                             | \$ 33.0            | \$ (5.5 )  | \$ 27.5       |

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. Therefore, 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.

**Sales Allowances** **Product sales are recorded net of allowances for estimated chargebacks, returns, discounts, and government rebates. Both in the U.S. and elsewhere, sales of pharmaceutical products depend on the availability of reimbursement to the consumer from third-party payers, such as government and private insurance plans. We estimate the portion of our sales that will be covered by government insurance and record allowances at a level that management believes is sufficient to cover estimated requirements for reimbursements. Significant judgment is required in making certain of these estimates. During Q3 2006, we recorded adjustments to our allowance for Medicaid rebates related to Synagis sales, resulting in lower product revenue of \$4.1 million.**

**Intangible Assets** - Management assesses the intangible asset associated with the reacquisition of the U.S. co-promotion rights for Synagis for impairment on a periodic basis; however, no impairments have occurred as of September 30, 2006. Further, the total future projected domestic sales of Synagis through the first half of 2009, used as the basis for amortization of the related intangible asset, have not been revised based on quarterly sales results through September 30, 2006. Management will assess the estimate of total future domestic Synagis sales in conjunction with the annual long range planning process to be performed in the fourth quarter of 2006. If the total of incremental payments, a portion of which are variable based on actual sales, made to Abbott in connection with the reacquisition of co-promotion rights are ultimately less than the amount of the associated liability recorded, the amount of the intangible asset will be adjusted accordingly.

**Investments in Debt and Equity Securities** During Q3 2006, we recorded an other-than-temporary impairment loss of \$8.1 million for one of our minority interest investments based on the duration and magnitude of the decline in the fair value as well as the financial condition and near-term prospects of the investee company.

#### **NEW ACCOUNTING STANDARDS**

Issued in December 2004, Statement of Financial Accounting Standards No.123R ( SFAS 123R ) requires public companies to recognize expense associated with share-based compensation arrangements, including employee stock options and stock purchase plans, 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 is effective for our fiscal year beginning January 1, 2006. Adoption of the expense provisions of SFAS 123R has a material impact on our results of operations. We have applied the modified prospective transition method; accordingly, compensation expense is reflected in the financial statements beginning January 1, 2006 with no restatement of prior periods. Compensation expense is 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. For the adoption of SFAS 123R, we have selected the straight-line expense attribution method, whereas our previous expense attribution method was the graded-vesting method, an accelerated method, described by FIN 28.

Any future changes to our share-based compensation strategy or programs would likely affect the amount of compensation expense recognized under SFAS 123R and the comparability to our prior period footnote disclosures of pro forma net earnings and earnings per share. Share-based compensation expense recognized in Q3 2006 and YTD 2006 totaled \$7.6 million and \$24.2 million, respectively, on a pre-tax basis, and \$6.0 million and \$19.2 million, respectively, after tax. Share-based compensation capitalized in inventory was \$0.4 million and \$1.5 million in Q3 2006 and YTD 2006, respectively.

In July 2006, the FASB issued FASB Interpretation Number 48, Accounting for Uncertainty in Income Taxes, an Interpretation of FASB Statement No. 109 ( FIN 48 ). FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and

**Sales Allowances** **Product sales are recorded net of allowances for estimated chargebacks, returns, discounts, and**

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measurement of a tax position taken or expected to be taken in a tax return, and provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. We are currently assessing the impact of the interpretation on our financial statements and will adopt the provisions of this interpretation beginning in the first quarter of 2007.

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Sales Allowances Product sales are recorded net of allowances for estimated chargebacks, returns, discounts, and

**RESULTS OF OPERATIONS****Q3 2006 compared to Q3 2005****Revenues - Product Sales**

| (in millions)              | Q3<br>2006 | Q3<br>2005 | Change |   |
|----------------------------|------------|------------|--------|---|
| <b>Synagis</b>             |            |            |        |   |
| Domestic                   | \$ 45.3    | \$ 42.8    | 6      | % |
| International              | 66.3       | 58.2       | 14     | % |
|                            | 111.6      | 101.0      | 11     | % |
| <b>Ethylol</b>             |            |            |        |   |
| Domestic                   | 22.3       | 23.5       | (5)    | % |
| International              | 0.1        | 1.2        | (9)    | % |
|                            | 22.4       | 24.7       | (9)    | % |
| <b>FluMist</b>             |            |            |        |   |
|                            | 15.9       | 10.4       | 52     | % |
| <b>Other Products</b>      |            |            |        |   |
|                            | 8.7        | 9.9        | (11)   | % |
| <b>Total Product Sales</b> | \$ 158.6   | \$ 146.0   | 9      | % |

*Synagis* - Synagis accounted for approximately 70% and 69% of our product sales in Q3 2006 and Q3 2005, respectively. In Q3 2006, domestic sales of Synagis increased 6% to \$45.3 million from Q3 2005 sales of \$42.8 million. The increase in domestic sales was primarily attributable to a 9.7% price increase and higher unit volumes, offset partially by a \$4.1 million adjustment to sales allowances. The volume increase largely reflects normal inventory stocking by new distributors added this year working in preparation for the upcoming season. These additional distributors are a result of our efforts to align our distribution network with payers with whom they have relationships, as well as to improve the relationships we have had in place for the past seasons.

We record Synagis international product sales based on a portion of Abbott International's (AI) sales price to customers, as defined in our distribution agreement. Our reported international sales of Synagis increased 14% to \$66.3 million for Q3 2006 as compared to \$58.2 million in Q3 2005, primarily due to increased unit volumes sold to AI.

*Ethylol* - Ethylol accounted for approximately 14% and 17% of our product sales in Q3 2006 and Q3 2005, respectively. Domestic sales of Ethylol decreased 5% to \$22.3 million in Q3 2006, compared to \$23.5 million in Q3 2005 due to lower unit volume partially offset by a 6% price increase. International sales of Ethylol were \$0.1 million in Q3 2006 as compared to \$1.2 million in the prior year quarter.

*FluMist* - Our Q3 2006 product sales of FluMist grew 52% to \$15.9 million, compared to \$10.4 million in Q3 2005, due to an increase in volume. This season, FluMist was the first influenza vaccine available for distribution when the first lots were released by the FDA in July. By mid-September, all FluMist lots manufactured for the 2006-2007 season had been released by the FDA and were available for distribution to customers. The majority of FluMist sales occur in the third and fourth quarters due to the applicability of the vaccine to preventing a seasonal virus.

*Other Products* - Sales of other products, which primarily represent sales of CytoGam and by-products that result from its manufacturing process, were \$8.7 million in Q3 2006 as compared to \$9.9 million in Q3 2005. The decrease was attributable to plasma supply constraints, as well as the transition to a new third-party manufacturer.

**Revenues - Other Revenues**

**Sales Allowances** - Product sales are recorded net of allowances for estimated chargebacks, returns, discounts, and

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Other revenues for Q3 2006 include \$6.9 million in sales royalties and milestone revenues upon Merck's HPV vaccine receiving approval by the European Union and achieving a predetermined sales-related goal. Sales royalties related to Merck's and GSK's HPV vaccine are based on graduated royalty rate structures up to certain annual sales levels. Other revenues also includes \$3.5 million recognized under the government contract, as well as \$8.2 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.

### Cost of Sales

Cost of sales was \$53.5 million for Q3 2006 compared to \$48.7 million in Q3 2005. Gross margins on product sales for Q3 2006 and Q3 2005 were 66% and 67%, respectively. The increase in the proportion of lower margin sales of FluMist exerted downward pressure on overall gross margins for Q3 2006. Without the impact of FluMist, third quarter gross margins were 73% in 2006 and 72% in 2005. Share-based compensation expense did not significantly impact gross margins in Q3 2006.

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### Research and Development Expenses

Research and development expenses increased 36% to \$162.0 million in Q3 2006, compared to \$119.1 million in Q3 2005. The increase is primarily due to the \$70.0 million of upfront payments for the Infinity collaboration and increased costs associated with expanded infrastructure, offset by lower clinical trial spending, as the 2005 quarter included expenses associated with the pivotal Phase 3 clinical trial for CAIV-T that was unblinded in December 2005. Research and development expense for Q3 2006 included share-based compensation expense of \$2.4 million.

### Selling, General and Administrative Expenses

Selling, general and administrative ( SG&A ) expenses increased 9% to \$88.2 million in Q3 2006 compared to \$81.1 million in Q3 2005. The increase is attributable to increased personnel costs due to the expansion of the pediatric sales organization and the marketing and sales management team during the first half of 2006, commissions on earlier FluMist sales, increased fees for legal and other professional services, and \$4.9 million of share-based compensation expense recognized in Q3 2006, partially offset by the absence of co-promotion expense to AI, which totaled \$8.1 million in Q3 2005. Effective July 1, 2006, co-promotion expense to Abbott has been discontinued and the intangible amortization costs related to the reacquisition of U.S. co-promotion rights will continue until we cease actively marketing Synagis, which is expected to occur sometime during the 2008/2009 season, when we expect to start marketing Numax. Intangible amortization expense was \$4.6 million and \$3.9 million in Q3 2006 and Q3 2005, respectively.

### Loss on Investment Activities

We recorded a loss on investment activities of \$8.2 million during Q3 2006, primarily due to the decline in fair value of one of our investee companies below the cost basis that was determined to be other-than-temporary.

### Taxes

We recorded an income tax benefit of \$68.1 million for Q3 2006, resulting in an effective tax rate of 55% for the period. We recorded an income tax benefit of \$26.5 million for Q3 2005, resulting in an effective rate of 29% for the period. The increase in the effective rate in Q3 2006 was attributable in part to the impact of share-based compensation, a portion of which is not deductible for income tax purposes, increased state taxes and the absence of certain federal tax credits associated with research and experimentation activities, offset in part by an increased orphan drug credit. 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 resulted in tax expense 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. The impact of the adjustment was not considered material for any of the impacted periods.

Share-based compensation expense is comprised of incentive stock options, non-qualified stock options and the discount on stock purchased by employees. If incentive stock options are exercised and sold within one year or stock purchased by employees through the employee stock purchase plan is sold within one year, thus becoming non-qualifying dispositions, we will be allowed to recognize tax deductions at that time. Until that time, for financial reporting purposes we assume that no tax deduction is allowed. The effective tax rate for Q3 2006 includes an impact of approximately 18 percentage points related to share-based compensation.

### Net Income

The reported net loss for Q3 2006 was \$55.8 million, or \$0.23 per share, compared to net loss for Q3 2005 of \$64.1 million, or \$0.26 per share. Shares used in computing basic and diluted net loss per share were 239.3 million in Q3 2006 compared to 245.9 million in Q3 2005, reflecting the impact of share repurchases of 10.0 million during YTD 2006.

**YTD 2006 compared to YTD 2005****Revenues Product Sales**

| (in millions)              | YTD<br>2006 | YTD<br>2005 | Change |
|----------------------------|-------------|-------------|--------|
| <b>Synagis</b>             |             |             |        |
| Domestic                   | \$ 503.4    | \$ 525.8    | (4)%   |
| International              | 104.6       | 97.7        | 7%     |
|                            | 608.0       | 623.5       | (2)%   |
| <b>Ethiol</b>              |             |             |        |
| Domestic                   | 66.0        | 66.1        | %      |
| International              | 1.6         | 3.9         | (60)%  |
|                            | 67.6        | 70.0        | (3)%   |
| <b>FluMist</b>             | 18.1        | 13.2        | 36%    |
| <b>Other Products</b>      | 22.7        | 32.7        | (31)%  |
| <b>Total Product Sales</b> | \$ 716.4    | \$ 739.4    | (3)%   |

**Synagis** - Synagis accounted for approximately 85% and 84% of our product sales in YTD 2006 and YTD 2005, respectively. For YTD 2006, domestic sales of Synagis decreased 4% to \$503.4 million from YTD 2005 sales of \$525.8 million. The decrease in domestic sales was primarily attributable to lower unit volumes for the second half of the 2005/2006 RSV season resulting from changes in payor guidelines and the distribution network, partially offset by a price increase of 9.7% effective beginning in Q3 2006 and higher unit volumes in Q3 2006 net of increased sales allowances.

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 7% to \$104.6 million for YTD 2006 as compared to \$97.7 million in YTD 2005 primarily due to higher unit volumes offset partially by unfavorable foreign exchange impacts.

**Ethiol** - For both YTD 2006 and YTD 2005, Ethiol accounted for approximately 9% of our product sales. Domestic sales of Ethiol were \$66.0 million in YTD 2006 compared to \$66.1 million in YTD 2005. The decline was attributable to lower unit volumes offset partially by a 6% price increase. International sales of Ethiol were \$1.6 million in YTD 2006 as compared to \$3.9 million in YTD 2005.

**FluMist** - Our YTD 2006 product sales of FluMist grew 36% to \$18.1 million from \$13.2 million in the prior year period due to an increase in volume.

**Other Products** - Sales of other products, which primarily represents sales of CytoGam and by-products that result from its manufacturing process, were \$22.7 million in YTD 2006 as compared to \$32.7 million in YTD 2005. The decrease was attributable to lower sales of CytoGam resulting from plasma supply constraints and the transition to a new third-party manufacturer.

**Revenues - Other Revenues**

During YTD 2006, we earned and recorded \$11.9 million in royalties and milestone revenues from Merck's HPV vaccine receiving approval by the FDA and European Union and achieving certain sales-related goals, as well as GSK's filing for its cervical cancer vaccine with the European Union. Sales royalties related to Merck's and GSK's HPV vaccines are based on graduated royalty rate structures up to certain annual sales levels.

Other revenues for YTD 2006 also include \$12.9 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. In addition, we recognized \$5.8 million in revenues under the government contract during YTD 2006.

**Cost of Sales**

Cost of sales was \$190.6 million for YTD 2006 compared to \$196.5 million for YTD 2005. Gross margins on product sales were 73% for both YTD 2006 and YTD 2005, respectively. Without the impact of FluMist in the nine months ended September 30, gross margins were 76% in 2006 and 75% in 2005. Cost of sales in YTD 2006 included \$0.7 million of share-based compensation expense.

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### **Research and Development Expenses**

Research and development expenses increased 28% to \$343.6 million in YTD 2006, compared to \$267.7 million in YTD 2005. The increase is primarily due to the \$70.0 million of upfront fees for the Infinity collaboration. The increase also relates to the increased costs associated with the expansion of infrastructure to support studies related to various in-licensing agreements and collaborations executed over the past several years, share-based compensation expense of \$7.6 million for YTD 2006, offset by slightly lower levels of clinical and preclinical study costs.

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

SG&A expenses increased 28% to \$382.1 million in YTD 2006 compared to \$299.5 million in YTD 2005. The increase is attributable to the amortization expense of \$50.0 million recognized during YTD 2006 associated with the intangible asset for U.S. co-promotion rights for Synagis as compared to \$3.9 million recognized during YTD 2005, as well as the expansion of the marketing and sales management team and the pediatric sales organization related to the assumption of full promotional responsibility for Synagis in the U.S. effective July 1, 2006. SG&A expense included co-promotion expense of \$95.2 million and \$110.7 million in YTD 2006 and YTD 2005, respectively. Effective July 1, 2006, normal co-promotion expense to Abbott was discontinued and the amortization costs of the buyout will continue until we cease actively marketing Synagis, which is expected to occur sometime during the 2008/2009 season which is when we expect to start marketing Numax. SG&A expense in YTD 2006 also includes \$15.9 million of share-based compensation expense.

### **Other Operating Expenses**

Other operating expenses were \$13.7 million and \$9.3 million in YTD 2006 and YTD 2005, respectively. YTD 2006 other operating expenses include \$6.2 million in costs associated with non-commercial process validation lots for CAIV-T. Commercial inventory production of CAIV-T is expected to begin in the fourth quarter of this year.

### **Loss on Investment Activities**

We recorded a loss on investment activities of \$8.1 million during YTD 2006, due to the decline in fair value of one of our investee companies below the cost basis that was determined to be other-than-temporary.

### **Taxes**

We recorded income tax benefit of \$79.8 million for YTD 2006, resulting in an effective tax rate of 53% for the period. We recorded income tax expense of \$11.1 million for YTD 2005, resulting in an effective rate of 65% for the period. The decrease in the effective rate in YTD 2006 was attributable in part to the impact of share-based compensation, a portion of which is not deductible for income tax purposes, increased state taxes and the absence of certain federal tax credits associated with research and experimentation activities, offset in part by increased orphan drug credit. During YTD 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. The impact of the adjustment was not considered material for any of the impacted periods.

Share-based compensation expense is comprised of incentive stock options, non-qualified stock options and the discount on stock purchased by employees. If incentive stock options are exercised and sold or stock purchased by employees through the employee stock purchase plan is sold within one year, becoming non-qualifying dispositions, we will be allowed to recognize tax deductions at that time. Until that time, for financial reporting purposes we assume that no tax deduction is allowed. The effective tax rate for YTD 2006 includes an impact of approximately 16 percentage points related to share-based compensation.

### **Net Income**

The reported net loss for YTD 2006 was \$72.0 million, or \$0.29 per share, compared to net earnings for YTD 2005 of \$5.8 million, or \$0.02 per share. Shares used in computing basic and diluted net loss per share in YTD 2006 were 244.3 million while shares used in computing basic and diluted earnings per share for YTD 2005 were 247.1 million and 249.4 million, respectively.

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



## LIQUIDITY AND CAPITAL RESOURCES

**Sources and uses of cash** - Cash and marketable securities totaled \$1.5 billion as of September 30, 2006 and December 31, 2005, respectively. Working capital increased to \$547.2 million at September 30, 2006 from \$(111.2) million as of December 31, 2005 primarily due to the net proceeds of the June 2006 issuance of \$1.15 billion in convertible senior notes and related transactions, offset by the redemption of the majority of our 1% convertible senior notes in July 2006.

### *Operating Activities*

Net cash used in operating activities was \$123.2 million in YTD 2006 as compared to \$24.3 million in YTD 2005, primarily due to the decrease in net earnings from the prior year period.

### *Investing Activities*

Cash used in investing activities during YTD 2006 amounted to \$10.3 million, as compared to \$48.9 million during YTD 2005. Cash used in investing activities in YTD 2006 included net reductions to our investment portfolio of \$124.9 million; capital expenditures totaling \$105.7 million, primarily for the construction of our new pilot lab and office facility in Gaithersburg, Maryland; and new investments in strategic partners through our venture capital subsidiary, net of proceeds from dispositions totaling \$29.5 million. We expect our capital expenditures for the full year to be approximately \$150 million.

### *Financing Activities*

Cash provided by financing activities during YTD 2006 amounted to \$264.4 million as compared to cash used of \$90.7 million during YTD 2005. The increase is primarily due to proceeds from the June 2006 issuance of \$1.15 billion in convertible senior notes, net of \$20.8 million of debt issuance costs, partially offset by net cash payments of \$139.5 million for convertible note hedge transactions (cost of \$316.5 million) and warrant transactions (proceeds of \$177.0 million) with respect to our common stock to reduce the potential dilution upon conversion of the newly issued notes and by the concurrent repurchase of 5.4 million shares of our common stock for \$148.0 million. During July 2006, we used \$489.6 million of the proceeds from the new notes to redeem the majority of our existing 1% convertible senior notes. A total of \$289.6 million and \$105.9 million was expended during YTD 2006 and YTD 2005, respectively, to repurchase approximately 10.0 million shares and 4.0 million shares of our common stock. During YTD 2006, \$51.5 million was received upon the exercise of employee stock options as compared to \$19.7 million received in YTD 2005.

We expend cash to finance our research and development and clinical trial programs; to fund acquisitions; 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. Our primary source of liquidity during 2006 was the issuance of \$1.15 billion in convertible notes. Standard & Poors subsequently reiterated their BBB rating, considered to be investment grade, on our outstanding public debt. In April 2006 we entered into a three-year \$600.0 million credit facility that provides for collateralized revolving borrowings and letters of credit. As of September 30, 2006, there were no outstanding borrowings. As of September 30, 2006, there was \$4.4 million of restricted collateral relating to our outstanding letters of credit under the credit facility.

Historically, our primary source of liquidity is operating cash flow. Management continues to believe that such internally generated cash flow as well as our existing funds, and borrowing capacity under our credit facility will be adequate to service our existing debt and other cash requirements. In July 2006, certain holders of the Company's 1% convertible senior notes exercised their put options requiring us to redeem the notes for cash at 100% of the principal amount of the notes, plus accrued and unpaid interest. We paid \$492.1 million to redeem the notes, including \$489.6 million in aggregate principal amount and \$2.5 million in accrued and unpaid interest. The remaining \$10.4 million aggregate principal amount of the 1% convertible senior notes was not redeemed; the notes are not subject to a put option by the holders until July 2009.

During May 2006, our Board of Directors authorized a new stock repurchase program for up to \$500 million of the Company's common stock in the open market or in privately negotiated transactions. As of June 2006, the original stock repurchase program, which was approved in July 2003 for \$500 million, was fully utilized. As of October 26, 2006, approximately \$344.6 million of the \$500.0 million newly authorized remained available 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.

### *Contractual obligations and commitments*

During 2006, we extended the lease terms for certain of our facilities. The future minimum lease payments under the amended leases are as follows: \$0.3 million for the three months ended December 31, 2006, \$1.9 million in 2007, \$2.2 million in 2008, \$1.8 million in 2009, \$1.4 million in 2010 and \$8.3 million thereafter.

**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We believe our primary market risks as of September 30, 2006 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, 2006 have not changed

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significantly from those discussed in our Annual Report on Form 10-K for the year ended December 31, 2005. For other information regarding our market risk exposure, please refer to Part II, Item 7A, "Quantitative and Qualitative Disclosures About Market Risk" of our Annual Report on Form 10-K for the year ended December 31, 2005.

#### **ITEM 4. CONTROLS AND PROCEDURES**

We maintain 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 (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, 2006, we carried out an evaluation, under the supervision and with the participation of our management, including our CEO and CFO, of the effectiveness of our disclosure controls and procedures, as required by Rule 13a-15(b) promulgated under the Exchange Act. Based upon that evaluation, our CEO and CFO concluded that our disclosure controls and procedures were effective.

In addition, our management, with the participation of our CEO and CFO, determined that there was no change in our internal control over financial reporting that occurred during Q3 2006 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

#### **PART II - OTHER INFORMATION**

##### **ITEM 1. LEGAL PROCEEDINGS**

Information with respect to legal proceedings is included in Note 16 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 our Annual Report on Form 10-K for the year ended December 31, 2005 and in our Quarterly Report on Form 10-Q for the quarters ended March 31, 2006 and June 30, 2006.

##### **ITEM 1A. RISK FACTORS**

Our business faces many risks. The risks described below may not be the only risks we face. Additional risks we do not yet know of or we currently believe are immaterial may also impair our business operations. If any of the events or circumstances described in the following risks actually occur, our business, financial condition or results of operations could suffer, and the trading price of our common stock could decline. You should consider the following risks, together with all of the other information in this Quarterly Report on Form 10-Q as read in conjunction with our Annual Report on Form 10-K for the year ended December 31, 2005 and our Quarterly Report on Form 10-Q for the quarters ended March 31, 2006 and June 30, 2006, before deciding to invest in our securities.

##### **Our revenues are largely dependent on sales of Synagis.**

Sales of Synagis accounted for approximately 87% and 85% of our total product sales in 2005 and YTD 2006, respectively, and our revenues will continue to be largely dependent on sales of Synagis for the foreseeable future. Any perceived or actual event or series of events that have a negative effect on sales of Synagis will have a detrimental effect on our financial condition and results of operations. Events which would affect sales of Synagis include, but are not limited to, any product liability claims (whether supported or not), any manufacturing or supply delays, any sudden loss of inventory, any inability to satisfy product demand, any unsuccessful sales, marketing or distribution strategies and any changes in the authorization, policies, or reimbursement rates for Synagis by private or public insurance carriers or programs.

In addition, Synagis is a biological product regulated and approved for marketing in the U.S. by the FDA and any adverse change in the marketing approval or label for Synagis required by the FDA will have a detrimental affect on our business.



We have also created an exclusive network for distribution of Synagis in the U.S., which has the effect of preventing certain entities from obtaining Synagis and may have the effect of limiting patient access to the product, changing the authorization, policies or reimbursement rates for Synagis by private or public insurance carriers or programs, any of which could result in reduced sales.

Outside of the U.S., AI is responsible for the distribution and commercialization of Synagis as well as obtaining and maintaining regulatory approval for commercialization. Accordingly, sales of Synagis outside of the U.S. are not within our direct control and any negative effect on AI's sales of Synagis could affect our revenues related to those sales. In addition, actions of AI related to the regulatory approval or commercialization of Synagis outside of the U.S. could negatively affect our sales of Synagis in the United States.

**The seasonal nature of a significant portion of our business causes significant fluctuations in our quarterly operating results.**

Sales of two of our products, Synagis and FluMist, are seasonal in nature. Synagis sales occur primarily in the first and fourth quarters of the calendar year and FluMist sales occur primarily in the second half of the calendar year. This high concentration of product sales in a portion of the year causes quarter-to-quarter operating results to vary widely and would exaggerate the adverse consequences on our revenues of any manufacturing or supply delays, any sudden loss of inventory, any inability to satisfy product demand, the inability to estimate the effect of returns and rebates, or of any unsuccessful sales or marketing strategies during the applicable sales season. Furthermore, our current product base limits our ability to offset in the second and third quarters any lower-than-expected sales of Synagis during the first and fourth quarters or FluMist during the second half of the year.

**The approval of CAIV-T is critical to the future of our influenza vaccine business.**

FluMist, in its current frozen formulation, has not been commercially successful. We do not expect our influenza vaccine business to contribute meaningfully to our revenues, income or earnings until and unless we are able to obtain regulatory approval of CAIV-T, the next-generation, refrigerator-stable formulation of FluMist, with a broader approved indication. The timing and outcome of obtaining approval from the U.S. Food and Drug Administration and other similar regulatory agencies in other parts of the world is uncertain. There can be no assurance that any such regulatory agency will approve CAIV-T without the need for additional costly and time-intensive measures; without restrictions as to its marketability; on a timely basis consistent with our expectations; or at all.

**Even if CAIV-T is approved, the commercial success of our influenza vaccine business is uncertain and we may not be able to recover the value of our investment.**

Even if CAIV-T is approved, the market for influenza vaccines is competitive and complex. The commercial success of the product will be limited if we cannot successfully manufacture, distribute and sell it in jurisdictions in which it is approved. The marketplace may view our influenza vaccines as competing against the injectable vaccine. FluMist and CAIV-T may have a higher cost of manufacturing at their historic and current volumes relative to injectable vaccines. There can be no assurance that demand for our vaccines will support a volume and price that will achieve a profit in accordance with our expectations, or that our revenues for these products will exceed our cost of goods.

The manufacturing process for FluMist and CAIV-T is complex and product supply will be adversely affected if we are unable to perform the annual update of the formulations for new influenza strains, if we encounter contamination or other problems or difficulties in the process, if we are unable to obtain eggs or other materials necessary for their manufacture, if the regulatory authorities do not approve the product for release, if there is a sudden loss of inventory or for other reasons.

Our distribution experience relates primarily to sales to wholesalers and specialty pharmaceutical distributors. We have limited experience in distributing and selling products like influenza vaccines that are generally sold in greater volume and smaller order quantities, so there can be no assurance that our distribution and sales systems have been optimally designed to yield the greatest return.

We have made significant investments in the development and commercialization of live, attenuated intranasal influenza vaccines. In addition to our internal research, development and commercialization activities, these investments also include the research and development conducted by Aviron before our acquisition of that company; the cost of our acquisition of Aviron; the cost of the activities conducted by Wyeth, our former collaboration partner for development, promotion and

distribution of these vaccines; the cost of dissolving the collaboration and reacquiring Wyeth's rights to this franchise; and losses incurred in manufacturing and selling FluMist after its launch. Our results of operations would be negatively affected by impairment charges for the write-down of manufacturing and intangible assets related to FluMist and CAIV-T. For various reasons, primarily those set forth above, there can be no assurance that we will be able to recover the value of our investment in the influenza vaccine business.

**Loss of our litigation against Sun Pharmaceutical Industries Limited would be detrimental to our Ethyol sales.**

Sun Pharmaceutical Industries Limited has submitted an abbreviated new drug application to the U.S. Food and Drug Administration for a generic version of Ethyol (amifostine). We have sued Sun for patent infringement and intend to defend our patents vigorously, but if we lose this litigation, it is probable that Sun will be able to secure approval for a generic version of Ethyol. If a generic version of Ethyol is approved, it is probable that its manufacturer will set a price for that product significantly lower than the current price of Ethyol and, as a result, our market share and sales of Ethyol would decline significantly. There can be no assurance that any actions we might take to mitigate the impact of the introduction of such a generic product would be successful. Likewise, there can be no assurance that the introduction of such a generic product would not adversely affect our manufacturing and/or commercial operations.

**Government involvement may limit the commercial success of our influenza vaccine business.**

If an influenza outbreak occurs and is classified as a pandemic or large epidemic by public health authorities, it is possible that one or more government entities may take actions that directly or indirectly have the effect of abrogating some of our rights or opportunities. We have not manufactured a pandemic vaccine to date, but even if we were to do so, the economic value of such a vaccine to the company could be limited. Our primary manufacturing facility for influenza vaccines is in the U.K. and, in an influenza pandemic, the U.K. government may limit our ability to export product outside the United Kingdom.

Various government entities, including the U.S. government, are offering incentives, grants and contracts to encourage additional investment by commercial organizations into preventative and therapeutic agents against influenza, which may have the effect of increasing the number of competitors and/or providing advantages to known competitors. Accordingly, there can be no assurance that we will be able to successfully establish competitive market share for our influenza vaccines.

In addition, current influenza vaccines are trivalent (contain three strains) and are derived from or analogous to two circulating influenza A viral strains and one circulating influenza B viral strain. If the World Health Organization, the U.S. Centers for Disease Control and Prevention or other similar agencies require or recommend changes in influenza vaccines, for example for a monovalent or quadravalent vaccine or for use of a strain that is not currently circulating in the human population, it is uncertain whether we will be able to manufacture such a product at commercially reasonable rates.

**We may not be able to bring our product candidates to market.**

Research and development activities are costly and may not be successful, and there can be no assurance that any of our product candidates, even if they are in or approved to enter Phase 3 clinical trials, will be approved for marketing by the FDA or the equivalent regulatory agency of any other country. A significant portion of our annual operating budget is spent on research, development and clinical activities. Currently, numerous products are being developed that may never reach clinical trials, achieve success in the clinic, be submitted to the appropriate regulatory authorities for approval, or be approved for marketing or manufacturing by the appropriate regulatory authorities. There can also be no assurance that we will be able to generate additional product candidates for our pipeline, either through internal research and development, or through the in-licensing or acquisition of products or technology. Even if a product candidate is approved for marketing by the applicable regulatory agency, there can be no assurance that we will be able to successfully manufacture the product on a commercial scale or effectively commercialize the product.

**A significant portion of our business is dependent on third parties.**

We license a significant portion of the technology necessary for our business from third parties and rely on third parties for a significant portion of the clinical development, supply of components, manufacturing, distribution, and promotion of our products. The actions of these third parties are outside of our control and the failure of these third parties to act in accordance with their obligations to us would have a material adverse effect on our business. Even if we are legally entitled to damages for a failure of a third party to fulfill its obligations to us, there can be no assurance that such damages will adequately compensate us for indirect or consequential losses such as the damage to a product brand or our reputation. If a third party





does not fulfill its obligations to us, we may have to incur substantial additional costs, which could have a material adverse effect on our business.

**Defending product liability claims could be costly and divert focus from our business operations and product recalls may be necessary.**

Our products contain biologically active agents that can alter the physiology of the person using the product. Accordingly, as a developer, tester, manufacturer, marketer and seller of biological products, we may be subject to product liability claims that may be costly to defend, regardless of whether the claims have merit, and may require removal of an approved product from the market. If a claim were to be successful, there is no guarantee that the amount of the claim would not exceed the limit of our insurance coverage and available cash or cash equivalents. Further, a successful claim could reduce revenues related to the product, result in the FDA taking regulatory action (including suspension of product sales for an indefinite period) or result in significant negative publicity for us or damage to our product brand. Any of these occurrences could have a material adverse effect on our business and could result in a clinical trial interruption or cancellation. Additionally, product recalls may be necessary either in connection with product liability claims or for other reasons. Any such recall would adversely affect sales of that product.

**We may not be able to meet the market demand for our products.**

We generally do not have or contract for redundant supply, production, packaging or other resources to manufacture our products. As a result, we are at risk for business interruption if there is any disruption in the manufacturing chain. Difficulties or delays in our or our contractors manufacturing of existing or new products could increase our costs, cause us to lose revenue or market share and damage our reputation. In addition, because our various manufacturing processes and those of our contractors are highly complex and are subject to a lengthy FDA approval process, alternative qualified production capacity may not be available on a timely basis or at all. In particular, the supply of our products is affected by several manufacturing variables, including the number of production runs, production success rate, product yield and the outcome of quality testing. If we are unable to provide an uninterrupted supply of our products to patients our reputation may be negatively affected, which could have a material and adverse effect on our results of operations.

**We may lose product due to difficulties in the manufacturing process.**

Our manufacturing operations expose us to a variety of significant risks, including: product defects; contamination of product or product loss; environmental problems resulting from our production process; sudden loss of inventory and the inability to manufacture products at a cost that is competitive with third party manufacturing operations. Furthermore, we collaborate and have arrangements with other companies related to the manufacture of our products and, accordingly, certain aspects of the manufacturing process are not within our direct control. In addition, we have not produced FluMist for commercial use at higher volumes and may encounter additional unforeseeable risks as we develop additional commercial manufacturing experience with this product.

**Certain developments in the United Kingdom could have an adverse effect on our ability to manufacture our products.**

Our operations in the U.K. expose us to additional business risks, and failure to manage those risks could have a material adverse effect on our ability to manufacture influenza vaccines. In particular, in the event of a regional or global influenza pandemic, our facilities in the U.K. may be subject to government nationalization. In addition, the facilities are unionized and manufacturing may therefore be interrupted due to labor action.

**Contamination of our raw materials could have a material adverse effect on our product sales, financial condition and results of operations.**

As with other biotechnology companies, the manufacture of our products requires raw materials obtained from a variety of sources including but not limited to animal products or by-products. If these raw materials contain contaminants that are not removed by our approved purification processes, it could result in a material adverse effect on our product sales, financial condition and results of operations and might negatively affect our ability to manufacture those products for an indefinite period of time, regardless of whether such contamination has any proven effect on the safety or efficacy of the product.

**Reimbursement by government and third-party payors is critical for the success of our products.**

The cost to individual consumers for purchase of our products can be significant. Accordingly, sales of our products are dependent to a large extent on the insurance reimbursement available for our products. Actions by government and third-party payers to contain or reduce the costs of health care by limiting reimbursement, changing reimbursement calculation methodologies, increasing procedural hurdles to obtain reimbursement or by other means may have a material adverse effect on sales of our products. We fund and accrue for rebates due to government entities subject to reimbursement, primarily Medicaid payments to state governments. State governments have the ability to collect rebates for prior periods activity without restriction by statute and, accordingly, we may be subject to future rebate claims by such entities for product use in the past for which reimbursement was not sought. In addition, there have been numerous proposals in the U.S., both at the state and federal level, as well as in other countries that would, if adopted, affect the reimbursement of our products and could have a material adverse effect on our product sales, results of operations and financial condition.

**We rely upon a limited number of pharmaceutical wholesalers and distributors that could affect the ability to sell our products.**

We rely largely upon specialty pharmaceutical distributors and wholesalers to deliver our currently marketed products to the end users, including physicians, hospitals, and pharmacies. There can be no assurance that these distributors and wholesalers will adequately fulfill the market demand for our products, nor can there be any guarantee that these service providers will remain solvent. Given the high concentration of sales to certain pharmaceutical distributors and wholesalers, we could experience a significant loss if one of our top customers were to declare bankruptcy or otherwise become unable to fulfill its obligations to us.

**Obtaining and maintaining regulatory approvals to develop, manufacture and market our products is costly and time consuming.**

The development, manufacturing and marketing of all of our products are subject to regulatory approval by the FDA in the U.S., as well as similar authorities in other countries. The approval process for each product is lengthy and potentially subject to numerous delays, which generally would not be in our control. There can be no assurance that any product candidate will be approved for marketing and, if approved, such approval may be limited in scope in such a manner that would harm the product's potential for market success. Even after a product is approved for marketing, it is still subject to continuing regulation. For example, if new adverse event information about a product becomes available from broader use in the market or from additional testing, we may be required by applicable authorities to recall the product or notify health care providers of additional risks associated with use of the product. In addition, our product labeling and marketing activities may be found to be inconsistent with applicable laws and regulations. Even if we have substantially complied with all applicable laws and regulations, the applicable regulatory authorities have the authority to and may revoke or limit approvals or licenses without consulting or obtaining our consent. If we fail to comply with applicable requirements, we may be subject to: fines; seizure of products; total or partial suspension of production; refusal by the applicable authority to approve product license applications; restrictions on our ability to enter into supply contracts; and criminal prosecution. If we are unable to obtain approvals on a timely basis or at all, if the scope of approval is more limited than expected by us or if we are unable to maintain approvals, our ability to successfully market products and to generate revenues will be impaired.

**Patent protection for our products may be inadequate or costly to enforce.**

We may not be able to obtain effective patent protection for our products in development. There are extensive patent filings in the biotechnology industry and the patent position of biotechnology companies generally is highly uncertain and involves complex legal and factual questions. There can be no assurance that our patent applications will result in patents being issued or that, if issued, such patents will afford protection against competitors with similar technology. Litigation may be necessary to enforce our intellectual property rights. Any such litigation will involve substantial cost and significant diversion of our attention and resources and there can be no assurance that any of our litigation matters will result in an outcome that is beneficial to us. We are also aware that regulatory authorities, including the FDA, are considering whether an abbreviated approval process for so-called generic or follow-on biological products is appropriate. We are uncertain as to when, or if, any such process may be adopted or how such a process would relate to our intellectual property rights, but any such process could have a material effect on the prospects of our products.

**If we fail to obtain and maintain any required intellectual property licenses from third parties, our product development and marketing efforts will be limited.**

Patents have been and will be issued to third parties, and patent applications have been filed by third parties, that claim one or more inventions used in the development, manufacture or use of our products or product candidates. These patents (including any patents issuing from pending patent applications), if valid and enforceable, would preclude our ability to manufacture, use or sell these products unless we obtain a license from the applicable third party. These third parties are not generally required to provide us with a license and, as such, obtaining any such licenses may not be possible or could be costly and impose significant ongoing financial burdens on us. There can be no assurance that a license will be available on terms acceptable to us or at all, which could have a material adverse effect on our business. In addition, there can be no assurance that we will be able to obtain an exclusive license to any such patent, and as a result, the third parties or their sublicensees may be able to produce products that compete with ours. Litigation may be necessary to challenge the intellectual property rights of third parties and would involve significant cost and significant diversion of management's time and resources. There can be no assurance that any such litigation will result in an outcome that is beneficial to us.

**Technological developments by competitors may render our products obsolete.**

If competitors were to develop superior products or technologies, our products or technologies could be rendered noncompetitive or obsolete. Developments in the biotechnology and pharmaceutical industries are expected to continue at a rapid pace. Success depends upon achieving and maintaining a competitive position in the development of products and technologies. Competition from other biotechnology and pharmaceutical companies can be intense. Many competitors have substantially greater research and development capabilities, marketing, financial and managerial resources and experience in the industry. If a competitor develops a better product or technology, our products or technologies could be rendered obsolete, resulting in decreased product sales and a material adverse effect to our business. Even if a competitor creates a product that is not technologically superior, our products may not be able to compete with such products, decreasing our sales.

**We are subject to numerous complex laws and regulations and compliance with these laws and regulations is costly and time consuming.**

U.S. federal government entities, most significantly the FDA, the U.S. Securities and Exchange Commission, the Internal Revenue Service, the Occupational Safety and Health Administration, the Environmental Protection Agency, the Centers for Medicare and Medicaid Services and the U.S. Department of Veterans Affairs, as well as regulatory authorities in each state and other countries, have each been empowered to administer certain laws and regulations applicable to us. Many of the laws and regulations administered by these agencies are complex and compliance requires substantial time, effort and consultation with our outside advisors. Because of this complexity, there can be no assurance that our efforts will be sufficient to ensure compliance or to ensure that we are in technical compliance with all such laws and regulations at any given time. In addition, we are subject to audit, investigation and litigation by each of these entities to ensure compliance, each of which can also be time consuming, costly, divert the attention of senior management and have a significant effect on our business, even if we are found to have been in compliance or the extent of our non-compliance is deemed immaterial. If we are found to not be in compliance with any of these laws and regulations, we and, in some cases, our officers may be subject to fines, penalties, criminal sanctions and other liability, any of which could have a material adverse effect on our business.

**We cannot control the use of our products.**

The product labeling for each of our products is approved by the FDA and other similar regulatory authorities in other countries and marketed only for certain medical indications, but treating health care practitioners, particularly in the oncology field, are not generally required to restrict prescriptions to the approved label. These practices make it likely that our products are being used for unapproved uses and may subject us to regulatory scrutiny, sanctions or product liability, any of which could have a material adverse effect on our business.

**We may not be able to hire or retain highly qualified personnel or maintain key relationships.**

The success of our business depends, in large part, on our continued ability to attract and retain highly qualified scientific, manufacturing and sales and marketing personnel, as well as senior management such as Mr. David M. Mott, our Chief Executive Officer, President and Vice Chairman, and Dr. James F. Young, our President, Research and Development. In addition, we rely on our ability to develop and maintain important relationships with leading research institutions and key distributors. Competition for these types of personnel and relationships is intense among pharmaceutical, biopharmaceutical and biotechnology companies, and any obstacles hindering our ability to attract or retain such employees and relationships could have a material effect on our business. We do not maintain or intend to purchase key man life insurance on any of our personnel and, accordingly, our business may be subject to disruption upon the sudden or unexpected loss of a key employee.

**If we fail to manage our growth properly, the business will suffer.**

We have expanded significantly in recent years due to both acquisition and internal growth. To accommodate our rapid growth and compete effectively, we will need to continue to improve our management, operational and financial information systems and controls, generate more revenue to cover a higher level of operating expenses, continue to attract and retain new employees, accurately anticipate demand for products manufactured and expand our manufacturing capacity. This rapid growth and increased scope of operations present risks not previously encountered and could result in substantial unanticipated costs and time delays in product manufacture and development, which could materially and adversely affect the business.

**Fluctuations in our common stock price over time could cause stockholders to lose investment value.**

The market price of our common stock has fluctuated significantly over time, and it is likely that the price will fluctuate in the future. During YTD 2006, the daily closing price of our common stock on the NASDAQ National Market ranged from a high of \$37.38 to a low of \$25.28. During 2005, the daily closing price of our common stock ranged from a high of \$37.06 to a low of \$23.32. Investors and analysts have been, and will continue to be, interested in our reported earnings, as well as how we perform compared to our expectations. Announcements by us or others regarding operating results, existing and future collaborations, results of clinical trials, scientific discoveries, commercial products, patents or proprietary rights or regulatory actions may have a significant effect on the market price of our common stock. In addition, the stock market has experienced price and volume fluctuations that have affected the market price for many biotechnology companies and that have often been unrelated to the operating performance of these companies. These broad market fluctuations may adversely affect the market price of our common stock.

**Changes in foreign currency exchange rates or interest rates could result in losses.**

We have entered into a supplemental manufacturing contract denominated in Euros. Fluctuations in the Euro-U.S. Dollar exchange rate would lead to changes in the U.S. Dollar cost of manufacturing. To reduce the risk of unpredictable changes in these costs, we may, from time to time, enter into forward foreign exchange contracts. However, due to the variability of timing and amount of payments under this contract, the forward foreign exchange contracts may not mitigate the potential adverse effect on our financial results. In addition, expenditures relating to our manufacturing operations in the U.K. and the Netherlands are paid in local currency. We have not hedged our expenditures relating to these manufacturing operations, and therefore foreign currency exchange rate fluctuations may result in increases or decreases in the amount of expenditures recorded. Additionally, certain of our distribution agreements outside the U.S. provide for us to be paid based upon sales in local currency. As a result, changes in foreign currency exchange rates could adversely affect the amount we expect to collect under these agreements. A substantial portion of our current assets is invested in marketable securities, particularly bonds and other fixed income securities, which are subject to fluctuations in value based on interest rates and other factors.

**As a U.S. government contractor, we are required to comply with a number of rules and regulations.**

As a result of our award in May 2006 of a contract from the U.S. Department of Health and Human Services (HHS) to develop cell-based seasonal and pandemic vaccines, we have become a government contractor. As a government contractor, we have become subject to a number of requirements that generally do not apply to agreement between private parties. These requirements include the provisions of the Federal Acquisition Regulations that regulate the formation, administration and performance of government contracts. Governments contracts are also subject to oversight audits by government representatives and contain provisions permitting termination, in whole or in part, without prior notice at the government's convenience upon the payment of compensation only for work done and commitments made at the time of termination. We have not been a government contractor in the past and compliance with necessary requirements is complex. Accordingly, there can be no assurance that we will be able to comply with all requirements and failure to comply could result in penalties to us, including but not limited to termination of the contract.

**ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS****(c) Issuer purchases of equity securities(1)**

| <b>Period</b>                                | <b>Total<br/>Number of<br/>Shares<br/>Purchased</b> | <b>Average<br/>Price Paid<br/>per Share</b> | <b>Total Number of<br/>Shares Purchased<br/>as Part of Publicly<br/>Announced Plans<br/>or Programs</b> | <b>Approximate Dollar<br/>Value that May Yet<br/>Be Purchased Under<br/>the Plans or<br/>Programs</b> |
|--|---|---|---|---|
| July 1, 2006 through July 31, 2006           | 300,000   | \$ 25.73                                    | 300,000   | \$ 344,621,245  |
| August 1, 2006 through August 31, 2006       |   | \$  |   | \$ 344,621,245  |
| September 1, 2006 through September 30, 2006 |   | \$  |   | \$ 344,621,245  |

(1) The Company's Board of Directors authorized the repurchase of up to \$500.0 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, which authority was fully utilized as of June 2006. In May 2006, the Board of Directors authorized a new stock repurchase program for up to \$500.0 million of the Company's common stock on the open market or in privately negotiated transactions during the period from May 2006 through June 2009.

**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS - NONE****ITEM 5. OTHER INFORMATION - NONE**

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**ITEM 6. EXHIBITS**

(a) Exhibits:

- |         |   |
|---------|---|
| 10.1(1) | Collaboration Agreement between MedImmune, Inc. and Infinity Pharmaceuticals, Inc. dated as of August 25, 2006. |
| 31.1    | Rule 13a-14(a)/15d-14(a) Certification of CEO   |
| 31.2    | Rule 13a-14(a)/15d-14(a) Certification of CFO   |
| 32.1    | Section 1350 Certifications   |

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(1) Confidential treatment has been requested for certain portions of the agreement. The copy 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: November 1, 2006

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

Date: November 1, 2006

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

Date: November 1, 2006

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

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